CONCLUSION ON PESTICIDE PEER REVIEW

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

Issued on 17 September 2008

SUMMARY

Dimethachlor is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on dimethachlor in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 2 May 2007. The peer review was initiated on 18 July 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Syngenta Europe Ltd. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in May-June 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in July-August 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on oilseed rape as proposed by the notifier. Full details of the GAP can be found in the attached list of end points.

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

The representative formulated product for the evaluation was "Teridox 500 EC", an emulsifiable concentrate (EC).

Adequate methods are available to monitor all compounds given in the respective residue definition. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. As yet it is not clear for the plant method if for the ILV the laboratory was truly independent. Also the residue definition for soil and water are provisional.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available for the active substance to ensure that quality control measurements of the plant protection product are possible. However, there is no method of analysis or storage stability data for the relevant impurity. In general however the specification is not agreed. It was also a concern that the formulation at low temperatures forms crystals.

Mammalian toxicology of dimethachlor was assessed in a series of tests. Dimethachlor is absorbed almost completely and moderately rapidly. It is widely distributed in the body and has no potential for accumulation in humans. It is excreted moderately rapidly and is completely metabolized. It is of moderate toxicity by the oral and of low toxicity by the dermal and inhalation route. It is neither a skin nor an eye irritant but a strong skin sensitizer. Based on the available data on acute toxicity a classification as **Xn; R22 "Harmful; Harmful if swallowed" and Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed. In short term tests with rats, mice and dogs the liver was the main target of toxicity and the relevant NOAELs obtained were 2.21 mg/kg bw/d (rat), 10 mg/kg bw/d (dog) and 17.5 mg/kg bw/d (mouse) respectively. Dimethachlor is not genotoxic but can bind to chromatin protein. A 2-year rat and two 18-month mouse studies have been reported. In the rat study a NOAEL of 11.1 mg/kg bw/d was derived based on bodyweight and liver effects that occurred together with nasal tumours (in males only). These tumours were considered relevant for humans and led to a proposal for classification as **Xn; R40 "Harmful; Limited evidence of a carcinogenic effect".** The pulmonary and liver tumours observed in the first murine carcinogenicity study were considered not relevant for humans. Dimethachlor did not cause effects on reproduction in rats. In rats dimethachlor impaired the ossification in pups at maternally toxic doses while none developmental effects were observed in rabbits. Seven dimethachlor metabolites with a high potential to occur in groundwater are considered as relevant according to guidance document Sanco/221/2000-rev. 10 – final on the basis of the available data. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were set at 0.1 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.5 mg/kg bw. In the German model operator exposure amounts to 88% of the AOEL when personal protective equipment (PPE) is worn. Re-entry worker and bystander exposure were estimated to be 4.3% (no PPE worn) and 2.2% respectively.

The metabolism of dimethachlor was investigated in oilseed rape where phenyl labelled dimethachlor was applied at a rate of 1.5 kg as/ha (1N). At harvest there were no significant residues of dimethachlor or its metabolites and the residue definition defaulted to dimethachlor only. There were a total of 18 residue trials available for the representative crop oilseed rape. Only one positive residue of dimethachlor was detected at 0.05 mg/kg. It was concluded that the residue at 0.05 mg/kg is not a correct result and perhaps was due to a matrix component or sample contamination. As this is the case it was concluded that the metabolites will also not occur at significant levels. Residues were seen to be stable under frozen conditions for a period of 2 years. No processing data were required. For rotational crops the study provided was not accepted and data gap was identified. Animal intakes were low and the need for a study is not triggered. All intakes using the WHO, UK and German models were less than 1% of the ADI and ARfD. Intakes are less than 1 % of the ADI and ARfD for WHO and German diets. However the risk assessment can not be finalised because of the rotational crops issue.

In soil under aerobic conditions dimethachlor exhibits low to moderate persistence forming the major soil metabolites CGA 50266[2] (accounting for up to 35% of applied radioactivity (AR)) which exhibits low to high persistence and CGA 354742[3] accounting for up to 15.8%AR which exhibits moderate persistence. The metabolites CGA 102935[4] (up to 9%AR), data gap identified for soil rate of degradation information and SYN 528702[5] (up to 6.3%AR) were present at levels that trigger a groundwater exposure assessment. Mineralisation of the phenyl ring to carbon dioxide accounted for 10-40% AR after 120 days. The formation of unextractable residues was a significant sink, accounting for 33-57 % AR after 120 days. Dimethachlor exhibits very high to high mobility in soil, CGA 50266 and CGA 354742 exhibit very high mobility in soil. A data gap was identified for information on the mobility of CGA 102935 in soil. There was no indication in the available data that adsorption of either dimethachlor or its identified soil metabolites was pH dependent. In a relevant lysimeter study the metabolites CGA 50266, CGA 354742, SYN 528702, CGA 369873[6], CGA 373464[7] and SYN 530561[8] were identified as being present in lysimeter leachate at annual average concentrations in the range 2.2 to 35.6µg/L.

In dark natural sediment water systems dimethachlor degraded exhibiting low to moderate persistence in both water and sediment to the metabolite CGA 50266 which was present predominantly in the water (up to 13%AR). The terminal metabolite, CO2, was a small sink in the material balance accounting for up to 2.2% AR (phenyl ring) at 112 days and 3.5% at 182 days (study end). Unextracted sediment residues were the major sink representing up to 53 % AR at 112 days and up to

[2] CGA 50266: N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)oxalamic acid
[3] CGA 354742: [(2,6-dimethylphenyl)-(2-methoxy-ethyl)carbamoyl]methanesulfonic acid sodium salt
[4] CGA 102935: N-carboxymethyl-N-(2,6-dimethyl-phenyl)oxalamic acid
[5] SYN 528702: 3-{2-[(2,6-dimethyl-phenyl)-(2-hy-droxyacetyl)amino]ethylsulfanyl}-2-hydroxypropionic acid
[6] CGA 369873: (2,6-dimethylphenylcarbamoyl)-methanesulfonic acid sodium salt
[7] CGA 373464: [(2,6-dimethylphenyl)-(2-sulfo-acetyl)amino]acetic acid sodium salt
[8] SYN 530561: 2-[(2-hydroxyacetyl)-(2-methoxy-ethyl)amino]-3-methylbenzoic acid

57% at the study end. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for dimethachlor at steps 1-4, with just spray drift mitigation being applied at step 4. For the metabolites CGA 50266 and CGA 345702 appropriate FOCUS step 3 calculations were carried out (that address the movement of residues from soil to surface water). These values are the basis for the risk assessment discussed in this conclusion.

The potential for groundwater exposure from the applied for intended uses by dimethachlor above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all pertinent (6) FOCUS groundwater scenarios. There is the potential for groundwater exposure from the applied for intended uses by the identified metabolites. The levels estimated for FOCUS scenarios resulting from the applied for intended use of the metabolites were: CGA 50266 (10.49-21.4µg/L), CGA 354742(4.1-13.4µg/L), SYN 528702 (1.52-9.21µg/L), CGA 369873 (0.24-1.45µg/L), CGA 373464 (0.39-2.35µg/L) and SYN 530561 (0.22-1.32-µg/L). A data gap was identified for a groundwater exposure assessment for CGA 102935. The available toxicological data do not allow it to be concluded that these metabolites are not relevant. In groundwater monitoring covering a limited geoclimatic area (northern and north eastern Germany), well water concentrations of up to 0.52µg/L for CGA 354742 and 2.1µg/L for CGA 369873 were found. Concentrations of the other metabolites were <0.05µg/L with the notable exception that no analysis was carried out for CGA 102935. These monitored levels from northern and north eastern Germany cannot be considered representative of groundwater levels that might be present in all territories of the EU as a result of the pattern of use assessed in this conclusion.

Five non-standard scenarios including medium herbivorous birds, insectivorous and granivorous birds were considered relevant for the bird risk assessment by RMS. TER values were above the Annex VI trigger for short-term risk for all five scenarios. The acute and long-term risk to birds, which was found to be high in the DAR, was revised following peer-review comments. Herbivorous birds was not considered relevant in the revised risk assessment, as dimethachlor is applied prior to crop emergence in to a clean seed-bed. Skylark (*Alauda arvensis*) was used as focal insectivorous species. A refined risk assessment based on a mixed diet of large and small insects gave TER values above the Annex VI trigger. The meeting of experts considered that the risk assessment to insectivorous birds may not fully cover risks for herbivorous birds as dimethachlor could be transferred from soil to the plant systemically. Exposure from germinating plants could therefore not be excluded. It was agreed in the meeting to base the refined risk assessment on skylark consuming a mixed diet of grass weed, weed seed and large insects. Calculated TER values were above the trigger and the experts concluded a low acute and long-term risk to omnivorous birds from the use in oilseed rape. The initial risk to mammals was calculated for the two scenarios leafy crop (non-grass herbs) and short grass (grass and cereal shoots) with the hare (*Lepus europaeus*) as focal species in the DAR. The TER values were above the Annex VI trigger for the acute risk assessment but below the trigger for the chronic risk assessment. PD and PT refinements of the long-term risk assessment were not accepted during the

peer-review. As for birds exposure of herbivorous mammals was considered not relevant (see above) and the long-term risk assessment was based on a 10g shrew as a representative insectivorous mammal, feeding on ground-dwelling insects. A TER value of 4.1 indicated a need for further refinements. The meeting of experts agreed to the latter risk assessment. In addition the experts agreed to include a refined long-term risk assessment for an omnivorous mammal, to address also the risk from exposure from emerging plants and off-field plant. Based on a mixed diet TER values in the range of 2.2 to 4.4 were derived and agreed by the meeting expert. Experts concluded that further refinements of the long-term risk assessment for insectivorous and omnivorous mammals were required. A low risk from consumption of contaminated drinking water was identified by EFSA after the expert meeting. The risk from metabolites was considered to be low.

Dimethachlor was very toxic to aquatic organisms. A potential high risk was indicated with FOCUS step 3 PECsw values based on formulation studies for algae and *Lemna*. At FOCUS Step 4 including non-spray buffer zones, (1) TER values were calculated based on formulation toxicity (algae and *Lemna*) divided by PECsw including only spray drift input, and (2) TER values based on the technical substance toxicity (algae and *Lemna*) divided by PECsw including spray drift, run-off and drainage inputs. Only one safe scenario was identified (R1) with a non-spray buffer zone of 20 m, based on the formulation toxicity to algae. In case of Annex I inclusion of dimethachlor MS should be given the opportunity to ask for further refinement of the aquatic risk assessment pertinent to national conditions, given the fact that Annex VI trigger was only met in one out of six scenarios based on the lower toxicity to algae. The risk to aquatic organisms from dimethachlor metabolites was estimated to be low. Dimethachlor was not considered to bio-accumulate ($logP_{ow}$ below 3).
The risk to bees was considered to be low. Tier 1 off-field risk assessment to non-target arthropods indicated a low risk as did the in-field risk based on extended laboratory studies. Additionally, the risk to earthworms, soil non-target micro and macro organisms was expected to be low. A non-spray buffer zone of 10 m was required for non-target plants to identify a low risk.

Key words: dimethachlor peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Dimethachlor is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on dimethachlor, hereafter referred to as the draft assessment report, received by EFSA on 2 May 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 18 July 2007 to the Member States and the main applicant Syngenta Europe Ltd as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the applicant as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in May-June 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in July-August 2008 leading to the conclusions as laid down in this report.

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

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

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

- the comments received,
- the resulting reporting table (rev 1-2 of 1 April 2008)

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

- the reports of the scientific expert consultation,
- the evaluation table (rev 2-1 of 27 August 2008).

Given the importance of the draft assessment report including its addendum (compiled version of August 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Dimethachlor is the ISO common name for 2-chloro-N-(2-methoxyethyl)acet-2´,6´-xylidide (IUPAC).

Dimethachlor, belongs to the class of chloroacetanilide herbicides. Other members of this class include propachlor and metazachlor. It is a selective herbicide, absorbed mainly by the shoots and secondarily by the roots of germinating plants. It may inhibit synthesis of very long chain fatty acids. The representative formulated product for the evaluation was "Teridox 500 EC", an emulsifiable concentrate (EC).

The evaluated representative use is as a herbicide on oilseed rape. Full details of the GAP can be found in the attached list of end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

At the moment no minimum purity of dimethachlor as manufactured can be given, because further clarification is needed. A justification must be given for the level of impurities in the specification. Some QC data were provided in the evaluation table that supported the specification however, it was not summarised in enough detail and the meeting of experts could not conclude on it. Also the applicant has to demonstrate that when the TK was dried down for analysis of the impurities no

volatile impurities are lost. In addition to all these issues the meeting of experts also identified that a specification is required for the TK which is directly used to formulate the plant protection product. So it can be concluded that there is no acceptable specification available at this time.

The technical material contains CGA 72649[9], which has to be regarded as a relevant impurity. See section 2. However, a maximum level can not be given at this time due to the above issues with the technical specification.

Beside the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of dimethachlor or the respective formulation. However, the following data gaps were identified:

- Method of analysis for the relevant impurity in the plant protection product.
- Storage stability data with analysis of the relevant impurity.
- Evidence to demonstrate that under practical conditions of use the crystallization in the formulation is not an issue.

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

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of dimethachlor in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. However, a data gap has been identified for a method of analysis for the relevant impurity in the formulation and storage stability data
Therefore, some data are available to ensure that at least some quality control measurements of the plant protection product are possible.

A multi-residue method like the Dutch MM1 or the German S19 is not applicable due to the nature of the residues. Oilseed rape can be analysed by GC-NPD with an LOQ of 0.01 mg/kg, confirmation is by GC-MS. It is currently not clear if the ILV laboratory was truly independent and a data gap was identified. Soil is analysed by GC-MS with an LOQ of 0.02 mg/kg . Water is analysed by LC-MS/MS with an LOQ of 0.05 µg/L. It should be noted however that the residue definition for water and soil can not be finalised, see section 6. Air is analysed by GC-NPD, the soil and water methods can be used for confirmation.

[9] CGA 72649: 2,6-dimethylaniline

An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2). A method for body fluids and tissues is not required as the active substance is not classified as toxic or highly toxic.

2. Mammalian toxicology

Dimethachlor is an existing active substance (list 3 B) and was discussed at a meeting of experts for mammalian toxicology (PRAPeR 49, round 10) in June 2008.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Dimethachlor is absorbed orally almost completely and moderately rapidly (more than 94% within 168 hours) based on urinary and biliary excretion and tissue residues. It is widely distributed. The highest residual activity was found in blood and highly perfused organs (lungs, heart, kidneys, liver and spleen). In rats dimethachlor can potentially accumulate because of binding to haemoglobin. A comparison of the distribution of radioactive labelled dimethachlor with rat and human blood revealed that the persistent binding of dimethachlor to rat blood is most likely attributed to a covalent binding to rat haemoglobin, whereas the covalent binding to human haemoglobin is unlikely because of the lack of a reactive cysteine residue (the moiety to which dimethachlor binds in the rat haemoglobin molecule). This is considered to be strong evidence that the binding of dimethachlor to rat blood is a species-specific phenomenon that is not relevant to humans. More than 91% of dimethachlor is excreted within 168 hours, with the urine (44.14% in males and 59.79% in females) and with faeces (47.07% in males and 30.95% in females). Dimethachlor is virtually completely metabolised. Major metabolic pathways are O-dealkylation leading to O-desmethyl derivatives, the substitution of chlorine by glutathione and the oxidation of the methyl-phenyl group to hydroxyl-methyl derivatives. Further metabolism reactions are conjugation reactions with glutathione and glucuronic acid leading to a variety of sulphur containing metabolites.

2.2. Acute toxicity

Dimethachlor is of moderate toxicity by the oral (LD_{50} = 1600 mg/kg bw) and of low toxicity by the dermal (LD_{50} > 2000 mg/kg bw) and inhalation route (LC_{50} > 4.45 mg/L). It is neither a skin nor an eye irritant. In a skin sensitisation test with guinea pigs (Magnusson & Kligman) all treated animals presented positive reactions. Based on the available data on acute effects a classification as **Xn; R22 "Harmful; Harmful if swallowed"** and **Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed.

2.3. Short term toxicity

With rats a 90-day dietary study and a 28-day dermal study are reported. With mice one and with dogs two 90-day oral feeding studies have been carried out. A 12-month dog study has not been presented

in the DAR but was considered not necessary by the experts since effects and effect levels were similar through species (the liver is the main target of dimethachlor induced toxicity). The experts agreed to set a NOAEL of 2.21 mg/kg bw/d based on changes in clinical chemistry seen at the LOAEL of 71.7 mg/kg bw/d in the 90-day rat study. At higher doses also effects on liver and kidney weights, liver hypertrophy and food consumption and body weight gain were observed.

In mice, effects on liver and kidneys (increased weight and histopathology) were observed, leading to a NOAEL of 17.5 mg/kg bw/d.

In the first dog study the experts agreed to set a NOAEL of 9.96 mg/kg bw/d based changes in clinical chemistry, increased relative and absolute weights and histopathology in liver, haematological changes, increased kidney weights, histopathology of thymus and oesophagus and changed red blood cell parameters. This NOAEL was confirmed by the NOAEL of the second dog study (10 mg/kg bw/d) derived from observations of increased liver weights and liver pathology.

No adverse effects were observed in the dermal rat study up to the top dose of 1000 mg/kg bw/d.

2.4. GENOTOXICITY

Dimethachlor did not show a genotoxic potential in an adequate battery of four *in vitro* and one *in vivo* genotoxicity tests.

In an *in vivo* study with rats (reported in section B. 6. 8. of the DAR) it could be shown that dimethachlor does not bind to DNA in liver cells, however, the extensive binding to chromatin protein that was observed might be an indication for a potential interference with DNA replication or transcription.

2.5. LONG TERM TOXICITY

With rats a 24-month combined toxicity/carcinogenicity study and with mice two 18-month carcinogenicity studies where identical doses were employed, are reported. From the rat study a systemic NOAEL of 11.1 mg/kg bw/d was derived based on decreased body weight, increased liver and kidney weights, liver histopathology and changes in clinical chemistry at the highest dose of 157 mg/kg bw/d. At that dose also adenomas of the respiratory epithelium were observed in male animals. In an addendum to the DAR an evaluation of the toxicological significance of these tumours in context with the occurrence of nasal tumours in long term studies with other chloroacetanilides (i.e. alachlor and acetochlor) and mechanistic considerations was provided. In this evaluation the RMS came to the conclusion that these tumours were not of toxicological relevance for humans. In contrast to that, a majority of the experts concluded that these tumours were of concern and consequently a classification of dimethachlor as **Xn; R40 "Harmful; Limited evidence of a carcinogenic effect"** was proposed. The rapporteur disagreed with this conclusion.

In the two mice studies almost identical systemic NOAELs of 31.2 and 31.4 mg/kg bw/d respectively were obtained based on findings of decreased bodyweights, increased liver and kidney weights and liver and kidney pathology in both studies. In the first mouse study pulmonary and liver tumours were

observed at the highest dose in males but they were considered as not relevant for human risk assessment by the experts since they were not dose related and within the historical control range.

2.6. REPRODUCTIVE TOXICITY

A two generation study, one developmental study with rats and one with rabbits are reported in the DAR. In the two-generation study the parental and the offspring NOAEL were set at 20 mg/kg bw/d based on observations of reduced body weight gain and food consumption in parental animals and on reduced postnatal growth in pups, while the NOAEL for reproduction was set at the highest dose of 267 mg/kg bw/d since no relevant effects were observed. In the rat developmental study both the maternal and the developmental NOAEL were set at 50 mg/kg bw/d based on decreased body weight gain and food consumption in the dams and increased incidences of poorly or non ossified bones in pups. The maternal NOAEL in the rabbit study was set at 100 mg/kg bw/d based on reduced body weight gain and food consumption while that for pups was set at the highest dose of 350 mg/kg bw/d since no relevant effects were detected.

2.7. NEUROTOXICITY

No specific studies have been carried out but dimethachlor belongs to the chemical class of chloroacetanilides which are not suspected to affect the nervous system in mammals. Moreover, in none of the studies reported in other chapters relevant effects have been detected.

2.8. FURTHER STUDIES

Metabolites

Toxicological studies were performed with the dimethachlor soil and groundwater metabolites **CGA 50266**[10] (FOCUS scenarios: 10.49 - 21.4 µg/L), **CGA 354742**[11] (FOCUS scenarios: 4.1 - 13.4 µg/L), **CGA 369873**[12] (FOCUS scenarios: 0.24 – 1.45 µg/L), **CGA 373464**[13] (FOCUS scenarios: 0.39 - 2.35 µg/L), **SYN 528702**[14] (FOCUS scenarios: 1.52 - 9.21 µg/L) and S**YN 530561**[15] (FOCUS scenarios: 0.22 – 1.32 µg/L).

An LD_{50} > 2000 mg/kg bw was obtained in acute toxicity tests with rats both with the metabolite CGA 50266 and CGA 354742. Both metabolites were negative in a battery *in vitro* genotoxicity tests consisting of a bacterial gene mutation, a mammalian mutagenicity and a cytogenicity test. In 90-day dietary studies with rats the NOAELs were set at 400 mg/kg bw/d based on kidney and adrenal histopathology and at 69.6 mg/kg bw/d based on kidney, liver, thyroid and thymus histopathology for CGA 50266 and CGA 354742 respectively. Metabolite CGA 369873 was also negative in a battery of

[10] CGA 50266: N-(2,6-dimethyl-phenyl)-N-(2-methoxy -ethyl)-oxalamic acid
[11] CGA 354742: [(2,6-dimethyl-phenyl)-(2-methoxy-ethyl)-carbamoyl]-methanesulfonic acid sodium salt
[12] CGA 369873: (2,6-dimethyl-phenylcarbamoyl)-methanesulfonic acid sodium salt
[13] CGA 373464: [(2,6-dimethyl-phenyl)-(2-sulfo-acetyl)-amino]-acetic acid sodium salt
[14] SYN 528702: 3-{2-[(2,6-dimethyl-phenyl)-(2-hy-droxy-acetyl)-amino]-ethylsulfanyl}-2-hydroxy-propionic acid
[15] SYN 530561: 2-[(2-hydroxy-acetyl)-(2-methoxy-ethyl)-amino]-3-methyl-benzoic acid

in vitro genotoxicity tests consisting of a bacterial gene mutation, a mammalian mutagenicity and a cytogenicity test. Negative results were also obtained in bacterial gene mutation tests carried out with metabolites CGA 373464, SYN 528702 and SYN 530561. No relevant data has been provided for the potential ground water metabolite **CGA 102935**[16] (no assessment of groundwater concentrations available but expected to be > 0.1 µg/L). The experts agreed that further toxicological data was necessary (and missing) for all these metabolites and that consequently the metabolites **CGA 50266, CGA 354742, CGA 369873, CGA 373464, SYN 528702,** SYN **530561 and CGA 102935** had to be considered as relevant according to guidance document Sanco/221/2000-rev. 10 - final.

Impurities

Based on the requirements laid down in the "*Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC" (Sanco/10597/2003 – rev. 7 final, 14 March)* in the DAR (13th of April 2007) the RMS requested the applicant to provide bacterial mutagenicity tests on dimethachlor impurities CGA 38501, CGA 173125 and CGA 173126. Information on these impurities was submitted in an *Evaluation report on the equivalence of technical material for the active substance dimethachlor (16th May, 2007)* which was resubmitted with an addendum to the DAR (22nd April, 2008). At the meeting of experts it was concluded that this information could not be considered in view of the restrictions concerning the acceptance of new (including newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, and consequently a data gap was set.

In the list of endpoints **CGA 72649** (2,6-dimethylaniline) is listed as a relevant impurity.

2.9. MEDICAL DATA

There are no reports of adverse effects from medical surveillance of personnel involved in manufacturing of dimethachlor.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

The experts agreed to derive an **ADI of 0.1 mg/kg bw/d** from the NOAEL obtained in the 24-month rat study, supported by the 90-day dog study applying a safety factor of 100.
The **AOEL of 0.1 mg/kg bw/d** was derived from the 90-day dog study employing a safety factor of 100.
The **ARfD of 0.5 mg/kg bw** was derived from maternal and developmental effects observed in the rat developmental toxicity study applying a safety factor of 100.

[16]CGA 102935: N-carboxymethyl-N-(2,6-dimethyl-phenyl)oxalamic acid

2.11. DERMAL ABSORPTION

The experts agreed that the values for dermal absorption of 3% for the concentrate and of 10% for the in use dilution based on the results from an *in vivo* dermal penetration study in rats and an *in vitro* percutaneous absorption study through rat and human skin performed with the formulation Teridox 500 EC A-5089 F (containing naphthalene as part of the aromatic hydrocarbon solvent ingredient) can be used for the formulation Teridox 500 EC A-5089 H that seeks approval (containing no naphthalene).

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product "TERIDOX 500 EC" is formulated as an emulsifiable concentrate containing 500 g/L dimethachlor. It is used as a pre-emergence herbicide to control annual grasses and broad-leaved weed species in oil seed rape. According to the intended use submitted by the applicant the maximum dose of dimethachlor applied is 1.5 kg/ha and the minimum volume is 100 L water/ha. It is applied once a year using a vehicle-mounted or a drawn boom sprayer.

Operator exposure

The exposures for operators have been estimated using the German model and the UK POEM. In the German model they are 119% without PPE (personal protective equipment) and 88% with PPE (gloves during mixing/loading) of the AOEL. In the UK POEM they are 1241% without and 195% with PPE (gloves during mixing/loading and application) of the AOEL.

Worker exposure

The predicted exposure for re-entry workers[17] is 4.3% and 0.2% without and with PPE respectively of the systemic AOEL of 0.1 mg/kg bw/d.

Bystander exposure

Predicted exposure from application of "TERIDOX 500 EC", was assessed using the input parameters from the from EU Technical Guidance Document[18] and the draft values proposed for the EUROPOEM II[19], and amounted to 2.2% the short term systemic AOEL of 0.1 mg/kg bw/d.

[17] Hoernicke E, Nolting HG, Westphal D (1998) Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen (worker re-entry) (1998) Nachrichtenblatt des Deutschen Pflanzenschutzdienstes. Vol 50 (10) 1998.

[18] Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Communities 2003.

[19] EUROPOEM II (2003) *The development, maintenance and dissemination of a European Predictive Operator Exposure Model* (EUROPOEM II) database. A EUROPEAN II Database and Harmonised Model, FAIR-3CT96-1406, TNO-BIBRA International, Carshalton.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The uptake, distribution and degradation of dimethachlor in oilseed rape was investigated after pre-emergence treatment of [Phenyl-U-14C]dimethachlor (specific activity: 0.37 MBq/mg) and formulated as EC 500. The rate of application was equivalent to 1.5 kg as/ha 1N. After 18 days the radioactivity mainly concentrated in the dicotyledons was identified as glutathione conjugate and derivatives almost quantitatively, as shown by Raney nickel reaction. Parent was not detectable.

After the fall off of the dicotyledons the major part of the early accumulated metabolites was lost, and the total radioactivity (as dpm) increased about 4-fold until maturity. After the loss of the dicotyledons parent concentration in soil was only 5 - 10 % of TRR in soil. Total residues in the plant decreased from 2.768 mg/kg parent equivalents at Day-18 to 1.023 mg/kg at Day-32, and to 0.076 mg/kg at Day-222.

At maturity (294 days after application) the total residues in stalks, pods and seeds amounted to 0.191 mg/kg parent equivalents, 0.161 mg/kg and 0.051 mg/kg, respectively. Total residues in oil accounted for 28.8 % of seed TRR. The glutathione conjugates and derivatives were possibly present in very small amounts, but could not be clearly detected or cleaved by Raney nickel reduction. The total radioactivity in the oilseed rape plant was characterised as a multitude of minor degradation products in the range of 0.001 to 0.006 mg/kg. Parent was not detectable. Two main metabolites were found in limited amounts in all plant parts:

CGA 50266, the oxalic acid derivative, a water soluble and acid metabolite (13.6 % of TRR in stalks (0.026 mg/kg), 20.8 % in pods (0.033 mg/kg) and 7.9 % in seeds [meal] (0.004 mg/kg)).

CGA 39981[20], an alcohol derivative partially found as sugar conjugate (6.4 % of TRR in stalks (0.012 mg/kg), 3.7 % in pods (0.006 mg/kg) and 0.9 % in seeds [meal] (0.001 mg/kg)).

Non-extractable radioactivity after microwave extraction at high temperature represented 43.7 % of TRR (0.084 mg/kg parent equivalent) in stalks, 51.0 % (0.082 mg/kg) in pods, and 51.4 % (0.023 mg/kg) in seeds.

After treatment with 25 % NH4OH, four to five products were released from the solid matrix. The major compound produced was CGA 50266: it was released from stalks and pods, 4.8 % and 7.4 % of the respective TRR. Non-extractables after drastic treatment amounted to 27.9 % of TRR in stalks, 22.3 % in pods and 38 % in seeds.

Treatment of non-extractable of seeds (after microwave extraction) with 1M NH4OH released ca 6.8 % of seed-TRR that was characterised as a protein fraction. An additional 2N HCl treatment of the resulting-NE released only 2 % of TRR of uncharacterised radioactivity.

[20] CGA 39981: N-(2,6-dimethyl-phenyl)-2-hydroxy-N-(2-methoxy-ethyl)-acetamide

It is concluded that the pre-emergence treatment of oilseed rape leads to a situation of no residue of concern in seed and oil.

In the meeting of experts PRAPeR 50 June 2008 the residue definition was considered. In the DAR the residue definition was dimethachlor only. The reasoning behind this was that at harvest residues in the seed are extremely low and therefore the residue definition defaulted to dimethachlor only. However it was pointed out that a positive residue of dimethachlor was found in one of the trials which would mean that the metabolites seen in the metabolism study could also be present at significant levels. The meeting considered the available residues data with 4 trials giving residues of dimethachlor of <0.01 mg/kg 13 trials <0.02 mg/kg and 1 trail a residue of 0.05 mg/kg. The meeting concluded that the 0.05 mg/kg is not a correct result and perhaps was due to a matrix component or sample contamination. As this is the case the metabolites do not occur at significant levels <0.005 mg/kg and the residue definition for risk assessment should remain as dimethachlor.

The stability of residual dimethachlor in analytical specimens of oilseed rape under deep-freeze conditions (–18 °C or below) was investigated using fortified samples. These samples were stable over a period of 2 years (no decline).
Processing studies are not necessary due to the low residue situation.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

An outdoor rotational crop study was performed after one time bare ground application of [Phenyl-U-14C]dimethachlor (specific activity: 0.37 MBq/mg) at a rate of 1500 g as/ha 1N. Winter wheat-1 was sown after 30 days, and spring wheat and radish at Day-187. Lettuce-1 was transplanted at Day 212. After one-year winter wheat-2 was sown and lettuce-2 transplanted.
Following soil application of [Phenyl-U-14C]dimethachlor, parent was not detectable in any rotational crop commodity above the LOQ (TLC) of 0.001 mg/kg.

The total radioactive residues in rotational crops following soil application of [Phenyl-U-14C]dimethachlor at a rate of 1500 g as/ha were:
0.042 mg/kg in grains of winter wheat-1, 0.130 mg/kg in husks and 0.149 mg/kg in straw at maturity (Day-309) for plant-back intervals of 30 days,
0.041 mg/kg in grains of spring wheat, 0.136 mg/kg in husks and 0.165 mg/kg in straw at maturity for plant-back intervals of 187 days,
0.007 mg/kg in grains of winter wheat-2, 0.006 mg/kg in husks and 0.008 mg/kg in straw at maturity for plant-back intervals of 360 days,
0.007 mg/kg in radish roots and 0.042 mg/kg in radish green part at maturity for plant-back interval of 187 days,
0.031 mg/kg in head of lettuce-1 for plant-back interval of 212 days,
0.014 mg/kg in head of lettuce-2 for plant-back interval of 365 days.

Identified metabolites CGA 50266 and CGA 39981 each amounted to 0.002 mg/kg in lettuce-1 and to 0.004 mg/kg in green part of radish. Parent was not detectable.

The meeting of experts partially considered the study and specifically the fact that at the 30 day plant back only cereals had been planted. However, the rapporteur informed the meeting that the DT90 in soil was less than a 100 days and the need for this study according to the current guidance documents is not triggered. After the meeting of experts in consultation with EFSA fate and behaviour specialist it was concluded that the DT90 is less than 100 days for dimethachlor but that there are relevant metabolites present in soil with much longer DT90 values. It can therefore be concluded that the DT90 for the total bio-available residue will be much greater than 100 days and the need for a rotational crop metabolism study is triggered. A new data gap is therefore identified to address this issue. It is noted that the rapporteur does not support this new data gap.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

In potential feeding stuffs only minor amounts of residues from the application of dimethachlor are detectable. Therefore no metabolism studies on livestock animals are necessary. A residue definition for animal products is neither proposed nor needed.

3.3. CONSUMER RISK ASSESSMENT

Intakes are less than 1 % of the ADI and ARfD for WHO and German diets. However the risk assessment can not be finalised because of the rotational crops issue.

3.4. PROPOSED MRLS

On the basis of the total residue trial data set the rapporteur proposed 0.05 mg/kg on the basis of one residue trail where all other trials gave residues of <0.01 mg/kg or <0.02 mg/kg. The meeting of experts considered that the 0.05 mg/kg was not a correct result and the MRL proposal has been changed to 0.02*.

4. Environmental fate and behaviour

Dimethachlor was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 47 in May 2008.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Soil experiments (4 different soils) were carried out under aerobic conditions in the laboratory (20°C and 75% 1/3 bar moisture holding capacity (MHC) or 40% maximum water holding capacity

(MWHC)) in the dark. The formation of residues not extracted by acetonitrile:water (including Soxhlet) were a sink for the applied phenyl ring-^{14}C-radiolabel (33-57 % of the applied radiolabel (AR) after 120 days). Mineralisation to carbon dioxide of this radiolabel accounted for 9.6-40 % AR after 120 days. The major (>10%AR) extractable breakdown product present were CGA 50266 (max. 12-35%AR at 7-63 days), CGA 354742 (max. 15.8%AR at 14 days). Metabolites accounting for > 5%AR at 2 consecutive sampling times for which a groundwater exposure assessment is triggered were CGA 102935 (max. 6-9%AR at 42-120 days) and SYN 528702 (max. 6.3%AR at 42-63 days). The member state experts agreed that these metabolites had been adequately identified and were all those for which groundwater exposure assessments were triggered on the basis of these soil route of degradation studies. Clarifications that allowed this conclusion to be reached and agreed by the experts were included in the addendum 1 to the DAR dated 22 April 2008 (pages 86-87 and 102-104).

Data on anaerobic degradation in soil were provided in two experiments (Ellgehausen, 1977 and Dean, 1995). The experts discussed these studies as there were some methodological problems with the experiments (limited numbers of samples taken during the anaerobic phases and low recoveries of total radioactivity). The experts agreed that taken together these 2 studies provided a sufficiently reliable and coherent indication of expected behaviour of dimethachlor under anaerobic conditions in soil and the endpoints from the studies could be relied on for exposure assessment. So as a consequence it was agreed that under anaerobic soil conditions the metabolite CGA 42443[21] not seen under aerobic soil conditions would be expected to be formed (max values of 6-11%AR at the end of the studies after 85 and 180 days of anaerobic conditions). In a laboratory soil photolysis study, no novel photo degradation products were identified, and the degradation rate of parent dimethachlor was comparable in irradiated samples and in the dark controls. These results indicated that photolysis is not an important process so would not be expected to contribute significantly to the degradation of dimethachlor in soil.

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

The rate of degradation of dimethachlor under aerobic conditions was estimated from the results of the studies described in 4.1.1 above and an additional study where incubations were carried out at 10-20°C and 30-60% field capacity soil moisture and in an additional 2 soils (incubations at 22°C and 40% MWHC soil moisture). DT_{50} were: 3.3-19.8 days, (values from 7 different soils). After normalisation to FOCUS reference conditions[22] (20°C and -10kPa soil moisture content) this range of single first order DT_{50} is 2.4-15.6 days (geometric mean that is appropriate for use in FOCUS modelling 6.5 days, see addendum 1 to the DAR dated 22 April 2008 (pages 88-90) where the derivation of these values is clarified).

[21] CGA 42443: N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)acetamide
[22] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002, utilising a Q10 of 2.2 and Walker equation coefficient 0.7.

The rate of degradation of CGA 50266 was estimated from the same studies discussed above where dimethachlor was applied as the test substance (with the exception of the incubations at 22°C and 40% MWHC soil moisture as levels of CGA 50266 were not determined in these experiments). DT_{50} were: 6.8-254 days, associated kinetic formation fractions from dimethachlor 0.31 to 0.49, (values from 5 different soils). After normalisation to FOCUS reference conditions (20°C and -10kPa soil moisture content) this range of single first order DT_{50} is 6.8-195.5 days (geometric mean that is appropriate for use in FOCUS modelling 26.1 days, arithmetic mean kinetic formation fraction from dimethachlor 0.4, see addendum 1 to the DAR dated 22 April 2008 (pages 88-100) where the derivation of these values is clarified).

The rate of degradation of CGA 354742 was estimated from the studies discussed above where dimethachlor was applied as the test substance and when this metabolite was present, (It was only identified as being present in 2 of the soils investigated when the incubation conditions were 20°C and 75% 1/3 bar MHC). DT_{50} were: 11.4 and 13.1 days, associated kinetic formation fractions from dimethachlor 0.33 (both soils). In a dark aerobic laboratory soil (sandy clay loam pH 5.6 oc 1.7%) incubation (20°C -10kPa soil moisture) where CGA 354742 was applied as test substance, a single first order DT50 of 23.2 days was estimated. In this case the available 3 experiments reflect FOCUS reference conditions or were done at higher soil moisture contents, so normalisation was not necessary. The geometric mean that is appropriate for use in FOCUS modelling is 15.1 days, kinetic formation fraction from dimethachlor 0.33, (see addendum 1 to the DAR dated 22 April 2008 (pages 94 and 100) where the derivation of these values is clarified).

Information on the rate of degradation in soil of the metabolites CGA 102935 and SYN 528702 were not available. The experts agreed that there was a data gap for this information for CGA 102935, which is necessary to complete the groundwater exposure assessment. (A groundwater exposure assessment for SYN 528702 is available based on information from lysimeter studies, this is not the case for CGA 102935 (see section 4.1.3 for further details).

The experts agreed that under anaerobic soil conditions in the laboratory from the studies described at 4.1.2 above, estimates for dimethachlor, single first order DT_{50} were 11.3 days at 25°C in the clay loam soil (16.4 days normalised to 20°C assuming a Q10 of 2.2) and 19.4 days at 20°C in the silt loam soil were the appropriate endpoints (and not the value indicate in the DAR for the silt loam soil of 123 days that was not reproducible).

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

The adsorption / desorption of dimethachlor was investigated in 10 soils in satisfactory batch adsorption experiments. Calculated adsorption $K_f oc$ values varied from 49 to 128 mL/g, (arithmetic

mean 70.2mL/g, median 68.9 mL/g) (1/n 0.85 – 0.95, arithmetic mean 0.89, median 0.9). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of CGA 50266 was investigated in 3 soils in satisfactory batch adsorption experiments. CGA 50266 remained almost entirely in the soil solution. The amount adsorbed was negligible, such that it was not possible to estimate soil adsorption values. A value of 0 mL/g was selected for use in FOCUS scenario calculations of groundwater exposure potential.

The adsorption / desorption of CGA 354742 was investigated in 3 soils in satisfactory batch adsorption experiments. Calculated adsorption $K_d$oc values varied from 3.4 to 4 mL/g, (arithmetic mean 3.7 mL/g). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of CGA 42443 (a major (>10%AR) anaerobic soil metabolite and minor (<10%AR) aerobic sediment / water system metabolite) was investigated in 3 soils in satisfactory batch adsorption experiments. Calculated adsorption $K_f$oc values varied from 24 to 41 mL/g, (arithmetic mean 31 mL/g) (1/n 0.87 – 0.95, arithmetic mean 0.9). There was no evidence of a correlation of adsorption with pH.

Information on the adsorption potential to soil of the metabolites CGA 102935 and SYN 528702 in batch adsorption studies was not available. The experts agreed that there was a data gap for this information for CGA 102935, which is necessary to complete the groundwater exposure assessment. (Information to estimate groundwater concentrations for SYN 528702 can be derived from the lysimeter study (see below)).

In a BBA guideline lysimeter study (2 x replicate 1.2m depth soil monoliths of sandy loam soil) carried out in Switzerland, an application was made in September to bare soil, (seed of oilseed rape having been planted 6 days earlier) at a dose of 1.5kg dimethachlor /ha (the applied for intended use in the EU dossier). The lysimeters were then cropped with Phacelia after harvesting the mature oilseed rape, followed by a crop of winter wheat. Leachate was collected for 2 years but the single application was only made in the first year. Precipitation was 1129mm in the first year and 944mm in the second year. Up to 32% of this precipitation volume was collected as leachate from the soil monoliths in the first calendar year. In the second calendar year this was up to 44%. Dimethachlor was not detected (>0.05µg/L) in any individual leachate sample collected. Annual average concentrations of the metabolites CGA 50266, CGA 354742, SYN 528702, CGA 369873, CGA 373464 and SYN 530561 were all > 0.1µg/L (35.6, 41.3, 15.3, 2.4, 3.9 and 2.2µg/L respectively (reported as up to 36.2, 35.1, 11.3, 2.5, 3.3 and 2.1µg dimethachlor equivalents/L respectively in the DAR)).

The known minor soil metabolite CGA 102935 was not present in lysimeter leachate. However the member state experts considered that as there was no experimental evidence available to demonstrate that CGA 102935 was a metabolite that was formed in this sandy loam lysimeter soil, that it's absence from lysimeter leachate was not sufficient evidence in isolation, to conclude that there would not be a potential leaching risk associated with this metabolite. It cannot be excluded that the reason that CGA 102935 was not in the lysimeter leachate was that in this soil, the amount of this metabolite formed was negligible. It was also noted that CGA 102935 was tentatively identified in the leachate of a laboratory aged column leaching study (see appendix 1 and for full details pages 448 to 450 of the DAR) indicating that when present in soil it has the potential to be mobile.

The experts also considered the information provided by the applicant and evaluated by the RMS on pages 101 and 102 in addendum 1 to the DAR dated 22 April 2008 regarding the efforts made to characterise of the mixture of 'small polar radioactive constituents' present in the lysimeter leachate. The experts accepted that the efforts made by the applicant to characterise the unidentified radioactivity were extensive and appropriate. They agreed that a further assessment regarding this would not be possible. They accepted that polar compounds may be present in individual leachate samples at up to 0.5µg/L (the estimated limit of detection). It might be surmised that it is unlikely that any of these components would exceed an annual average leachate concentration of 0.1µg/L.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Dimethachlor and the metabolites CGA 50266, CGA 354742 and CGA 42443 were stable under sterile hydrolysis conditions at 50°C at pH 4, 5, 7 and 9.
Dimethachlor and the metabolites CGA 50266, CGA 354742 and CGA 42443 were stable under sterile direct aqueous photolysis conditions at environmentally relevant pH.
A ready biodegradability test (OECD 301B) indicated that dimethachlor is 'not readily biodegradable' using the criteria defined by the test.

In water-sediment studies (2 systems studied at 20°C in the laboratory) dimethachlor degraded rapidly in the water and sediment (first order whole system DT_{50} 8.7 to 22.8 days). The only major metabolite formed was CGA 50266 (max. 10.1-13 % AR at 112-182 days after treatment, in water). The terminal metabolite, CO_2, accounted for only 1.1-2.2 %AR of the phenyl ring-^{14}C-radiolabel by 112 days. Residues not extracted from sediment by acetonitrile:water (including Soxhlet) were a significant sink representing 49-53%AR at 112 days. The experts agreed that for dimethachlor a sediment DT_{50} of 14 days (geomean whole system value) combined with a value of 1000 days for water were the appropriate values for use in FOCUSsw scenario calculations.

FOCUS surface water modelling was evaluated up to step 4 for dimethachlor and step 3 for the metabolites CGA 50266 and CGA 354742 (simulations that account for movement from soil, (kinetic

formation fractions in soil from dimethachlor 0.37 utilised for CGA 50266 and 0.33 utilised for CGA 254742) to surface water systems, but not formation in the surface water systems). The peer review agreed these PEC surface water and sediment as presented in the DAR, with a summary table of surface water results included on page 112 of the addendum 1 to the DAR dated 22 April 2008 as appropriate for use in risk assessment (noting that the sediment DT50 used of 3 days should have been 14 days, though accepting that this would not be expected to impact the initial PEC values calculated significantly). At step 4 the only mitigation considered was no spray drift buffer zones of 5 and 10m that were implemented following the methods prescribed by FOCUSsw guidance. In addition as some aspects of the aquatic risk assessment are driven by the endpoints from formulated product ecotoxicity tests, PEC from spray drift alone were also appropriately calculated for no spray zones of 1-20m (see page 113 of the addendum 1 to the DAR dated 22 April 2008, it is appropriate to do this in relation to a formulation risk assessment, as the formulated product cannot reach a surface water body via drainage or surface runoff, but only by drift). It should be noted that FOCUS landscape and mitigation guidance[23] (2007) indicates that spray drift should not be mitigated by more than 95% and that buffer zones of 20 and 25m would respect this maximum mitigation value but that a larger buffer of 30m would mitigate drift by more than 95% of the base FOCUS defined distance.

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

Following FOCUSgw scenarios guidance[24] the most appropriate substance parameters appropriate for use in FOCUSgw scenario modelling based on the available (July 2008) data were: dimethachlor single first order soil DT_{50} 6.5, K_{foc} 69 mL/g, 1/n=0.9; CGA 50266 single first order soil DT_{50} 26.1 days, formation fraction from dimethachlor 0.4, K_{foc} 0 mL/g, 1/n=0.9; CGA 354742 single first order soil DT_{50} 15.1 days, formation fraction from dimethachlor 0.33, K_{doc} 3.7 mL/g, 1/n=1. Data gaps are identified for the relevant soil DT50, soil kinetic formation fraction and adsorption values for the metabolite CGA 102935.

The applied for representative use of autumn applications (on the emergence date defined for each scenario) to winter oilseed rape with the application occurring every third year was simulated using FOCUSPELMO 3.3.2 using the input parameters as listed above except that the kinetic formation fraction of CGA 50266 from dimethachlor used was 0.37 instead of 0.4, (see pages 106 to 108, addendum 1 to the DAR dated 22 April 2008). The results of these simulations were that at 5 of the 6 pertinent FOCUS groundwater scenarios dimethachlor was calculated to be present in leachate leaving the top 1m soil layer at 80th percentile triannual average concentrations of <0.001µg/L. At the Piacenza scenario this value was 0.026µg/L. For metabolite CGA 50266 these values were 10.49

[23] FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.
[24] Version 1.1 (April 2002) Generic guidance for FOCUS groundwater scenarios (Q10 2.2, Walker equation coefficient 0.7).

to 21.44µg/L. For metabolite CGA 354742 these values were 4.11 to 13.45µg/L. By interpolating the annual average concentrations of the metabolites present in the lysimeter leachate using these modelled (triannual) values and annual average lysimeter concentrations for CGA 50266 and CGA 354742, indications of triannual average leachate concentrations pertinent to the FOCUS groundwater scenarios were obtained for CGA 369873 (0.24 to 1.45µg/L), SYN 530561 (0.22 to 1.32 µg/L), SYN 528702 (1.52 to 9.21µg/L) and CGA 373464 (0.39 to 2.35µg/L) (see addendum 3 dated 1 July 2008, where the highest values in these ranges were calculated by the RMS but expressed as active ingredient equivalents rather than the true concentrations that are included here in this conclusion and in appendix 1[25]).

Following the meeting of experts some worst case FOCUS groundwater scenario simulation modelling was carried out for metabolite CGA 102935 (see addendum 3 dated 1 July 2008), based on application rate of the parent of 1.5 kg a.s./ha and factored by the molecular weight and the maximum peak percentage observed in soil of 9%. It was assumed that there was no adsorption (Koc= 0) and a DT_{50} of 51.9 days was estimated by fitting a first order degradation to measured values in a single soil experiment in a way that was not clearly described (i.e. no formation fraction reported). The approach used did not follow the recommendation the experts had made regarding this estimate (which was that a DT_{50} should be estimated as a decline rate from the maximum observed which would have given a longer value of ca. 97 days). Therefore the simulation results in addendum 3 of 1 July 2008 are likely to be best case in relation to soil persistence and might underestimate the leaching potential of CGA 102935. Therefore this modelling for CGA 102935 (from addendum 3) is not peer reviewed. Whilst it used a relatively best case degradation rate, it does confirm that leaching of CGA 102935 above the parametric drinking water limit may well be an issue.

The results of a groundwater monitoring program from the Schleswig-Holstein (Northern Germany) and Mecklenburg-West Pomerania (North Eastern Germany) regions from 14 wells in vulnerable locations (groundwater tables 2-9m in depth) were reported in the DAR with clarification being provided on details of the wells sampled included on page 114 of addendum 1 to the DAR dated 22 April 2008. Monthly samples were taken over 2 years. The experts discussed the monitoring program design. They agreed that the applicant had provided information that provided some evidence that a proportion of the fields in the areas monitored had received treatment in accordance with the pattern of use of dimethachlor assessed in the DAR. The analyses included in the program were: dimethachlor, CGA 50266, CGA 354742, SYN 528702, CGA 369873, CGA 373464 and SYN 530561. It should be noted that the metabolite CGA 102935 was not analysed for in the program. The limit of quantification was 0.05µg/L for all analyses. Dimethachlor, CGA 50266, SYN 528702, CGA 373464 and SYN 530561 were not detected in this monitoring (>0.05µg/L). The ranges of concentrations for the remaining 2 metabolites were: CGA 354742 <0.05-0.52µg/L and CGA 369873 <0.05-2.1µg/L. The experts agreed that, with the exception of the metabolite not analysed for (CGA

[25] calculated by EFSA using a factor of the relative molecular weight of the metabolites compared to the active substance

102935), **in the regions monitored**, a good indication was provided that a parametric level of 10µg/L in groundwater[26] was not exceeded for the metabolites sought. However the majority of the fate and behaviour experts indicated that they would wish to see comparable monitoring exercises carried out more extensively across Europe to see if this conclusion might be more generally applicable. Any future monitoring exercises should include analysis for CGA 102935. Following the later discussions in the toxicology meeting of experts that indicated these metabolites need to be considered relevant at the moment, when using the available database of toxicological studies, this discussion in relation to a 10µg/L concentration is superseded as the parametric groundwater limit for relevant metabolites is 0.1µg/L.

A groundwater exposure assessment is triggered for CGA 102935. Such an assessment cannot be completed based on the available information. A data gap was therefore identified by the member state experts for such an assessment. Although this assessment was not available it was the expert judgement of the member state experts that a groundwater non relevance assessment would probably be triggered for CGA 102935.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of dimethachlor ($6.4x10^{-4}$ Pa at 20°C) means that dimethachlor would be classified under the national scheme of The Netherlands as slightly volatile, indicating some losses due to volatilisation may occur. Based on the results of a laboratory controlled air flow experiment where a dimethachlor emulsifiable concentrate formulation was applied to a soil at 60% MWHC, measurements demonstrated that only 0.14% of the dimethachlor applied was lost to the air compartment (collected in volatile traps) in 24 hours. Calculations using the method of Atkinson for indirect photo oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 2.5 to 4.5 hours (assuming an atmospheric hydroxyl radical concentration of $1.5x10^{6}$ radicals cm^{-3}) indicating the small proportion of applied dimethachlor that will volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Dimethachlor was discussed in the meeting of experts PRAPeR 48 (May 2008) on the basis of the DAR (April, 2007), addendum 1 (April, 2008) and addendum 3 (July, 2008).
Dimethachlor is the active substance in the herbicidal formulation TERIDOX 500EC A-5089 F/H. The representative use is one spray application of 1.5 kg a.s./ha in winter oil seed rape.
During the peer-review, it was concluded that the metabolite CGA 42443 could be considered relevant for uses in territories where anaerobic soil conditions could not be excluded (see section

[26] 10µg/L is a parametric level noted in: Sanco/221/2000-rev.10, 25 February 2003, Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC.

4.1.1). As a consequence EFSA has identified a data gap (when drafting the conclusion) for data to address the risk to aquatic organisms and soil dwelling organisms.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Five non-standard scenarios including medium herbivorous birds, insectivorous and granivorous birds were considered relevant for the bird risk assessment by RMS. Whereas TER values were above the Annex VI trigger for short-term risk for all scenarios, the acute and long-term TER values were below the trigger for insectivorous and medium herbivorous birds. The acute and long-term risk assessments were refined considering a PT value of 0.25. The resulting TER values were above the Annex VI trigger. As further support for the PT refinement was requested during the peer-review, RMS provided a revised risk assessment in Addendum 1 (April, 2008). Following the guidance document[27], herbivorous birds was no longer considered relevant to the risk assessment, as dimethachlor is applied prior to crop emergence (BBCH09) in to a clean seed-bed. For insectivorous birds skylark (*Alauda arvensis*) was used as focal species. The refined risk assessment was based on a mixed diet (PD refinement) including 11% small insects and 89% large insects on a weight basis. The PT factor was not refined and standard RUD values were used for the TER calculation. TER values above the Annex VI trigger were derived for insectivorous birds indicating a low acute and long-terms risk from uses in oilseed rape. The meeting of experts considered that the risks to insectivorous birds may no fully cover the risks to herbivorous birds, as dimethachlor can be transferred from soil to the plant systemically. Exposure from germinating plants could therefore not be excluded. It was agreed in the meeting to base the refined risk assessment on skylark consuming a mixed diet of grass/weed, weed seed and large insects. Whereas standard RUD values[27]were used for seed and large insects, the residue concentration used for grass/weeds included different options, including standard RUD values[27] RUDs based on an off-field overspray situation or based on plant concentration equivalent to the maximum soil concentration. TER values were above the Annex VI trigger for all scenarios and the experts concluded a low acute and long-term risk to omnivorous birds from use in oilseed rape.

The initial risk to mammals was calculated for the two scenarios leafy crop (non-grass herbs) and short grass (grass and cereal shoots) with the hare (*Lepus europaeus*) as focal species. The TER values were above the Annex VI trigger for the acute risk assessment but below trigger for the chronic risk assessment. In the DAR a refined long-term risk assessment was based on literature data indicating a mixed diet (PD-factor) of 50% grass and cereal shoots and 50% of non-grass herbs for the brown hare and a PT-factor of 26%. The resulting higher tier TER value was 7.1. The PD and PT refinements were questioned during the peer-review and RMS provided a revised risk assessment in addendum 1 (April 2008). Following the guidance document[27] the tier 1 long-term risk assessment for mammals in leafy crop gave a TER value of 1, and further refinement was required. As dimethachor is applied pre-emergence to a clean seed-bed, no weeds or crop vegetations were expected to be

[27] Guidance document for Birds and Mammals (SANCO/4145/2002)

exposed and standard RUD values were deemed inappropriate. However, because dimethachlor is taken up via the root, emerging crop shoots were expected to have a maximum concentration equivalent to the maximum PECsoil. RMS suggested using a 10g shrew as a representative insectivorous mammal, feeding on ground-dwelling insects. A TER value of 4.1 indicated a need for further refinements. The meeting of experts agreed to the latter risk assessment. In addition the experts in the meeting agreed on a refined long-term risk assessment for an omnivorous mammal to address also the risk from exposure from off-field plant and residues in emerging plants. Based on a mixed diet (cereal seeds, weed seeds, grass and non-grass weeds, large insects and earthworms) and using standard residue data the TER value for an omnivorous small mammal was 2.2. If the residue concentration in plants was considered to equal the maximum soil concentration, the TER value was 4.4, which was also the case if the residue exposure was considered to be from off-field plants, i.e. including drift reduction of 2.77% in the residue calculation. TER values, based on a mixed diet, were calculated in the expert meeting and subsequently agreed by experts. (See addendum 3, July 2008). In conclusion the TER values were below the Annex VI trigger for the long-term risk assessment to insectivorous and omnivorous mammals, and a need for further refinements was concluded.

Secondary poisoning of birds and mammals was not considered as the $\log P_{ow}$ of 2.17 for dimethachlor is below 3.

The risk for consumption of contaminated drinking water was not addressed in the DAR or during the peer-review. EFSA provided an acute risk assessment while drafting the conclusion, based on the opinion of the PPR panel on the revision of the guidance document on risk assessment for birds and mammals[28]. In case of puddles formation, the intended application of dimethachlor to oilseed rape shortly after sowing, i.e. into a clean seed bed and prior to crop emergence, may provide the opportunity for birds and mammals to consume contaminated drinking water. Based on the new recommendations the acute TER values indicated a low risk to small granivorous birds (TER = 61.5) and small granivorous mammals (TER = 258) from intake of contaminated drinking water.

Toxicological studies with mammals were performed with the potential groundwater metabolites CGA 50266 and CGA 354742. The studies comprised acute, short-term, and mutagenicity studies. In comparison to the parent dimethachlor, the metabolites were less toxic at comparable dose levels. It was concluded that the risk to birds and mammals from metabolites was addressed by the risk assessment to dimethachlor.

[28] Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals (Question No EFSA-Q-2006-064) Adopted on 17 June 2008

5.2. RISK TO AQUATIC ORGANISMS

Acute toxicity data were available for fish, invertebrates and algae. Chronic toxicity data were available for fish, invertebrates, aquatic plants and sediment-dwelling invertebrates. The toxicity of the formulated product was found to be higher than the toxicity of the technical active substance for all species except fish where the toxicity was comparable. The lower toxicity endpoints were used in the aquatic risk assessment. The lowest end point value was obtained for algae in a formulation study, with an EC_{50} of 0.006 mg a.s./L, based on increase in biomass. Dimethachlor was proposed to be classified as very toxic to aquatic organisms.

In the DAR the TER calculations were provided for FOCUSsw Step 1 to 3. TER values did not meet the Annex VI trigger for any organism group based on the maximum PECsw values FOCUSsw Step 2, except for sediment-dwellers, were the risk was estimated to be low. At FOCUSsw Step 3 TER values were above Annex VI trigger for fish and invertebrates in acute and chronic risk assessment respectively. Only one scenario (D2) did not meet the Annex VI trigger in the acute risk assessment for fish. However, this scenario would meet a reduced trigger value of 50 (as suggested by RMS) based on the availability of toxicity endpoints from 6 fish species. The risk assessment was revised further to identify low risk, based on PECtwa and use of non-spray buffer zones for invertebrates (long-term), algae and higher plants.

The use of PECtwa was not supported in the peer-review. In response RMS provided a revised aquatic risk assessment in addendum 1 (April, 2008), where it was deemed inappropriate to use PECsw-twa, as no data on time to onset of effects was available. In the addendum the TER values meet the Annex VI trigger for the chronic risk assessment to fish and the acute risk assessment to invertebrates, based on FOCUS Step 3 maximum PECsw values. The acute risk assessment to fish was maintained from the DAR. Only TER-values from the D2 scenario did not meet the Annex VI trigger for the chronic risk assessment to invertebrates, based on a chronic toxicity endpoint for the formulation. As D2 was driven by drain input it was considered inappropriate to use a formulation endpoint in the risk assessment because the formulation would separate and breakdown before reaching surface water as it migrated through soil and the drains. Applying the chronic invertebrate endpoint from the technical substance instead, indicated a low risk in the D2 scenario (TERditch = 31and TERstream = 48). In accordance, a TER of 49 was calculated on the basis of a PECsw derived for spray drift only and the corresponding formulation endpoint. None of the TER values were above the Annex VI trigger for algae and *Lemna* based on maximum FOCUS Step 3 PECsw values. As the lowest endpoint of algae and *Lemna* was based on formulation data, the risk assessment was refined by splitting the TER calculations in two. I.e. (1) TER values based on formulation toxicity divided by PECsw including only spray drift input, and (2) TER values based on the technical substance toxicity divided by PECsw including spray drift, run-off and drainage inputs. In addition the risk assessment for algae and *Lemna* was refined by application of non-spray buffer zones (up to 20 m). The most critical risk assessment was for algae, using formulation toxicity. TER values were above the Annex VI trigger for only one scenario (R1) out of 6 scenarios, applying non-spray buffer zone of 20 m. The technical dimethachlor risk assessment for algae indicated TER values above the trigger for 5 out of 6

scenarios with a non-spray buffer zone of 5 m. The formulation risk assessment for *Lemna* indicated TER values above the trigger for 0, 3 and 6 scenarios out of 6 scenarios with a non-spray buffer zone of 5 m, 10 m and 20 m respectively. The technical dimethachlor risk assessment for *Lemna* indicated TER values above the trigger for 4 and 5 scenarios out of 6 scenarios with a non-spray buffer zone of 5 m and 10 m respectively. Experts in PRAPeR 48 agreed to the revised aquatic risk assessment provided in addendum 1 (April, 2008). However, the experts concluded that in case of Annex I inclusion of dimethachlor MS should be given the opportunity to ask for further refinement of the aquatic risk assessment pertinent to national conditions, given the fact that Annex VI trigger was only met in one scenario (R1) based on the lower toxicity to algae. (Please note the limitation on mitigation measures mentioned in section 4.2.1.)

Short term toxicity data on fish, invertebrates and algae were available for the two metabolites CGA 50266 and CGA 354742, identified in the water/sediment system. TER values were above the Annex VI trigger for the two metabolites at FOCUSsw Step1. The algae toxicity of the further breakdown metabolites CGA 373464, CGA 369873, SYN 528702 was found to be low, compared to dimethachlor. The risk to aquatic organisms from dimethachlor metabolites was considered to be low.

Bioaccumulation was not considered an issue as the logPow is below 3.

5.3. RISK TO BEES

Technical and formulated dimethachlor was considered to be of low toxicity to bees, based on the available data. The acute oral and contact HQ values for an application rate of 1.5 kg dimethachlor/ha was <50 indicating a low risk to bees. It is concluded that the risk to bees is low for the representative use.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The in-field HQ value exceeded the trigger of 2, whereas the off-field HQ values for the uses in oilseed rape were <2 for the standard indicator species. Further laboratory data with *Chrysoperla carnea*, and *Pardosa sp*. and extended laboratory studies with *T. pyri* and *A. rhopalosiphi* was available for higher tier assessment. No mortality or sublethal effects of >50% were observed in the tests at an application rate of 1.5 kg a.s./ha suggesting a low in-field risk for non-target arthropods for the representative use evaluated.

5.5. RISK TO EARTHWORMS

The acute toxicity to earthworms of dimethachlor and the formulation (TERIDOX) was found to be comparable (140-200 mg as/kg soil), based on the available data. The acute toxicity of the metabolites CGA 50266 and CGA 354742 found to be low (>1000 mg as/kg soil). The acute endpoints were corrected by a factor 2, as logP_{ow} was > 2. TER values based on a maximum PECsoil of dimethachlor (2.0 mg as/kg soil) and the metabolites all exceeded the Annex VI trigger (TER = 35-

48 for the active substance and formulation and; TER > 1440 for the metabolites). As dimethachlor has a laboratory soil DT_{90} of only 47 days and TERIDOX is intended for use as a single application, TERIDOX is considered to have low potential for accumulation in soil. Therefore, TERIDOX can be considered to pose a low long-term risk to earthworms.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

In accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002), compounds with a soil DT_{90} of > 100 days should be evaluated for effects on soil organisms contributing to organic matter breakdown. As dimethachlor has a laboratory soil DT90 of 47 days and shows low risk to non-target arthropods and earthworms, further tests on soil macro-organisms were not considered necessary.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The toxicity of dimethachlor, its metabolites, CGA 50266 and CGA 354742 and the formulated product TERIDOX, to non-target soil micro-organisms was evaluated in soil respiration and nitrification tests. Results indicated that exposure to dimethachlor at concentrations up to and including 7.5kg as/ha (equivalent to 10mg as/kg) caused <25% effect on soil respiration and nitrification processes. Similarly, exposure to CGA 50266 and CGA 354742 at concentrations of 3.79 and 2.02 mg/kg dry soil respectively, caused less than 25% effect on respiration and nitrification processes in soil. Exposure to the formulation at concentrations of 4 and 20µL/kg dry soil (equivalent to 2 and 10mg as/kg) also caused <25% effect on respiration and nitrification processes in soil over 29 days. The applicant did not submit studies with the metabolites CGA 50266 and CGA 354742. Overall it was concluded that the risk to soil non-target micro organisms was considered to be low for the representative use in oilseed rape.

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

Glasshouse tests indicated that post-emergence applications of the formulation at 1.5 kg as/ha did not cause more than 50 % effect on biomass in six species measured after 21 days. Therefore, the EC_{50} for all species tested was considered to be > 1.5 kg as/ha. Pre-emergence application of the formulation at rates up to 1.5 kg as/ha did not cause > 50 % effect in 3 of the 10 species tested. Effects of > 50 % were seen in the remaining 7 species. The lowest EC_{50} of 42 g as/ha was seen in *Echinochloa crusgalli*. The Annex VI trigger was met in TER calculations for all plant species if a non-spray buffer zone of 10 m was applied. In the tests with 33 plant species, the phytotoxicity of the metabolites CGA 50266 and CGA 354742 was found to be lower (< 50 % effect on seedling emergence and vegetative vigour at exposure rate of 2000 g as/ha) than the toxicity of the parent active substance. Therefore, these metabolites are considered to pose negligible risk to non-target plants. In a separate test with CGA 50266, CGA 354742, CGA 369873, CGA 373464, SYN 528702 and SYN 530561 (found in the lysimeter leachates), pre- and post emergence applications were made to 6 plant species at rates between 31 and 1000 g/ha. Effects up to 30% were seen for some

metabolites in a few plant species. Hence, CGA 373464, CGA 369873, SYN 528702 and SYN 530561 was considered to pose negligible herbicidal activity at concentrations where the parent dimethachlor caused effects of > 70%. Overall it was concluded that the risk from dimethachlor used in oilseed rape was considered to be low provided a non-spray buffer zone of 10 m was applied.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The EC_{50} and NOEC for effects on respiration of activated sewage sludge was determined as >100 mg dimethachlor/L. It is not expected that dimethachlor would reach biological sewage treatment plants in amounts greater than 100 mg/L if applied according to the GAP and therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: dimethachlor, CGA 50266, CGA 354742. If anaerobic conditions occur CGA 42443.

Definition for monitoring: dimethachlor, except in territories where anaerobic soil conditions cannot be excluded where a data gap needs to be filled before this definition can be finalised.

Water

Ground water

Definition for exposure assessment: dimethachlor, CGA 50266, CGA 354742, CGA 102935, SYN 528702, CGA 369873, CGA 373464 and SYN 530561

Definition for monitoring: At least dimethachlor, but data gaps need to be filled before this definition can be finalised.

Surface water

Definition for risk assessment: surface water: dimethachlor, CGA 50266, CGA 354742, If anaerobic soil conditions occur CGA 42443

Sediment: dimethachlor

Definition for monitoring: dimethachlor, except in territories where anaerobic soil conditions cannot be excluded where a data gap needs to be filled before this definition can be finalised.

Air

Definition for risk assessment: dimethachlor

Definitions for monitoring: dimethachlor

Food of plant origin

Definition for risk assessment: dimethachlor (provisional as data gap for rotational crops)

Definition for monitoring: dimethachlor (provisional as data gap for rotational crops)

Food of animal origin

Definition for risk assessment: no residue definition required.

Definition for monitoring: no residue definition required.

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
dimethachlor	Low to moderate persistence Single first order DT_{50} 2.4-15.6 days (20°C, -10kPa soil moisture)	Low risk to earthworms and to soil micro-organisms.
CGA 50266	low to high persistence Single first order DT_{50} 6.8-195.5 days (20°C, -10kPa soil moisture)	Low risk to earthworms and to soil micro-organisms
CGA 354742	moderate persistence Single first order DT_{50} 11.4-23.2 days (20°C, -10kPa soil moisture)	Low risk to earthworms and to soil micro-organisms
Anaerobic conditions CGA 42443	No data available	No data available, data gap.

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
dimethachlor	Very high to high mobility K_{foc} 49-128 mL/g	No	Yes	Yes	Yes
CGA 50266	Very high mobility K_{foc} 0 mL/g	Yes at all pertinent FOCUS scenarios (triannual average) 10.49-21.4µg/L Lysimeter leachate (annual average) 35.6µg/L	No	Yes	No
CGA 354742	Very high mobility K_{doc} 3.4-4 mL/g	Yes at all pertinent FOCUS scenarios (triannual average) 4.1-13.4µg/L Lysimeter leachate (annual average) 41.3µg/L	No	Yes	No
CGA 102935	No reliable data available, data gap	No reliable assessment available but would be expected to be >0.1µg/L	No	Yes	No
SYN 528702	Present in	Yes at all pertinent FOCUS	No	Yes	No

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
	lysimeter leachate	scenarios (interpolated triannual average) 1.52-9.21 µg/L Lysimeter leachate (annual average) 15.3µg/L			
CGA 369873	Present in lysimeter leachate	Yes at all pertinent FOCUS scenarios (interpolated triannual average) 0.24-1.45 µg/L Lysimeter leachate (annual average) 2.4µg/L	No	Yes	No
CGA 373464	Present in lysimeter leachate	Yes at all pertinent FOCUS scenarios (interpolated triannual average) 0.39-2.35 µg/L Lysimeter leachate (annual average) 3.9µg/L	No	Yes	No
SYN 530561	Present in lysimeter leachate	Yes at all pertinent FOCUS scenarios (interpolated triannual average) 0.22-1.32µg/L Lysimeter leachate (annual average) 2.2µg/L	No	Yes	No

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
dimethachlor	Very toxic to aquatic organisms (lowest endpoint observed for *Pseudokirchneriella subcapitata* EbC_{50} = 0.0065 mg/L).
CGA 50266	More than 3 orders of magnitude less toxic to aquatic organisms compared to dimethachlor. The risk to aquatic organisms was assessed as low.
CGA 354742	More than 3 orders of magnitude less toxic to aquatic organisms compared to dimethachlor. The risk to aquatic organisms was assessed as low.
When anaerobic soil conditions CGA 42443	No data available, data gap

Air

Compound (name and/or code)	Toxicology
dimethachlor	**Dimethachlor is of low inhalation toxicity (LC_{50} > 4.45 mg/L)**

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

- The specification needs to be justified (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- Method of analysis for the relevant impurity in the plant protection product (relevant for all uses evaluated, data gap identified by EFSA August 2008, proposed submission date unknown, refer to chapter 1).
- Storage stability with the analysis of the relevant impurity before and after storage (relevant for all uses evaluated, data gap identified by EFSA August 2008, proposed submission date unknown, refer to chapter 1).
- It should be proven that when the TK is dried to form the TC for analysis no volatile impurities are lost (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- It should be proven that under practical conditions of use crystallisation in the plant protection product is not an issue (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- For the ILV for the plant method it must be demonstrated that the laboratories were truly independent. (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- In order to conclude on non-relevance according to guidance document Sanco/221/2000-rev.10-final, further toxicological data has to be provided for the potential groundwater metabolites CGA 50266, CGA 354742, CGA 369873, CGA 373464, SYN 528702, SYN 530561 and CGA 102935 (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to point 2.8).
- A toxicological assessment of impurities CGA 38501, CGA 173125 and CGA 173126 is necessary (relevant for all uses evaluated, data gap confirmed by the meeting of experts May 2008, an assessment was already provided by the applicant that was evaluated by the RMS in an addendum, however this information could not be considered in view of the restrictions concerning the acceptance of new (including newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, refer to point 2.8)
- The lack of the 30 day plant back interval in the rotational crop metabolism study for lettuce and radish with regard to the metabolite situation in rotational crops has been identified as a data gap (relevant for all uses evaluated, data gap identified by EFSA June 2008, proposed submission date unknown, refer to chapter 3)
- Rate of degradation of soil metabolite CGA 102935 (aerobic laboratory conditions) in at least 3 different soils (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; refer to point 4.1.2)

- Soil adsorption experiments for metabolite CGA 102935 in at least 3 different soils (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; refer to point 4.1.3)
- Groundwater exposure assessment for soil metabolite CGA 102935 (at the first tier FOCUS scenario modelling) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; refer to point 4.2.2)
- Further refinements are required to address the long-term risk to insectivorous and omnivorous mammals (relevant for the representative uses evaluated; submission date proposed by the applicant: unknown; data gap agreed by the meeting of experts (PRAPeR 48); refer to point 5.1)
- Effects data are not available for soil dwelling organisms or aquatic organisms to complete a risk assessment for exposure from metabolite CGA 42443. (relevant for the representative uses evaluated in territories where anaerobic soil conditions cannot be excluded; submission date proposed by the applicant: unknown; data gap identified by EFSA when drafting the conclusion; refer to point 5.0)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on oilseed rape. Full details of the GAP can be found in the attached list of end points.

The representative formulated product for the evaluation was "Teridox 500 EC", an emulsifiable concentrate (EC).

Adequate methods are available to monitor all compounds given in the respective residue definition. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. As yet it is not clear for the plant method if for the ILV the laboratory was truly independent. Also the residue definition for soil and water are provisional.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available for the active substance to ensure that quality control measurements of the plant protection product are possible. However, there is no method of analysis or storage stability data for the relevant impurity. In general however the specification is not agreed. It was also a concern that the formulation at low temperatures forms crystals.

Dimethachlor is absorbed almost completely and moderately rapidly. It is widely distributed in the body and has no potential for accumulation in humans. It is excreted moderately rapidly and is completely metabolized. It is of moderate toxicity by the oral and of low toxicity by the dermal and

inhalation route. It is neither a skin nor an eye irritant but a strong skin sensitizer. Based on the available data on acute toxicity a classification as **Xn; R22 "Harmful; Harmful if swallowed" and Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed. In short term tests with rats, mice and dogs the liver was the main target of toxicities and the relevant NOAELs obtained were 2.21 mg/kg bw/d (rat), 10 mg/kg bw/d (dog) and 17.5 mg/kg bw/d (mouse) respectively. Dimethachlor is not genotoxic but can bind to chromatin protein. A 2-year rat and two 18-month mouse studies have been reported. In the rat study a NOAEL of 11.1 mg/kg bw/d was derived based bodyweight and liver effects that occurred together with nasal tumours (in males only). These tumours were considered relevant for humans and led to a proposal for classification as **Xn; R40 "Harmful; Limited evidence of a carcinogenic effect".** The pulmonary and liver tumours observed in the first murine carcinogenicity study were considered not relevant for humans. Dimethachlor did not cause effects on reproduction in rats. In rats dimethachlor impaired the ossification in pups at maternally toxic doses while no any developmental effects were observed in rabbits. Seven dimethachlor metabolites occurring in groundwater are considered as relevant according to guidance document Sanco/221/2000-rev.10 – final. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were set at 0.1 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.5 mg/kg bw. In the German model operator exposure amounts to 88% of the AOEL when personal protective equipment (PPE) is worn. Re-entry worker and bystander exposure were estimated to be 4.3% (no PPE worn) and 2.2% respectively.

The metabolism of dimethachlor was investigated in oilseed rape where phenyl labelled dimethachlor was applied at a rate of 1.5 kg as/ha (1N). At harvest there were no significant residues of dimethachlor or its metabolites and the residue definition defaulted to dimethachlor only. There were a total of 18 residue trials available for the representative crop oilseed rape only one positive residue of dimethachlor was detected at 0.05 mg/kg. It was concluded that the residue at 0.05 mg/kg is not a correct result and perhaps was due to a matrix component or sample contamination. As this is the case it was concluded that the metabolites will also not occur at significant levels. Residues were seen to be stable under frozen conditions for a period of 2 years. No processing data were required. For rotational crops the study provided was not accepted and data gap was identified. Animal intakes were low and the need for a study is not triggered. All intakes using the WHO, UK and German models were less than 1% of the ADI and ARfD. Intakes are less than 1 % of the ADI and ARfD for WHO and German diets. However the risk assessment can not be finalised because of the rotational crops issue.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level, with the notable exception that further data are necessary to address the potential for groundwater exposure of the metabolite CGA 102935. For the applied for intended uses, the potential for groundwater exposure by dimethachlor

above the parametric drinking water limit of 0.1 µg/L, is low. However for the metabolites CGA 50266, CGA 354742, SYN 528702, CGA 369873, CGA 373464 and SYN 530561, contamination of groundwater above the 0.1 µg/L parametric limit and also above the groundwater non relevance assessment level of 0.75 µg/L cannot be excluded, so metabolite non relevance assessments were necessary for these metabolites. The levels estimated for FOCUS scenarios resulting from the applied for intended use are: CGA 50266 (10.49-21.4µg/L), CGA 354742(4.1-13.4µg/L), SYN 528702 (1.52-9.21µg/L), CGA 369873 (0.24-1.45µg/L), CGA 373464 (0.39-2.35µg/L) and SYN 530561 (0.22-1.32-µg/L). The available toxicological data do not allow it to be concluded that these metabolites are not relevant. In groundwater monitoring covering a limited geoclimatic area (northern and north eastern Germany), well water concentrations of up to 0.52µg/L for CGA 354742 and 2.1µg/L for CGA 369873 were found. Concentrations of the other metabolites were <0.05µg/L with the notable exception that no analysis was carried out for CGA 102935. The fate and behaviour experts indicated that they would wish / it would be necessary for the applicant to provide appropriate monitoring exercises carried out more extensively across Europe, should it be considered possible to include dimethachlor in annex 1.

Five non-standard scenarios including medium herbivorous birds, insectivorous and granivorous birds were considered relevant for the bird risk assessment by RMS. TER values were above the Annex VI trigger for short-term risk for all five scenarios. The acute and long-term risk to birds, which was found to be high in the DAR, was revised following peer-review comments. Herbivorous birds was not considered relevant in the revised risk assessment, as Dimethachlor is applied prior to crop emerge in to a clean seed-bed. Skylark (*Alauda arvensis*) was used as focal insectivorous species. A refined risk assessment based on a mixed diet of large and small insects gave TER values above the Annex VI trigger. The meeting of experts considered that the risk assessment to insectivorous birds may not fully cover risks for herbivorous birds as dimethachlor could be transferred from soil to the plant systemically. Exposure from germinating plants could therefore not be excluded. It was agreed in the meeting to base the refined risk assessment on skylark consuming a mixed diet of grass weed, weed seed and large insects. Calculated TER values were above the trigger and the experts concluded a low acute and long-term risk to omnivorous birds from the use in oilseed rape. The initial risk to mammals was calculated for the two scenarios leafy crop (non-grass herbs) and short grass (grass and cereal shoots) with the hare (*Lepus europaeus*) as focal species in the DAR. The TER values were above the Annex VI trigger for the acute risk assessment but below the trigger for the chronic risk assessment. PD and PT refinements of the long-term risk assessment were not accepted during the peer-review. As for birds exposure of herbivorous mammals was considered not relevant (see above) and the long-term risk assessment was based on a 10g shrew as a representative insectivorous mammal, feeding on ground-dwelling insects. A TER value of 4.1 indicated a need for further refinements. The meeting of experts agreed to the latter risk assessment. In addition the experts agreed to include a refined long-term risk assessment for an omnivorous mammal, to address also the risk from exposure from emerging plants and off-field plant. Based on a mixed diet TER values in the

range of 2.2 to 4.4 were derived and agreed by the meeting expert. Experts concluded that further refinements of the long-term risk assessment for insectivorous and omnivorous mammals were required. A low risk from consumption of contaminated drinking water was identified by EFSA after the expert meeting. The risk from metabolites was considered to be low.

Dimethachlor was very toxic to aquatic organisms. A potential high risk was indicated with FOCUS step 3 PECsw values based on formulation studies for algae and *Lemna*. At FOCUS Step 4 including non-spray buffer zones, (1) TER values were calculated based on formulation toxicity (algae and *Lemna*) divided by PECsw including only pray drift input, and (2) TER values based on the technical substance toxicity (algae and *Lemna*) divided by PECsw including spray drift, run-off and drainage inputs. Only one safe scenario was identified (R1) with a non-spray buffer zone of 20 m, based on the formulation toxicity to algae. In case of Annex I inclusion of dimethachlor MS should be given the opportunity to ask for further refinement of the aquatic risk assessment pertinent to national conditions, given the fact that Annex VI trigger was only met in one out of six scenarios based on the lower toxicity to algae. The risk to aquatic organisms from dimethachlor metabolites was estimated to be low. Dimethachlor was not considered to bio accumulate ($logP_{ow}$ below 3).
The risk to bees was considered to be low. Tier 1 off-field risk assessment to non-target arthropods indicated a low risk as did the in-field risk based on extended laboratory studies. Additionally, the risk to earthworms, soil non-target micro and macro organisms was expected to be low. A non-spray buffer zone of 10 m was required for non-target plants to identify a low risk.

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

- For operators the use of personal protective equipment is needed.
- Risk mitigation e.g. non-spray buffer zones are required to identify low risk to aquatic organisms
- Risk mitigation e.g. non-spray buffer zones are required to identify low risk for non-target plants

Critical areas of concern

- The specification can not be finalised
- The consumer risk assessment can not be finalised.
- There is a high potential for groundwater contamination by the metabolites CGA 50266, CGA 354742, CGA 369873, CGA 373464, SYN 528702, SYN 530561 and CGA 102935 in geoclimatic situations represented by all pertinent FOCUS groundwater scenarios. Non-relevance assessments according to guidance document Sanco/221/2000-rev.10 final for these

metabolites are not available. Therefore annex VI decision making criteria regarding groundwater contamination can not be satisfied when using the available data.

- Further refinements of the risk to insectivorous and omnivorous mammals are needed for the intended use in oilseed rape.
- A low risk was identified for aquatic organisms in only one out of six scenarios for the intended use and formulation, applying a no-spray buffer zone of 20 m.

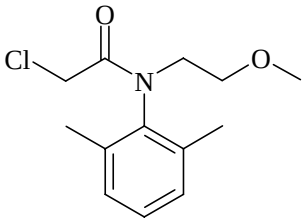
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Dimethachlor
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-chloro-*N*-(2-methoxyethyl)acet-2´,6´-xylidide
Chemical name (CA) ‡	2-chloro-N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)-acetamide
CIPAC No ‡	688
CAS No ‡	50563-36-5
EC No (EINECS or ELINCS) ‡	256-625-6
FAO Specification (including year of publication) ‡	not available
Minimum purity of the active substance as manufactured ‡	Open for the TK and TC
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	2,6-Dimethylaniline: max content open
Molecular formula ‡	$C_{13}H_{18}ClNO_2$
Molecular mass ‡	255.8 g/mol
Structural formula ‡	

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

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	45.8 - 46.7 °C (99.4 %)
Boiling point (state purity) ‡	approximately 320 °C (99.4 %)
Temperature of decomposition (state purity)	Thermal decomposition starts at about 300 °C (99.4 %)
Appearance (state purity) ‡	pure: colourless crystals (99.4 %) technical: light beige waxy solid (97.8 %)
Vapour pressure (state temperature, state purity) ‡	6.4×10^{-4} Pa at 20 °C (extrapolated) (99.4 %) 1.5×10^{-3} Pa at 25 °C (extrapolated) (99.4 %)
Henry's law constant ‡	1.7×10^{-4} Pa · m^3/mol at 25 °C
Solubility in water (state temperature, state purity and pH) ‡	2.3 g/L at 25 °C (99.4%)
	no dependence on pH
Solubility in organic solvents ‡ (state temperature, state purity)	acetone > 500 g/L ethyl acetate > 500 g/L hexane 42 g/L methanol > 500 g/L dichloromethane > 500 g/L octanol 440 g/L toluene > 500 g/L all at 25 °C
Surface tension ‡ (state concentration and temperature, state purity)	TC, 20 °C (Wilhelmy plate method): σ = 57.2 - 58.9 mN / m (1.9 g/L) σ = 66.1 - 67.0 mN / m (0.19 g/L) 55 % TK at 20 °C (Wilhelmy plate method): σ = 60.6 - 61.5 mN / m (1.0 g/L) σ = 69.9 - 70.0 mN / m (0.1 g/L)
Partition co-efficient ‡ (state temperature, pH and purity)	log Pow = 2.17 at 25 °C
	no dependence on pH
Dissociation constant (state purity) ‡	no dissociation in an accessible pH-range

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	solution / wavelength [nm] / ε [L / mol · cm] *neutral* (MeOH): 215 / 14461; 265 / 486 *acidic* (MeOH/HCl): 215 / 14768; 265 / 572 *basic* (MeOH/NaOH): 215 / 9576; 265 / 469 No absorption at 290 nm (baseline)
Flammability ‡ (state purity)	Dimethachlor is not considered highly flammable (55 % premix). Not applicable for dimethachlor (melting point > 40 °C). No self-ignition under the test conditions (dimethachlor and its 55 % premix)
Explosive properties ‡ (state purity)	Dimethachlor and its 55 % premix are not considered an explosive in the sense of EEC Method A.14 (experimental data).
Oxidising properties ‡ (state purity)	none (dimethachlor, experimental data)

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

Summary of representative uses evaluated (Dimethachlor)*

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) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Winter oil seed rape	**EU**	**Teridox 500 EC A-5089 F/H**	**F**	**grasses and dicot weeds**	**EC**	**500 g/L**	**broad-cast spray applica-tion**	**pre-emer-gence BBCH 00-09**	**1**	**n.a.**	**0.375-1.5**	**100 - 400**	**1.5**	**n.a.**	[1] [2] [3] [4]

[1] The technical material specification for the active substance can not be finalised
[2] The necessary mammalian toxicology data are not available to conclude that metabolites (7) that have the potential to leach to groundwater in significant concentrtatiomns are not relevant. A reliable groundwater exposure assessment is not available for one of these metabolites.
[3] The consumer risk assessment was not finalised
[4] Furter refinements were required to address the risk for insectivorous and omnivorous mammals. A low risk was identified for aquatic organisms in only one out of six scenarios when applying a no-spray buffer zone of 20 m

* Uses for which the risk assessment can not be concluded are marked grey.
‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(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 plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
The minimum and maximum number of application possible under practical conditions of use must be provided
(k) PHI - minimum pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions
(m)

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

Methods of analysis

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

Technical as (principle of method)	GC/FID
Impurities in technical as (principle of method)	GC/FID
Plant protection product (principle of method)	GC/FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Dimethachlor (provisional)
Food of animal origin		–
Soil		Dimethachlor
Water	surface	Dimethachlor (provisional)
	drinking/ground	Dimethachlor (provisional)
Air		Dimethachlor

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-NPD	0.01 mg/kg (rape seed, rape oil) 0.05 mg/kg (rape press cake) ILV: independence of second lab to be confirmed
	GC-MS	0.02 mg/kg (rape seed, rape oil, press cake)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No methods required, because no MRL is proposed by the RMS	
Soil (analytical technique and LOQ)	GC-MS	0.02 mg/kg
Water (analytical technique and LOQ)	LC-MS/MS	0.05 µg/L (drinking water, surface water)
Air (analytical technique and LOQ)	GC-NPD	0.5 µg/m³
Body fluids and tissues (analytical technique and LOQ)	not relevant, because active substance is not considered as toxic or highly toxic (T/T^+)	

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

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

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

Impact on human and animal health

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

Rate and extent of absorption ‡	> 94 % (based on urinary and biliary excretion and tissue residues within 168 h)
Distribution ‡	Initially widely distributed; highest residues in highly perfused organs (lungs, heart, kidneys, liver, spleen)
Potential for accumulation ‡	Accumulation due to the binding of dimethachlor to the rat haemoglobin molecule (rat specific)
Rate and extent of excretion ‡	> 91 % within 168 h, mainly via urine (44.14 % male; 59.79 % female) and via faeces (47.07 % male, 30.95 % female)
Metabolism in animals‡	Almost completely metabolized; major metabolic reactions were the O-dealkylation leading to O-desmethyl derivatives, the substitution of the chlorine glutathione, and the oxidation of the methyl-phenyl group resulting in hydroxy-methyl derivatives, conjugation with glucuronic acid or glutathione followed by degradation, neither free aniline derivatives nor sulfate ester of the p-hydroxylated aniline were detectable
Toxicologically relevant compounds ‡ (animals and plants) ‡	Parent compound and metabolites
Toxicologically relevant compounds ‡ (environment)	Parent compound potential groundwater metabolites CGA 50266, CGA 354742, CGA 373464, CGA 369873, CGA 373464, SYN 528702, SYN 530561 and CGA 102935

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1600 mg/kg bw (Xn- R22)
Rat LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC_{50} inhalation ‡	> 4.45 mg/L (nose-only, 4 h, aerosol)
Skin irritation‡	Non irritating
Eye irritation ‡	Non irritating
Skin sensitisation (test method used and result) ‡	Sensitising (Maximisation Test) R43

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

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver; kidney, red blood cell parameters (only at high dose)
Relevant oral NOAEL ‡	90-day, rat: 2.21mg/kg bw/d (LOAEL 71.7 mg /kg bw/d 90-day, mouse: 17.5 mg/kg bw/d 90-day, dog: 10 mg/kg bw/d
Relevant dermal NOAEL ‡	28-day, rat: > 1000 mg/kg bw/d
Relevant inhalation NOAEL ‡	Not tested, not required

Genotoxicity ‡ (Annex IIA, point 5.4)

	No evidence for a genotoxic potential

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

Target / critical effect ‡	Liver, kidney, nasopharynx	
Lowest relevant NOAEL / NOEL ‡	2-year, rat: 11.1 mg/kg bw/d 18-month, mouse: ca. 31 mg/kg bw/d	
Carcinogenicity ‡	Liver tumours found in mice not relevant for humans In male rats at 4000 ppm (157 mg/kg bw) 3/60 adenomas in nasopharynx (control group: 0/60)	Carc. Cat. 3, R40 *

* not supported by the RMS

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reduced postnatal pup growth Reduced body weight gain and food consumption in parents	
Relevant parental NOAEL ‡	20 mg/kg bw	
Relevant reproductive NOAEL ‡	267 mg/kg bw	
Relevant offspring NOAEL ‡	20 mg/kg bw	

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

Developmental toxicity

Developmental target / critical effect ‡	Rat: Increased incidence of poor or non ossified bones Rabbit: reduced body weight gain in dams	
Relevant maternal NOAEL ‡	50 mg/kg bw (rat) 100 mg/kg bw (rabbit)	
Relevant developmental NOAEL ‡	50 mg/kg bw (rat) 350 mg/kg bw (rabbit)	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data; no evidence for a neurotoxic potential was found in other studies	
Repeated neurotoxicity ‡	No data; no evidence for a neurotoxic potential was found in other studies	
Delayed neurotoxicity ‡	No data; no evidence for a neurotoxic potential was found in other studies	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Dimethachlor: High persistent binding of dimethachlor in vitro to rat haemoglobin in comparison to human haemoglobin. No DNA-binding activity in the rat liver in vivo.
Studies performed on metabolites or impurities ‡	CGA 50266 (soil metabolite): Acute toxicity, oral, rat: LD_{50} > 2000 mg/kg bw; 90 day oral, feeding, rat: 15000 ppm (1031 mg/kg bw): kidney (tubular atrophy), adrenal gland (fatty change); NOAEL: 6000 ppm (400 mg/kg bw); No evidence for a genotoxic potential (Bacterial gene mutation assay with *S. typhimurium* and *E. coli*; Mouse lymphoma; Cytogenetic test on Chinese hamster cells in vitro) CGA 354742(soil metabolite): Acute toxicity, oral, rat: LD_{50} > 2000 mg/kg bw 90 day oral, feeding, rat: 6000 ppm (437 mg/kg): kidney (tubular lesions), liver (hepatocellular hypertrophy), thyroid (follicular cell hypertrophy), thymus (atrophy); NOAEL: 1000 ppm (69.6 mg/kg); No evidence for a genotoxic potential (Bacterial gene mutation assay with *S. typhimurium* and *E. coli*; Mouse lymphoma; Cytogenetic test on Chinese hamster cells in

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

	vitro) CGA 369873 (soil metabolite): No evidence for a genotoxic potential (Bacterial gene mutation assay with *S.typhimurium* and *E. coli*; Mouse lymphoma; Cytogenetic test on Human lymphocytes) CGA 373464 (soil metabolite): No evidence for a genotoxic potential (Bacterial gene mutation assay with *S.typhimurium* and *E. coli*) SYN 528702 (soil metabolite): No evidence for a genotoxic potential (Bacterial gene mutation assay with *S.typhimurium* and *E. coli*) SYN 530561 (soil metabolite): No evidence for a genotoxic potential (Bacterial gene mutation assay with *S.typhimurium* and *E. coli*).

Medical data ‡ (Annex IIA, point 5.9)

	No evidence of adverse effects from medical surveillance of manufacturing plant personnel

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.1 mg/kg bw/d	2-year, rat, supported by 90-day dog	100
AOEL systemic ‡	0.1 mg/kg bw/d	90 day, dog	100
ARfD (acute reference dose) ‡	0.5 mg/kg bw	developmental toxicity, rat (maternal and developmental toxicity)	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Teridox 500 EC (A5089F)	3 % for concentrate, 10 % for field dilution (based on rat in vivo; rat/human in vitro) performed with EC formulation

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

Exposure scenarios (Annex IIIA, point 7.2) (including method of calculation)

Operator	Acceptable for proposed use (oil seed rape; 1.5 kg as/ha) German model: Exposure = 119 % of the AOEL syst. (no PPE); 88 % (gloves: m/L) UK-POEM: Exposure = 1241 % of the AOEL syst. (no PPE); 195 % (gloves: m/L and appl.)
Workers	Acceptable for proposed use (according to Hoernicke et al., 1998) 4.3% of the AOEL without PPE.
Bystanders	Acceptable for proposed use. Using the EUROPOEM model 2.2% of the AOEL.

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

	RMS
Substance classified	Xn; R22 "Harmful; Harmful if swallowed" Xi; R43 "Irritant; May cause sensitisation by skin contact " Xn; Carc. Cat. 3; R40 "Harmful; Limited evidence of a carcinogenic effect"

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

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

Plant groups covered	Rape
Rotational crops	Open
Metabolism in rotational crops similar to metabolism in primary crops?	Open
Processed commodities	None
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Dimethachlor provisional
Plant residue definition for risk assessment	Dimethachlor
Conversion factor (monitoring to risk assessment)	Not applicable

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

Animals covered	Not applicable
Animal residue definition for monitoring	-
Animal residue definition for risk assessment	-
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	- no information

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

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

Open

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

Residues of dimethachlor in rape seeds stored at -18 ºC are stable over the period of 2 years.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	no	no	no
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No

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

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Oilseed rape	Northern	< 0.01(4), < 0.02(13) mg/kg	Since currently uses are only authorised in northern European countries the available residue data are sufficient to derive an MRL of rape seed.	0.02		0.02
	Mediterranean	none				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

ADI	0.1 mg/kg bw / d
TMDI (% ADI) according to WHO European diet	< 1 %
TMDI (% ADI) according to national (to be specified) diets	< 1 %
IEDI (WHO European Diet) (% ADI)	< 1 %
NEDI (specify diet) (% ADI)	< 1 %
Factors included in IEDI and NEDI	
ARfD	0.5 mg/kg bw
Acute exposure (UK, large portions) (% ARfD)	No consumption data
Acute exposure (DE, large portions) (% ARfD)	< 1 %
IESTI (% ARfD)	< 1 %
NESTI (% ARfD) according to national (to be specified) large portion consumption data	< 1 %
Factors included in IESTI and NESTI	none

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No processing data available.				

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

Rapeseed (dimethachlor)	0.02* mg/kg

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

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

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

Mineralisation after 100 days ‡	9.6 – 39.9 % after 120 d, [phenyl-(U)^{14}C]-label 24.3 % after 85 d, [phenyl-(U)^{14}C]-label
Non-extractable residues after 100 days ‡	33.4 – 56.8 % after 120 d, [phenyl-(U)^{14}C]-label 41.3 % after 85 d, [phenyl-(U)^{14}C]-label
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	CGA 50266, [phenyl-(U) ^{14}C]-label: max % of appl.: after day: soil: 15.3 14 loamy sand 12.3 14 loamy sand 18.73 7 sandy silt loam 33.7 21 loamy sand 35.5 21 sandy silt loam 19.23 14 sandy silt loam (20 °C, 60 % FM, 16 mg as/ha) (1) 21.1 63 sandy silt loam (10 °C, 60 % FM, 16 mg as/ha) (1) 22.7 28 sandy silt loam (20 °C, 30 % FM, 16 mg as/ha) (1) 23.04 4 sandy silt loam (20 °C, 60 % FM, 316 mg as/ha) (1) CGA 354742, [phenyl-(U)^{14}C]-label: max % of applied: after days: 15.8 14 CGA 102935: 2 x > 5% in sandy silt loam as stated below: % of applied: after days: 8.8 42 9.0 63 6.0 120 SYN528702 Study 1 6,3 % after 42 d Study 2 6,3 % after 63 d

(1) supplemental information taken from studies for rate of degradation in soil

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

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

Anaerobic degradation ‡

Mineralisation after 100 days	0.7 % after 180 d, [phenyl-(U)^{14}C]-label 2.2 % (total) after 7 + 180 d, [phenyl-(U)^{14}C]-label
Non-extractable residues after 100 days	23 % after 180 d, [phenyl-(U)^{14}C]-label 50.5 % (total) after 7 + 180 d, [phenyl-(U)^{14}C]-label
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	CGA 50266, [phenyl-(U)^{14}C]-label: % of applied: compartment: after day: 15.9 (max) soil+aqueous 7 +30 10.5 (max) aqueous 7 + 30 5.4 (max) soil 7 + 30 5.0 aqueous 7 + 180 5.3 soil 7 + 180 CGA 354742, [phenyl-(U)^{14}C]-label: % of applied: compartment: after day: 12.3 (max) soil+aqueous 7 +60 6.9 (max) aqueous 7 + 60 11.0 (max) soil 7 6.2 aqueous 7 + 180 5.7 soil 7 + 180 CGA 42443 Study 1 % of applied: compartment: after day: 6.3 soil+aqueous 7 + 70 6.3 soil+aqueous 7 + 180 Study 2 11.5 % after 85 days (end of the study)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Met CGA 50266: 6.6 % at 5 d Met CGA 354742: up to 2.5 % [phenyl-(U)^{14}C]-label

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

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 (site)	X[1]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Model, Kinetics; Method of calculation
silt loam (Les Evouette)		7.5	20 °C / 75 % FC 0.33 bar	6.6 / 21.8	6.6	0.997	SFO
loamy sand (Collombey)		7.4	20 °C / 75 % FC 0.33 bar	6.3 / 21	6.3	0.999	SFO
clay loam		7.5	25 °C / 75 % FC	8.1 / 27	9.8	0.990	SFO
silt loam (Les Evouette)		7.4	20 °C / 40 % MWHC	3.9 / 12.8	2.4	0.997	SFO
loamy sand (Speyer 2.2)		5.7	20 °C / 40 % MWHC	7.7 / 25.4	4.8	0.998	SFO
silt loam (Strassenacker)		7.8	20 °C / 40 % MWHC	4.6 / 15.4	2.4	0.998	SFO
silt loam (Les Evouette)		7.5	20 °C / 60 % FC	4.8 / 16.1	3.4	0.996	SFO
silt loam (Les Evouette)		7.5	10 °C / 60 % FC	12.7 /42.1	4.0	0.996	SFO
silt loam (Les Evouette)		7.5	20 °C / 30 % FC	8.1 / 27.02	3.5	0.998	SFO
silt loam (Les Evouette)		7.5	20 °C / 60 % FC	3.3 / 10.98	2.3	0.994	SFO
sand (Neuhofen)		6.8	22 °C / 40 % MWHC	14.3 / 47.5	12.9	0.994	SFO
loamy sand / sandy loam (Hatzenbühl)		5.2	22 °C / 40 % MWHC	19.8 / 65.9	15.6	0.990	SFO
Geometric mean/median (DT_{50})				**7.3 / 7.2**	**6.5/6.3**[x2]		

x[1] This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
X[2] Geomean of individual soil names calculated before overall geomean calculated (Les Evouettes geomean = 3.5 days);

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

Met : CGA 50266	Aerobic conditions							
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
clay loam		7.5	25 °C / 75 % FC	19.9 / 66.1	0.49	24.3	0.991	SFO
silt loam (Les Evouette)		7.5	20 °C / 75 % FC 0.33 bar	6.8	0.38	6.8	0.998	SFO
loamy sand (Collombey)		7.4	20 °C / 75 % FC 0.33 bar	7.4	0.44	7.4	0.999	SFO
silt loam (Les Evouette)		7.5	20 °C / 60 % FC	18.7 / 61.99	0.34	13.1	0.996	SFO
silt loam (Les Evouette)		7.5	10 °C / 60 % FC	73.0 / 242.48	0.35	23.2	0.996	SFO
silt loam (Les Evouette)		7.5	20 °C / 30 % FC	51.3 / 170.5	0.34	22.1	0.997	SFO
silt loam (Les Evouette)		7.5	20 °C / 60 % FC	7.8 / 25.8	0.39	5.5	0.985	SFO
silt loam (Les Evouette)		7.4	20 °C / 40 % MWHC	11.1 / 36.7	0.36	6.8	0.997	SFO
silt loam (Strassenacker)		7.8	20 °C / 40 % MWHC	61.4 / 204	0.4	31.5	0.991	SFO
loamy sand (Speyer 2.2)		5.7	20 °C / 40 % MWHC	254.4 /	0.31	195.5	0.998	SFO

x[1] This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
x[2] Geomean of individual soil names calculated before overall geomean calculated (Les Evouettes geomean = 10.9 days);

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

Geometric mean / median (DT_{50})				**19.3 / 25.0**		**26.1 /24.3** x2		
Arithmetic mean					**0.4**			
Met : CGA 354742	Aerobic conditions							
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
silt loam (Les Evouette)		7.5	20 °C / 75 % FC 0.33 bar	13.1	0.33	13.1	0.997	SFO
loamy sand (Collombey)		7.4	20 °C / 75 % FC 0.33 bar	11.4	0.33	11.4	0.999	SFO
sandy clay loam (18 Acres)		5.6	20 °C / pF2	23.2		23.2	0.98	SFO
Geometric mean (DT_{50})				**15.1**		**15.1**		

Field studies ‡

Parent	Aerobic conditions							
Soil type	Location	X[1]	pH	Depth (cm)	DT_{50} (d)	DT_{90}(d)	St. (r^2)	Method of calculation
clay (bare soil)	St. Aubin, France		6.6	0 – 10	3.2	10.5	0.926	1st order, non-linear regression model
Geometric mean/median								

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	no accumulation, i.e. not applicable

x[1] This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

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

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Clay loam soil		7.5	25	11.3 / 37,5		0.984	SFO
Silt loam		7.5	20	19.4/ 64.4		0.955	SFO
Geometric mean/median							

Met CGA50266	Anaerobic conditions							
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
				not measured				
Geometric mean/median								

Met CGA 42443	Anaerobic conditions							
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
				not measured				
Geometric mean/median								

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d	K_{oc}	K_f (mL/g)	K_{foc} (mL/g)	1/n
loamy sand (Collombey, study I)	1.17	7.3			1.12	95.37	0.9052
loamy sand (Collombey, study II)	0.81	7.4			0.46	56.65	0.90
silty loam (Les Evouette, study I)	2.1	7.3			1.47	69.97	0.8444
silty loam (Les Evouette, study II)	1.5	6.2			1.18	62	0.92
silty loam (Vetroz, study I)	4.39	7.1			1.3	29.72	0.7598
silty loam (Vetroz, study II)	5.4	7.3			3.72	69	0.92
silty loam (Illarzaz, study I)	19.34	6.6			13.3	68.77	0.9392
silty loam (Illarzaz, study II)	25.0	6.9			18.4	73.6	0.95
sand (Speyer 2.2)	0.66	5.5			0.32	48.72	0.8515
?? (Lakeland, Florida, USA)	0.56	6.5			0.76	128	0.90
Median for PELMO calculation						**$K_{f,oc}$ = 69**	**0.910**
pH dependence, Yes or No			no (r^2 = 0.3382 and -0.0413, respectively)				

Metabolite CGA 50266							
Soil Type	OC %	Soil pH	K_d	K_{oc} (mL/g)	K_f	K_{foc}	1/n
loamy sand (Collombey)	1.17	7.3		0			
silty loam (Les Evouette)	2.1	7.3		0			
silty loam (Vetroz)	4.39	7.1		0			
arithmetic mean used for PELMO calculation				**K_{oc} = 0**			**0.9**
pH dependence (yes or no)			no				

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

Metabolite CGA 354742							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f	$K_{foc(mL/g)}$	1/n
loamy sand (Collombey)	1.17	7.3	0.05	4.0			
silty loam (Les Evouette)	2.1	7.3	0.1	3.4			
silty loam (Vetroz)	4.39	7.1	0.1	3.6			
arithmetic mean used for PELMO calculation						**K_{doc} = 3.7**	**1.0**
pH dependence (yes or no)			no				
Metabolite CGA 42443							
Soil Type	OC %	Soil pH	K_d	K_{oc}	$K_{f(mL/g)}$	$K_{foc(mL/g)}$	1/n
sandy loam (Hyde Farm, Berkshire, UK)	2.204	6.6			0.9	41	0.87
sandy loam (Kenny Hill, Suffolk, UK)	3.596	7.4			0.87	24	0.89
sandy loam (Borstel, Niedersachsen, Germany)	1.392	4.9			0.39	28	0.95
arithmetic mean used for PELMO calculation						**K_{oc} = 31**	**0.9**
pH dependence (yes or no)			no				

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

Column leaching ‡	Eluation (mm): 200 mm Time period (d): 48 h; 71 h (Les Evouettes); 120 h (Vetroz)			
		Collombey	Speyer 2.2	Les Evouettes	Vetroz
	leachate (%):	1.68	41.1	0.62	0.14
	extractables (%):	84.71	40.14	84.84	73.08
	non-extract. (%):	3.5	9.1	4.06	18.41
	balance (%):	89.89	90.25	89.52	91.63
Aged residues leaching ‡	Aged for (d): 8 d (Les Evouettes); 12 d (Collombey) Time period (d): 48 h irrigation Eluation (mm): 200 mm			

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

	Les Evouettes	Collombey
remaining as after ageing (%):	42.3	39.7
reaction products:	CGA 50266 and CGA 354742 between 10 – 13 % further 9 metabolites present with < 4 % each and including CGA 102935 and CGA 103699	
% applied radioact. in leachate:	21.1	30.7
	determinable: CGA 50266 and CGA 354742	
soil (0 – 5 cm):	non extractable residues: 22 %	
	as up to 20 cm soil depth	
soil (> 20 cm)	main components: CGA 50266 and CGA 354742	

Aged for (d):	5 months
Time period (d):	48 h irrigation
Elution (mm):	200 mm

	Speyer 2.2
remaining as after ageing (%):	24.3
% applied radioact. in leachate:	49.3
in detail:	2.5 % as 34.8 % CGA 50266 5.6 % unidentified polar metabolite P2 6.2 % further polar metabolites

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

Lysimeter/ field leaching studies ‡	Location: Itingen, Baselland, Switzerland Study type: lysimeter Soil properties (0 - 30 cm): 83.5 % sand, 10.9 % silt, 5.6 % clay pH (KCl) = 6.1 (0 - 30 cm), 5.9 (30 - 60 cm), 6.1 (60 - 90 cm), 7.3 (90 - 120 cm) % C_{org} = 1.05 (0 - 30 cm), 0.49 (30 - 60 cm), 0.14 (60 - 90 cm), 0.00 (90 - 120 cm) MWHC (g H_2O/100g dry soil) = 34.5 (0 - 30 cm), 28.6 (30 - 60 cm), 23.2 (60 - 90 cm), 23.6 (90 - 120 cm) Date of application : 14/09/1992 (6 days after seeding of winter rape) Crop : winter rape – *phacelia* – winter wheat Number of applications: 1 year, 1 applications per year Duration: 14/09/1992 – 12/09/1994 (2 years) Application rate: 1.5 kg as/ha Annual rainfall (mm): 1135 mm (1. year including irrigation); 944 mm (2. year without irrigation) Average annual leachate volume (mm): 369 mm % radioactivity in leachate (total/year): 20.9 %AR (1. year); 7.95 %AR (2.year) % radioactivity in leachate (maximum/year): 7.8 %AR (1. year); 3.2 %AR (2.year) Maximum concentration [µg as equi/L]: as < 0.05 (for the whole period) CGA 50266 85.2 (lys 1, d = 84); 91.4 (lys 2, d = 94) CGA 354742 88.3 (lys 1, d = 94); 85.7 (lys 2, d = 171) CGA 369873 10.6 (lys 1, d = 438); 8.5 (lys 2, d = 465) SYN 530561 5.0 (lys 1, d = 94); 5.2 (lys 2, d = 171) SYN 528702 24.1 (lys 1, d = 94); 36.5 (lys 2, d = 171) CGA 373464 4.6 (lys 1, d = 84); 13.9 (lys 2, d = 171) mixture of polar metabolites at retention time 11 - 18 min < 0.5 µg/L each Individual annual average concentrations*) [µg as equi/L]: 1. year 2. year total

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

as	< 0.05	< 0.05	< 0.05
CGA 50266	32.2	1.4	15.5
CGA 354742	33.8	12.6	22.3
CGA 369873	2.1	2.3	2.2
SYN 530561	2.1	0.9	1.4
SYN 528702	9.0	0.3	4.2
CGA 373464	2.4	1.3	1.8
mixture of polar metabolites at retention time 11-18 min			< 0.5 µg/L each

* values given as mean of both lysimeters

Highest annual average concentrations) [µg metabolite/L]:

	Annual average
as	< 0.05
CGA 50266	35.6
CGA 354742	41.3
CGA 369873	2.4
SYN 530561	2.2
SYN 528702	15.3
CGA 373464	3.9

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): 14.1 days
Method of calculation	Kinetics: SFO representative worst case (90th percentile from lab. studies.
Application data	Crop: oil seed rape Depth of soil layer: 5 cm % plant interception: 0 Number of applications: 1 Interval (d): - Application rate(s): 1500 g as/ha

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

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.000		not applicable	
Short term 24h	1.904	1.952	not applicable	not applicable
2d	1.813	1.905	not applicable	not applicable
4d	1.643	1.816	not applicable	not applicable
Long term 7d	1.418	1.692	not applicable	not applicable
28d	0.505	1.086	not applicable	not applicable
50d	0.171	0.744	not applicable	not applicable
100d	0.015	0.404	not applicable	not applicable
Plateau concentration	not applicable			

Metabolite I: CGA 50266 Method of calculation: maximum formation	Molecular weight relative to the parent: 0.98 In case PECsoil values at other time points than initial are requied a DT_{50lab} of 195.5 d (max., SFO) should be used. .
Application data	Application rate assumed: 522 g as/ha (assumed Met I is formed at a maximum of 35.5 % of the applied dose

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.6956		not applicable	
Plateau concentration	not applicable			

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

Metabolite II: CGA 354742 Method of calculation: maximum formation	Molecular weight relative to the parent: 1.26 In case PECsoil values at other time points than initial are requied a DT_{50lab} of 23.2 d (max., SFO) should be used.
Application data	Application rate assumed: 299 g as/ha (assumed Met II is formed at a maximum of 15.8 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.3982		not applicable	
Plateau concentration	not applicable			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 1: hydrolytically stable, DT_{50} > 200 d (incubation time 30 d at 20 °C and 5 d at 50 °C) Met CGA 39981: identified
	pH 4: Met CGA 50266: stable (incubation time 7 d at 50 °C) Met CGA 354742: stable (incubation time 7 d at 50 °C) Met CGA 42443: stable (incubation time 7 d at 50 °C)
	pH 5: hydrolytically stable, DT_{50} > 200 d (incubation time 30 d at 20 °C and 5d at 50 °C) Met CGA 50266: stable (incubation time 7 d at 50 °C) Met CGA 354742: stable (incubation time 7 d at 50 °C) Met CGA 42443: stable (incubation time 7 d at 50 °C)
	pH 7: hydrolytically stable, DT_{50} > 200 d (incubation time 30 d at 20 °C and 5 d at 50 °C) Met CGA 50266: stable (incubation time 7 d at 50 °C) Met CGA 354742: stable (incubation time 7 d at 50 °C) Met CGA 42443: stable (incubation time 7 d at 50 °C)
	pH 9: hydrolytically stable, DT_{50} > 200 d (incubation time 30d at 20 °C and 5 d at 50 °C) Met CGA 50266: stable (incubation time 7 d at 50 °C) Met CGA 354742: stable (incubation time 7 d at 50 °C) Met CGA 42443: stable (incubation time 7 d at 50 °C)

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

	pH 13: DT_{50} 9.3 d (at 5 °C, 30 °C and 50 °C) Met CGA 39981: identified
Photolytic degradation of active substance and metabolites above 10 % ‡	as: stable (for natural light, 40°N, pH = 7) CGA 50266: DT_{50} = 21.7 d (for natural light, 40°N, pH = 4, citrate buffer) stable (for natural light, 40°N, pH = 4, acetate buffer, pH = 7 and pH = 9) stable under conditions for simulated natural water CGA 354742: DT_{50} = 29 d (for natural light, 40°N, pH = 4, citrate buffer) stable (for natural light, 40°N, pH = 4, acetate buffer, pH = 7 and pH = 9) stable under conditions for simulated natural water CGA 42443: stable (for natural light, 40°N, pH = 7)
Quantum yield of direct phototransformation in water at Σ > 290 nm	not applicable
Readily biodegradable ‡ (yes/no)	not readily biodegradable

Degradation in water / sediment

Parent	Distribution: in sediment max of 16 % at day 3 (river) and 17.2 % at day 14 (pond); in water max of 101 % at day 0									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (days)	St. (r^2)	DT_{50}-DT_{90} Water (days)	St. (r^2)	DT_{50}-DT_{90} Sed (days)	St. (r^2)	Method of calculation
I	7.9	6.9	20 °C	8.7 / 24.3	0.989	6.3 / 21.8	0.989	1.5 / 5.02	0.989	SFO
II	7.9	6.8	20 °C	22.8 / 63.6	0.998	15.6 / 56.2	0.998	4.5 14.8	0.998	SFO
Geometric mean/median				14.1		10/11		4.9/8.8		
Met CGA 50266	Distribution: in sediment max of 4.2 % (pond) at day 112; in water max of 13.0 % (pond) at day 182									

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

Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median						1000[a)]		1000[a)]		
Met CGA 42443	Distribution: in sediment max of 4.5 % (pond) at day 112; in water max of 5.5 % at day 112									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median						1000[a)]		1000[a)]		

Mineralisation and non extractable residues

Water / sediment system	pH w	pH sed	Mineralisation 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)
I	7.9	6.9	3.5 % after 182 d (end of study)	59.3 % after 84 d	56.7 % after 182 d (end of study)
II	7.9	6.8	3.1 % after 182 d (end of study)	50.9 % after 182 d (end of study)	50.9 % after 182 d (end of study)

a) default used in FOCUS $_{SW}$ simulations

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

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

Parent Parameters used in FOCUSsw step 1 2 and 3	Molecular weight (g/mol): 255.5 Water solubility (mg/L): 2300 K_{oc} (L/kg): 70 DT_{50} soil (d): 4.4 days (Lab or field. In accordance with FOCUS SFO (median n = 12)) DT_{50} water/sediment system (d): 1000 (representative worst case from sediment water studies) DT_{50} water (d): 1000 (default) $DegT_{50}$ sediment (d): 3 Crop interception (%):0
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 1.5 x 10^{-3} Pa at 25 °C K_{oc}: 70 1/n: 0.9 (Freundlich exponent general or for soil, susp. solids or sediment respectively)
Application rate	Crop: oil seed rape (winter) Crop interception: not applicable Number of applications: 1 Interval (d): - Application rate(s): 1500 g as/ha Depth of water body: 30 cm Application window: 28th August to 26th September
Main routes of entry	2.759 % drift from 1 meter 10 % runoff/ drainage (at FOCUSsw Step 1) 5 % (northern EU) – 4 % (southern EU) runoff/drainage + 4 days after application (at FOCUSsw Step 2)

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	471		320	
	24 h	450	450	315	318
	2 d	430	450	301	313
	4 d	395	431	276	301
	7 d	347	405	243	283
	14 d	256	352	179	246
	21 d	169	308	132	216
	28 d	139	272	98	190
	42 d	76	216	53	151

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	134.3		89.8	
Southern EU	0 h	109.9		72.8	

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 ditch		0 h	73.4		10.9	
		24 h	23.4	39.1	10.8	10.9
		2 d	21.9	31.0	10.8	10.8
		4 d	20.0	26.0	10.5	10.8
		7 d	17.9	23.0	10.0	10.7
		14 d	14.4	19.6	8.74	10.5
		21d	11.9	17.4	7.56	10.0
		28 d	10.1	15.8	6.54	9.53
		42 d	2.86	13.4	2.25	8.31

FOCUS STEP 3	Time	D2		D3	D4		D5		R1		R3
		ditch	stream	ditch	pond	stream	pond	stream	pond	stream	stream
Water	Global Maximum	73.4	48.1	9.54	0.340	8.23	0.335	8.87	0.328	6.29	8.79
(µg as/L)	TWA 1 days	39.1	16.2	8.43	0.337	2.42	0.332	3.45	0.325	1.33	5.41
	TWA 2 days	31.0	12.1	6.85	0.335	1.21	0.330	1.73	0.322	0.667	2.72
	TWA 4 days	26.0	10.2	4.04	0.332	0.608	0.327	0.868	0.318	0.334	1.36
	TWA 7 days	23.0	7.31	2.34	0.327	0.347	0.323	0.496	0.313	0.191	0.779
	TWA 14 days	19.6	4.47	1.17	0.318	0.174	0.315	0.248	0.301	0.095	0.566
	TWA 21 days	17.4	3.45	0.78	0.310	0.116	0.307	0.165	0.291	0.072	0.377
	TWA 28 days	15.8	2.89	0.585	0.302	0.087	0.299	0.124	0.281	0.054	0.284
	TWA 42 days	13.4	2.31	0.39	0.287	0.058	0.286	0.083	0.262	0.037	0.190
Sediment	Global Maximum	10.9	6.92	2.06	0.221	0.831	0.201	1.03	0.212	0.542	1.45
(µg as/kg)	TWA 4 days	10.8	3.85	1.54	0.220	0.280	0.201	0.280	0.212	0.155	0.619
	TWA 7 days	10.7	3.30	1.14	0.220	0.195	0.201	0.195	0.211	0.107	0.432
	TWA 14	10.5	2.53	0.711	0.219	0.114	0.200	0.114	0.210	0.061	0.287

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

	days										
	TWA 21 days	10.0	2.11	0.51	0.217	0.080	0.198	0.080	0.207	0.048	0.231
	TWA 28 days	9.53	1.84	0.395	0.216	0.061	0.196	0.061	0.204	0.037	0.182

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 ditch 5 m buffer		Maximum	73.3		10.4	
		1 days	23.4	39.1	10.4	10.4
		2 days	21.9	31.0	10.3	10.4
		4 days	19.9	26.0	10.1	10.4
		7 days	17.8	22.9	9.63	10.3
		14 days	14.3	19.5	8.44	10.0
		21 days	11.8	17.3	7.30	9.62
		28 days	10.0	15.7	6.33	9.18
		42 days	2.86	12.8	2.09	8.05

FOCUS STEP 4 5 m buffer	Time	D2		D3	D4		D5		R1		R3
		ditch	stream	ditch	pond	stream	pond	stream	pond	stream	stream
Water (µg as/L)	Global Maximum	73.4	48.1	2.59	0.295	3.0	0.290	3.24	0.283	2.30	4.29
	TWA 1 days	31.0	9.12	1.86	0.292	0.885	0.287	1.26	0.280	0.485	2.67
	TWA 2 days	28.6	7.78	1.44	0.290	0.312	0.285	0.453	0.277	0.168	1.06
	TWA 4 days	26.0	6.05	1.09	0.288	0.222	0.283	0.317	0.275	0.121	0.671
	TWA 7 days	22.9	4.48	0.633	0.284	0.127	0.280	0.181	0.270	0.069	0.383
	TWA 14 days	19.5	3.03	0.317	0.276	0.063	0.272	0.091	0.260	0.035	0.252
	TWA 21 days	17.3	2.48	0.211	0.269	0.043	0.266	0.060	0.251	0.027	0.168

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

	TWA 28 days	15.7	2.15	0.158	0.262	0.036	0.259	0.045	0.242	0.020	0.127
	TWA 42 days	12.8	1.82	0.106	0.249	0.030	0.247	0.030	0.226	0.014	0.084
Sediment	Global Maximum	10.4	5.43	0.59	0.193	0.315	0.175	0.391	0.184	0.204	0.742
(µg as/kg)	TWA 4 days	10.4	2.66	0.442	0.192	0.107	0.175	0.144	01.83	0.059	0.311
	TWA 7 days	10.3	2.20	0.329	0.192	0.075	0.175	0.098	0.183	0.041	0.217
	TWA 14 days	10.0	1.75	0.204	0.191	0.044	0.174	0.055	0.182	0.023	0.129
	TWA 21 days	9.62	1.53	0.147	0.190	0.038	0.172	0.038	0.179	0.019	0.106
	TWA 28 days	9.18	1.38	0.114	0.189	0.034	0.170	0.029	0.177	0.015	0.084

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 ditch 10 m buffer		Maximum	73.3		10.3	
		1 days	23.4	39.1	10.3	10.3
		2 days	21.8	31.0	10.3	10.3
		4 days	19.9	26.0	10.0	10.3
		7 days	17.8	22.9	9.57	10.2
		14 days	14.3	19.5	8.39	9.95
		21 days	11.8	17.3	7.26	9.55
		28 days	9.98	15.7	6.30	9.12
		42 days	2.86	12.8	2.08	8.01

FOCUS STEP 4 10 m buffer	Time	D2		D3	D4		D5		R1		R3
		ditch	stream	ditch	pond	stream	pond	stream	pond	stream	stream
Water	Global Maximum	73.3	48.1	1.37	0.215	1.59	0.210	1.72	0.204	1.219	1.701

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

(µg as/ L)	TWA 1 days	31.0	8.92	0.984	0.212	0.235	0.207	0.336	0.2	0.129	0.268
	TWA 2 days	28.6	7.35	0.763	0.211	0.178	0.206	0.241	0.199	0.089	0.201
	TWA 4 days	26.0	5.33	0.580	0.210	0.118	0.205	0.168	0.197	0.064	0.134
	TWA 7 days	22.9	3.73	0.336	0.207	0.069	0.202	0.096	0.194	0.037	0.077
	TWA 14 days	19.5	2.64	0.168	0.201	0.052	0.197	0.048	0.187	0.018	0.07
	TWA 21 days	17.3	2.22	0.112	0.196	0.043	0.192	0.032	0.18	0.013	0.047
	TWA 28 days	15.7	1.96	0.084	0.191	0.036	0.188	0.024	0.173	0.01	0.035
	TWA 42 days	12.8	1.70	0.056	0.181	0.030	0.179	0.018	0.162	0.007	0.024
Sediment	Global Maximum	10.3	5.01	0.332	0.142	0.171	0.129	0.213	0.134	0.111	0.169
(µg as/kg)	TWA 4 days	10.3	2.41	0.241	0.142	0.058	0.129	0.078	0.133	0.032	0.07
	TWA 7 days	10.2	2.01	0.179	0.142	0.045	0.128	0.053	0.133	0.022	0.049
	TWA 14 days	9.95	1.61	0.112	0.141	0.041	0.128	0.030	0.132	0.013	0.041
	TWA 21 days	9.55	1.41	0.080	0.140	0.038	0.126	0.021	0.13	0.009	0.032
	TWA 28 days	9.12	1.28	0.062	0.140	0.034	0.125	0.020	0.128	0.007	0.025

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

Metabolite CGA 50266 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 251 Water solubility (mg/L): 490000 Soil or water metabolite: K_{oc}/K_{om} (L/kg): 0 DT_{50} soil (d): 13.1 days In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 0 Maximum occurrence observed (% molar basis with respect to the parent) Water/Sediment: 16 Soil: 35
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 8.0×10^{-5} Pa at 25 °C K_{om}/K_{oc}: 0 1/n: 0.9 (Freundlich exponent general or for soil, susp. solids or sediment respectively) Metabolite kinetically generated (yes/no): yes Formation fraction in soil (k_{dp}/k_f): 0.37 (If formation degradation of metabolite is kinetically simulated by PRZM)
Application rate	Crop: oil seed rape Number of applications: 1 Interval (d): - Application rate(s): 1500 g as/ha Depth of water body: 30 cm Application window: 28th August to 26th September
	0 % drift from 0 metre 10 % runoff/ drainage (at FOCUSsw Step 1) 4 % (northern EU) – 5 % (southern EU) runoff/ drainage + 4 days after application (at FOCUSsw Step 2)

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	174		0.0172	
	24h	174	174	0.0174	0.0173
	2d	174	174	0.0174	0.0173
	4d	174	174	0.0174	0.0174
	7d	173	174	0.0173	0.0174
	14d	173	173	0.0172	0.0173
	21d	172	173	0.0172	0.0173
	28d	171	172	0.0171	0.0172
	42d	169	172	0.0169	0.0172

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	71.7		0.0	
Southern EU	0 h	57.8		0.0	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 ditch		0 h	48.3		11.0	
		24 h	35.2	39.3	10.9	11.0
		2 d	30.7	36.8	10.8	10.9
		4 d	25.1	31.8	10.7	10.9
		7 d	21-8	30.2	10.3	10.8
		14 d	12.3	27.8	8.73	10.4
		21 d	9.93	26.2	7.38	9.91
		28 d	5.51	24.8	6.18	9.68
		42 d	3.24	24.3	4.31	9.30

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

FOCUS STEP 3 Scenario	Com-partment	Time	D2		D3	D4		D5		R1		R3
			ditch	stream	ditch	pond	stream	pond	stream	pond	stream	stream
CGA 50266	Water	Global Maximum	48.3	32.9	6.83	10.7	7.36	5.17	2.73	< 0.001	0.060	1.77
	(µg/L)	TWA 21 days	26.2	12.6	6.76	10.6	6.12	5.15	2.45	< 0.001	0.001	0.054
	(µg/L)	TWA 28 days	24.8	12.0	6.75	10.5	5.73	5.13	2.45	< 0.001	0.001	0.040
	(µg/L)	TWA 42 days	3.24	1.98	6.61	9.33	4.14	4.89	2.02	< 0.001	< 0.001	< 0.001
	Sediment	Global Maximum	11.0	5.71	3.57	6.00	2.32	2.72	1.05	< 0.001	0.002	0.103
	(µg/kg)	TWA 21 days	9.91	5.12	3.55	6.00	2.24	2.72	1.03	< 0.001	< 0.001	0.019
	(µg/kg)	TWA 28 days	9.68	4.95	3.55	5.99	2.18	2.72	1.02	< 0.001	< 0.001	0.016
	(µg/kg)	TWA 42 days	4.51	2.49	3.40	5.78	1.42	2.65	0.904	< 0.001	< 0.001	0.003

Metabolite CGA 354742

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 323

Water solubility (mg/L):1000000

Soil or water metabolite:

K_{oc}/K_{om} (L/kg): 3.7

DT_{50} soil (d): 15.6 days In accordance with FOCUS SFO (arithmetic mean n=3)

DT_{50} water/sediment system (d): 1000 (representative worst case from sediment water studies)

DT_{50} water (d): 1000

DT_{50} sediment (d): 1000

Crop interception (%): 0

Maximum occurrence observed (% molar basis with respect to the parent)

Water/Sediment: 0

Soil: 16

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

Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 2 x 10^{-11} Pa at 25 °C K_{om}/K_{oc}: 3.7 1/n: 0.9 (Freundlich exponent general or for soil, susp. solids or sediment respectively) Metabolite kinetically generated (yes/no): yes Formation fraction in soil (k_{dp}/k_f): 0.33 (If formation degradation of metabolite is kinetically simulated by PRZM)
Application rate	Crop: oil seed rape Number of applications: 1 Interval (d): - Application rate(s): 1500 g as/ha Depth of water body: 30 cm Application window: 28th August to 26th September
	0 % drift from 0 metre 10 % runoff/drainage (at FOCUSsw Step 1) 4 % (northern EU) – 5 % (southern EU) runoff/drainage + 4 days after application (at FOCUSsw Step 2)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	99		3.7	
	24 h	99	99	3.7	3.7
	2 d	99	99	3.7	3.7
	4 d	99	99	3.7	3.7
	7 d	99	99	3.7	3.7
	14 d	98	99	3.6	3.7
	21 d	98	99	3.6	3.7
	28 d	97	98	3.6	3.6
	42 d	97	98	3.6	3.6

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	41.6		1.5	
Southern EU	0 h	33.3		1.2	

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

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		0 h	71.5		17.2	
		24 h	51.1	56.7	17.0	17.2
		2 d	44.4	53.6	16.7	17.2
		4 d	37.7	46.5	16.2	17.2
		7 d	33.0	41.7	15.4	17.0
		14 d	18.8	33.3	13.4	16.6
		21 d	15.3	29.0	11.5	15.9
		28 d	8.45	27.3	9.89	15.1
		42 d	4.70	27.7	7.65	14.1

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

FOCUS STEP 3 Scenario	Com-partment	Time	D2		D3	D4		D5		R1		R3
			ditch	stream	ditch	pond	stream	pond	stream	pond	stream	stream
	Water	Global Maximum	71.5	54.6	6.73	13.5	9.13	5.98	3.32	< 0.001	0.077	2.42
	(µg/L)	TWA 21 days	15.3	9.83	6.63	12.6	3.63	5.86	2.18	< 0.001	< 0.001	< 0.001
	(µg/L)	TWA 28 days	8.45	5.08	6.62	12.3	2.53	5.84	2.32	< 0.001	< 0.001	< 0.001
	(µg/L)	TWA 42 days	4.70	2.85	6.60	11.7	5.62	5.69	2.00	< 0.001	< 0.001	< 0.001
	Sediment	Global Maximum	17.2	9.04	4.81	9.82	3.66	4.48	1.57	< 0.001	0.004	< 0.001
	(µg/kg)	TWA 21 days	11.5	6.32	4.72	9.71	2.82	n/a	1.49	0.001	0.001	0.016
	(µg/kg)	TWA 28 days	9.89	5.45	4.69	9.64	3.42	n/a	1.49	0.001	0.001	0.016
	(µg/kg)	TWA 42 days	7.65	4.28	4.66	9.48	3.14	n/a	1.45	< 0.001	< 0.001	0.008

n/a: not available, simulation period too short

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

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 PELMO Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.2: Scenarios (list of names): Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto Crop: oil seed rape Parent DT_{50}lab 6.5 d (geometric mean, n =6) (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2). K_{oc}: 69, 1/n = 0.91 (median). Met 1 (CGA 50266) DT_{50}lab 26.1 d (geometric mean, n = 5) (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2). K_{oc}: 0 (worst case), 1/n = 0.9 (default). calculated average formation fraction: 37 % Met 2 (CGA 354742) DT_{50}lab 15.1 d (geometric mean, n = 3) (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2). K_{oc}: 3.7 (arr. mean), 1.0 calculated average formation fraction: 33 % Metabolites CGA269873, SYN 530561, SYN 528702 and CGA 373464: For minor metabolites of the lysimeter study (CGA269873, SYN 530561, SYN 528702 and CGA 373464) lysimeter study results of CGA 50266 and CGA 354742 compared to modelled results of CGA 50266 and CGA 354742. Transfer factors derived for lysimeter concentrations to modelled concentrations. Maximum transfer factor applied to each metabolite (CGA269873, SYN 530561, SYN 528702 and CGA 373464) and a pseudo modelled PECgw value calculated. For field and lysimeter studies Location: Itingen, Baselland, Switzerland Study type (e.g.lysimeter, field): lysimeter Soil properties (0 - 30 cm): 83.5 % sand, 10.9 % silt, 5.6

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

	% clay pH (KCl) = 6.1 (0 - 30 cm), 5.9 (30 - 60 cm), 6.1 (60 - 90 cm), 7.3 (90 - 120 cm) % C_{org} = 1.05 (0 - 30 cm), 0.49 (30 - 60 cm), 0.14 (60 - 90 cm), 0.00 (90 - 120 cm) MWHC (g H_2O/100g dry soil) = 34.5 (0 - 30 cm), 28.6 (30 - 60 cm), 23.2 (60 - 90 cm), 23.6 (90 - 120 cm) Date of application : 14/09/1992 (6 days after seeding of winter rape) Crop : winter rape – *phacelia* – winter wheat Number of applications: 1 year, 1 applications per year Duration: 14/09/1992 – 12/09/1994 (2 years) Application rate: 1.5 kg as/ha Annual rainfall (mm): 1135 mm (1. year including irrigation); 944 mm (2. year without irrigation) Average annual leachate volume (mm): 369 mm
Application rate	Application rate: 1500 g/ha. No. of applications: 1, yearly and triennial Time of application (month or season):autumn

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			1 (CGA 50266)	2 (CGA 354742)
FOCUS PELMO Oil seed rape 1500 g as/ha triennial Model /Crop	Châteaudun	< 0.001	13.370	4.875
	Hamburg	< 0.001	21.440	11.337
	Kremsmünster	< 0.001	13.795	6.187
	Okehampton	< 0.001	13.324	7.042
	Piacenza	0.026	20.828	13.447
	Porto	< 0.001	10.490	4.106

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

	Metabolites (µg/L) estimated by factoring lysimeter results (annual average concentrations compared to CGA 50266 annual averge concentrations) for the metabolites with modelled triannual average concentrations for CGA 50266 at each scenario.			
	CGA 369873	SYN 530561	SYN 528702	CGA 373464
Châteaudun	0.90	0.83	5.75	1.46
Hamburg	1.44	1.32	9.21	2.35
Kremsmünster	0.93	0.85	5.93	1.51
Okehampton	0.90	0.82	5.73	1.46
Piacenza	1.40	1.29	8.95	2.28
Porto	0.71	0.65	4.51	1.15

PEC$_{(gw)}$ From lysimeter / field studies (reported as active substance equivalents)

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	< 0.05	< 0.05	not applicable

Metabolite CGA 50266	1st year	2nd year	3rd year
Annual average (µg/L)	32.2	1.4	not applicable

Metabolite CGA 354742	1st year	2nd year	3rd year
Annual average (µg/L)	33.8	12.6	not applicable

Metabolite CGA 369873	1st year	2nd year	3rd year
Annual average (µg/L)	2.1	2.3	not applicable

Metabolite SYN 530561	1st year	2nd year	3rd year
Annual average (µg/L)	2.1	0.9	not applicable

Metabolite SYN 528702	1st year	2nd year	3rd year
Annual average (µg/L)	9.0	0.3	not applicable

Metabolite CGA 373464	1st year	2nd year	3rd year
Annual average (µg/L)	2.4	1.3	not applicable

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

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

Direct photolysis in air ‡	Not studied
Quantum yield of direct phototransformation	not applicable
Photochemical oxidative degradation in air ‡	AOP-calculations: AOP version 1.5a: DT_{50} = 0.21 d (= 2.5 h, 12 h day; 1.5 x 106 OH/cm3) AOP version 1.91: DT_{50} = 0.397 d (= 9.522 h, 24 h day; 0.5 x 106 OH/cm3)
Volatilisation ‡	from plant surface: no data
	from soil surfaces (BBA guideline: BBA IV 6-1): negligible after up to 24 hours
Metabolites	not applicable

PEC (air)

Method of calculation	no data submitted

$PEC_{(a)}$

Maximum concentration	no data submitted

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	(Metabolites with > 10 % of applied a.s. [or > 5 % of applied a.s. in 2 sequential measures, regarding groundwater assessment only]) Soil: dimethachlor, CGA 50266, CGA 354742, if anaerobic conditions occur CGA 42443 Groundwater: dimethachlor (default), from soil and lysimeter: CGA 50266, CGA 354742, SYN528702 from soil only: CGA 102935, from lysimeter only: CGA 369873, SYN 530561, CGA 373464 Surface Water: dimethachlor, CGA 50266, CGA 354742, if anaerobic soil conditions occur CGA 42443 Sediment: dimethachlor Air: dimethachlor

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

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

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	Fourteen groundwater wells in two agricultural areas = Schleswig-Holstein (Northern Germany) and Mecklenburg-West Pomerania (Northern East Germany) with traditionally high winter oil seed rape growing intensity. The groundwater tables at the well locations are generally at about 2 – 3 m depth in Schleswig-Holstein and at about 2 – 9 m depth in Mecklenburg-West Pomerania. 12 monitoring wells were sampled in monthly and 2 wells in bimonthly intervals starting in November 2002 to April 2005. No measurable residues of parent dimethachlor were found in the wells as well as for the metabolites CGA 373464, SYN 528702 and SYN 530561. For the major soil metabolites CGA 354742 and CGA 50266 the highest observed individual residue values were 0.52 µg/L and < 0.05 µg/L, respectively. For CGA 369873 the highest observed individual residue value was 2.1 µg/L. Based on these findings it can be concluded that residues of dimethachlor are not present in groundwater at concentrations above the EC limit value of 0.1 µg/L for the active substance. It is also highly unlikely that the metabolites of dimethachlor are present in ground water above the EC guidance value of 10 µg/L in the monitored agricultural regions with a long-term history of dimethachlor use and in comparable worse case scenarios. Note CGA 102935 was not analysed for in the results reported.
Air (indicate location and type of study)	not available

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

Dimethachlor should be classified as ”not readily biodegradable”: Candidate for R53, May cause long-term adverse effects in the aquatic environment

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

Appendix 1 – list of endpoints

Effects on non-target species

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/d)	End point (mg/kg feed)
Birds ‡				
Coturnix coturnix japonica	Dimethachlor	Acute	LD_{50} 524	Not relevant
	Preparation	Acute	No data submitted – justification accepted	
	Metabolites	Acute		
Coturnix coturnix japonica	Dimethachlor	Short-term	LD_{50} > 1470	LC_{50} > 5200
Coturnix coturnix japonica	Dimethachlor	Long-term 140 d food consumption	NOEL 102	NOEL 900
Mammals ‡				
Rat	Dimethachlor	Acute	LD_{50} 1600	Not relevant
Rat	Preparation	Acute	LD_{50} > 2000	Not relevant
Rat	Metabolite CGA 50266	Acute	LD_{50} > 2000	Not relevant
	Metabolite CGA 354742	Acute	LD_{50} > 2000	Not relevant
Rat	Dimethachlor	Long-term, 2-generation repro study reduced offspring bw	NOEL 20	NOEL 300
Rat	Metabolite	Long-term	No data submitted - not relevant	
Additional higher tier studies ‡ No data submitted – justification accepted				

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

Appendix 1 – list of endpoints

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

Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Indicator species/Category[2]	Time scale		ETE (mg/kg bw/d)	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)					
Medium herbivorous birds	Acute	Dimethachlor	162	3.2	10
Small granivorous bird	Acute	Dimethachlor	29.6	18	10
Insectivorous birds	Acute	Dimethachlor	81.1	6.5	10
Medium herbivorous birds	Short-term	Dimethachlor	86.6	17	10
Small granivorous bird	Short term	Dimethachlor	16.5	89	10
Insectivorous birds	Short-term	Dimethachlor	45.2	33	10
Medium herbivorous birds	Long-term	Dimethachlor	45.9	2.2	5
Small granivorous bird	Long-term	Dimethachlor	16.5	6.1	5
Insectivorous birds	Long-term	Dimethachlor	45.2	2.2	5
Consumption of contaminated drinking water	Acute	Dimethachlor	8.5	61.5[4]	10
Higher tier refinement (Birds)					
Insectivorous bird (skylark, 37 g) PD / FIR/bw 25 % grass weeds / 0.124 25 % weed seeds / 0.124 50 % large arthropods / 0.247	Acute	Dimethachlor	47.619 22.040 b) 21.680 c)	11.0 a) 23.8 b) 24.2 c)	10
	Long-term	Dimethachlor	13.282 6.026 b) 6.015 c)	7.6 a) 16.8 b) 16.8 c)	5
a) RUD for plant material based on default values →However, contamination of crop or weeds by overspray not very probable according to GAP (application shortly after sowing into a clean seed-bed but prior to crop emergence) →therefore RUD expected to be much lower than default since contamination only systemically by uptake of a.s. from soil b) RUD for plant material (only herbage) based on off-field overspray situation (2.77 % of application rate as drift entry in 1 m) c) RUD for plant based on uptake of in-field plants growing after treatment with ´Teridox´ →worst case assumption that expected PECsoil of 2.0 mg/kg soil will be reached in the plants by uptake of the a.s. from soil					
Tier 1 (Mammals)					
Medium herbivorous mammal	Acute	Dimethachlor	44.7	36	10
Medium herbivorous mammal	Acute	Metabolite	Not relevant		10

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

Appendix 1 – list of endpoints

Indicator species/Category[2]	Time scale	ETE (mg/kg bw/d)	TER[1]	Annex VI Trigger[3]
Medium herbivorous mammal	Long-term Dimethachlor	12.7	1.6	5
Medium herbivorous mammal	Long-term Metabolite	Not relevant		5
Consumption of contaminated drinking water	Acute Dimethachlor	6.2	258[4]	10
Higher tier refinement (Mammals)				
Omnivorous mammal (wood mouse, 21.7 g) PD / FIR/bw: 31% cereal grain / 0.063 17% weed seeds / 0.127 17% grass and non-grass weeds / 0.034 27 % large insects / 0.161 8% earthworm / 0.091	Long-term Dimethachlor	9.076 4.554 a) 4.543 b)	2.2 4.4 a) 4.4 b)	5

[1] in higher tier refinement provide brief details of any refinements used (e.g, residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
[4] Calculated by EFSA after the peer-review, based on PPR panel revision of guidance document on RA for birds and mammals (Question No EFSA-Q-2006-064) adopted 17 July 2008 (soil DT_{50} 6.5 days, K_{oc} = 69mL/g, PEC_{puddle}= 1.2 mg/L, drinking water rate of 7 and 5.1 mL/d for a small granivorous bird and mammal respectively).
a) RUD for plant based on uptake of in-field plants growing after treatment with ´Teridox´ worst case assumption that expected PECsoil of 2.0 mg/kg soil will be reached in the plants by uptake of the a.s. from soil
b) RUD for plant material (only herbage) based on off-field overspray situation (2.77 % of application rate as drift entry in 1 m)

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

Appendix 1 – list of endpoints

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				
Oncorhynchus mykiss	Dimethachlor	96 hr (static)	Mortality, EC_{50}	3.9 $_{nom}$
Oncorhynchus mykiss	Dimethachlor	21 d (flow-through)	Juvenile growth NOEC	0.85 $_{mm}$
Oncorhynchus mykiss	Preparation	96 hr (static)	Mortality, EC_{50}	4.5 as $_{nom}$ 9.5 product
Oncorhynchus mykiss	Metabolite CGA 50266	96 hr (static)	Mortality, EC_{50}	> 100 $_{nom}$
Oncorhynchus mykiss	Metabolite CGA 354742	96 hr (static)	Mortality, EC_{50}	> 100 $_{nom}$
Aquatic invertebrate				
Daphnia magna	Dimethachlor	48 hr (static)	Mortality, EC_{50}	24 $_{nom}$
Daphnia magna	Dimethachlor	22 d (semi-static)	Reproduction, NOEC	2.3 $_{mm}$
Daphnia magna	Preparation	48 hr (static)	Mortality, EC_{50}	8.54 as $_{nom}$ 18.1 product
Daphnia magna	Preparation[2]	21 d (semi-static)	Reproduction, NOEC	0.476 as $_{nom}$ 1.0 product
Daphnia magna	Metabolite CGA 50266	48 hr (static)	Mortality, EC_{50}	> 100 $_{nom}$
Daphnia magna	Metabolite CGA 354742	48 hr (static)	Mortality, EC_{50}	> 100 $_{nom}$
Sediment dwelling organisms				
Chironomus riparius	Dimethachlor	28 d (static)	NOEC sed. NOEC water	25 mg/kg dw $_{mm}$ 4 mg/L
Algae				
Desmodesmus subspicatus	Dimethachlor[3]	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.054 $_{nom}$ 0.091 $_{nom}$

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

Appendix 1 – list of endpoints

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Pseudokirchneriella subcapitata	Preparation[4]	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.013 $_{real}$ product 0.0065 as$_{real}$ 0.025 $_{real}$ product 0.0125 as$_{real}$
Navicula pelliculosa	Metabolite CGA 50266	96 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	39.6 $_{nom}$ 46.5 $_{nom}$
Pseudokirchneriella subcapitata	Metabolite CGA 354742	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	84 $_{nom}$ 123 $_{nom}$
Pseudokirchneriella subcapitata	Metabolite CGA 369873	72 hr (static)	Biomass: E_bC_{50}	> 100 $_{nom}$
Pseudokirchneriella subcapitata	Metabolite CGA 373464	72 hr (static)	Biomass: E_bC_{50}	> 43 $_{real}$
Pseudokirchneriella subcapitata	Metabolite SYN 530561	72 hr (static)	Biomass: E_bC_{50}	> 100 $_{nom}$
Pseudokirchneriella subcapitata	Metabolite SYN 528702	72 hr (static)	Biomass: E_bC_{50}	> 100 $_{nom}$
Higher plant				
Lemna gibba	Dimethachlor	7 d (semi-static)	Fronds E_bC_{50} Fronds E_rC_{50}	0.035 $_{nom}$ 0.0658 $_{nom}$
Lemna gibba	Dimethachlor	14 d (semi-static)	Fronds (yield) E_yC_{50}	0.00217 $_{mm}$[5]
Lemna gibba	Preparation	7 d (static)	Fronds: E_bC_{50} Fronds: E_rC_{50}	0.0158 as $_{nom}$ 0.033 product 0.0229 as $_{nom}$ 0.048 product
Lemna gibba	CGA 50266, CGA 354742, CGA 369873, SYN 530561, SYN 528702, CGA 373464	72 hr (static)	No data submitted, data not required since data for algae are available	
Microcosm or mesocosm tests				
Not required, not relevant				

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

Appendix 1 – list of endpoints

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".
[2] very steep concentration-response curve. At the next higher concentration (3 mg formulation/L; 1.43 mg as/L) 100 % mortality of the adults was observed. The calculated EC_{50} describes the effect of the formulation on the survival of *Daphnia magna* after 21 d.
[3] data were recalculated with ToxRat Professional 2.09. ToxRat Solutions GmbH, Naheweg 15, D-52477 Alsdorf (http://www.toxrat-solutions.de).
[4] data were reclaculated with Uba ToxTool Version 2.09
[5] This test is based on a US EPA guideline with unusually low pH (about 5.0). An organic solvent was used. EbC_{50} after 6 days of this test (0.033 mg as/L) is comparable to the E_bC_{50} of 0.035 mg as/L obtained in the 7-day test.

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

FOCUS Step1

Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PECi sw (µg as/L)	TER	Annex VI Trigger[1]
Dimethachlor	Fish	3.9	acute	471	**8.3**	100
	Fish	0.85	Chronic	471	**1.8**	10
Product	Daphnia	8.54 (as)	acute	471 (as)	**18**	100
	Daphnia	0.476 (as)	chronic	471 (as)	**1**	10
	Algae	0.0065 (as)	chronic	471 (as)	**0.01**	10
Metabolite CGA 50266	Fish	> 100	acute	174	> 574	100
	Invertebrate	> 100	acute	174	> 574	100
	Algae	46.5	chronic	174	267	10
Metabolite CGA 354742	Fish	> 100	acute	99.4	> 1006	100
	Invertebrate	> 100	acute	99.4	> 1006	
	Algae	123	chronic	99.4	1237	10

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

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

Appendix 1 – list of endpoints

FOCUS Step 2

Oil seed rape, application rate 1.5 kg as/ha, pre-emergence, Northern Europe = worst case

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC_{SW}[3] (µg as/L)	TER	Annex VI Trigger[4]
Dimethachlor	N	Fish	3.9	Acute	134.3	**29**	100
Dimethachlor	N	Fish	0.85	Chronic	134.3	**6.3**	10
Product	N	Aquatic invertebrates	8.54 (as)	Acute	134.3	64	100
Product	N	Aquatic invertebrates	0.476 (as)	Chronic	134.3	3.5	10
Product	N	Algae	0.0065 (as)	Chronic	134.3	**0.05**	10
Product	N	Higher plants[5]	0.0158 (as)	Chronic	134.3	**0.12**	10
Dimethachlor	N	Sediment-dwelling organisms[6]	4.0 water 25 sed	Chronic	134.3 sed 89.8	29 278	10

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} (mg/L) and PEC_{sed} (mg as/ kg dry weight) and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Spray drift inputs only
Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity end point (mg/L)	PEC_{SW} Max[4] (µg as/L)	TER	Annex VI trigger[5]
product	D2	Ditch	algae (*Pseudokirchneriella subcapitata*)	chronic	0.0065 (as)	9.63	**0.7**	10
	D2	Stream				8.57	**0.8**	
	D3	Ditch				9.54	**0.7**	
	D4	Pond				0.328	19.8	
	D4	Stream				8.23	**0.8**	

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

Appendix 1 – list of endpoints

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity end point (mg/L)	PEC_{SW} Max[4] (µg as/L)	TER	Annex VI trigger[5]
	D5	Pond				0.328	19.8	
	D5	Stream				8.88	**0.7**	
	R1	Pond				0.328	19.8	
	R1	Stream				6.29	**1.0**	
	R3	Stream				8.80	**0.7**	
product	D2	Ditch	Higher plants *(Lemna gibba)*	chronic	0.0158 (as)	9.63	**1.6**	10
	D2	Stream				8.57	**1.8**	
	D3	Ditch				9.54	**1.7**	
	D4	Pond				0.328	48.2	
	D4	Stream				8.23	**1.9**	
	D5	Pond				0.328	48.2	
	D5	Stream				8.88	**1.8**	
	R1	Pond				0.328	48.2	
	R1	Stream				6.29	**2.5**	
	R3	Stream				8.80	**1.8**	

[1] drainage (D1 - D6) and run-off (R1 - R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4]Spray drift input only[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Total inputs (spray drift, run-off, drainage)
Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity end point[4] (mg/L)	PEC_{SW} Max[6] (µg as/L)	TER	Annex VI trigger[5]
Dimethachlor	D2	Ditch	algae (*Pseudokirchneriella subcapitata*)	chronic	0.054 (as)	73.4	**0.7**	10
	D2	Stream				48.1	**1.1**	
	D3	Ditch				9.54	**5.7**	

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

Appendix 1 – list of endpoints

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity end point[4] (mg/L)	PEC_{SW} Max[6] (µg as/L)	TER	Annex VI trigger[5]
	D4	Pond				0.34	158.8	
	D4	Stream				8.23	**6.6**	
	D5	Pond				0.335	161.2	
	D5	Stream				8.87	**6.1**	
	R1	Pond				0.328	164.6	
	R1	Stream				6.29	**8.6**	
	R3	Stream				8.79	**6.1**	
Dimethachlor	D2	Ditch	Higher plants *(Lemna gibba)*	chronic	0.035 (as)	73.4	**0.5**	10
	D2	Stream				48.1	**0.7**	
	D3	Ditch				9.54	**3.7**	
	D4	Pond				0.34	102.9	
	D4	Stream				8.23	**4.3**	
	D5	Pond				0.335	104.5	
	D5	Stream				8.87	**3.9**	
	R1	Pond				0.328	106.7	
	R1	Stream				6.29	**5.6**	
	R3	Stream				8.79	**4.0**	

[1] drainage (D1 - D6) and run-off (R1 - R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] endpoint of dimethachlor (technical)
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[6] total input (spray drift, drainage, run-off)

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

Appendix 1 – list of endpoints

FOCUS Step 4

Spray drift inputs only
Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point[7] (mg/L)	Buffer zone distance[6]	PEC_{SW}[4] Max(µg as/L)	TER	Annex VI trigger[5]
D2	Ditch	algae (*Pseudokirchneriella subcapitata*)	chronic	0.0065 (as)	5 m 20 m	2.61 0.719	**2.5** **9.0**	10
D2	Stream				5 m 20 m	3.13 0.863	**2.1** **7.5**	10
D3	Ditch				5 m 20 m	2.59 0.713	**2.5** **9.1**	10
D4	Pond				5 m 20 m	0.284 0.136	**22.94** 7.8	10
D4	Stream				5 m 20 m	3 0.828	**2.2** **7.9**	10
D5	Pond				5 m 20 m	0.284 0.136	22.9 47.8	10
D5	Stream				5 m 20 m	3.24 0.893	**2.0** **7.3**	10
R1	Pond				5 m 20 m	0.284 0.136	22.9 47.8	10
R1	Stream				5 m 20 m	2.3 0.633	**2.8** 10.3	10
R3	Stream				5 m 20 m	3.21 0.885	**2.0** **7.3**	10
D2	Ditch	Higher plants	chronic	0.0158 (as)	5 m 20 m	2.61 0.71	**6.1** 22.0	10
D2	Stream				5 m 20 m	3.13 0.863	**5.0** 18.3	10
D3	Ditch				5 m 20 m	2.59 0.71	**6.1** 22.2	10
D4	Pond				5 m 20 m	0.284 0.136	55.6 116.2	10

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

Appendix 1 – list of endpoints

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point[7] (mg/L)	Buffer zone distance[6]	PEC_{SW}[4] Max(µg as/L)	TER	Annex VI trigger[5]
D4	Stream				5 m 20 m	3 0.828	**5.3** 19.1	10
D5	Pond				5 m 20 m	0.284 0.136	55.6 116.2	10
D5	Stream				5 m 20 m	3.24 0.893	**4.9** 17.7	10
R1	Pond				5 m 20 m	0.284 0.136	55.6 116.2	10
R1	Stream				5 m 20 m	2.3 0.633	**6.9** 25.0	10
R3	Stream				5 m 20 m	3.21 0.885	**4.9** 17.9	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] spray drift input only
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[6] buffer strip to reduce spray drift inputs only
[7] Endpoint from formulation study

Total inputs (spray drift, run-off, drainage)
Oil seed rape, application rate 1.5 kg as/ha, pre-emergence

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point[7] (mg/L)	Buffer zone distance[6]	PEC_{SW}[4] Max. (µg as/L)	TER	Annex VI trigger[5]
D2	Ditch	algae (*Pseudokirchneriella subcapitata*)	chronic	0.054 (as)	5 m 10 m	73.4 73.3	**0.7** **0.7**	10
D2	Stream				5 m 10 m	48.1 48.1	**1.1** **1.1**	10

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

Appendix 1 – list of endpoints

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point[7] (mg/L)	Buffer zone distance[6]	PEC_{SW}[4] Max. (µg as/L)	TER	Annex VI trigger[5]
D3	Ditch				5 m	2.59	20.8	10
D4	Pond				5 m	0.295	183.1	10
D4	Stream				5 m	3	18.0	10
D5	Pond				5 m	0.29	186.2	10
D5	Stream				5 m	3.24	16.7	10
R1	Pond				5 m	0.283	190.8	10
R1	Stream				5 m	2.3	23.5	10
R3	Stream				5 m	4.29	12.6	10
D2	Ditch	Higher plants	chronic	0.035(as)	5 m 10 m	73.4 73.3	**0.5** **0.5**	10
D2	Stream				5 m 10 m	48.1 48.1	**0.7** **0.7**	10
D3	Ditch				5 m	2.59	13.5	10
D4	Pond				5 m	0.295	118.6	10
D4	Stream				5 m	3	11.7	10
D5	Pond				5 m	0.29	120.7	10
D5	Stream				5 m	3.24	10.8	10
R1	Pond				5 m	0.283	123.7	10
R1	Stream				5 m	2.3	15.2	10
R3	Stream				5 m 10 m	4.29 1.701	**8.2** 20.6	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] Total inputs (spray drift, run-off, drainage)
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[6] buffer strip to reduce spray drift inputs only
[7] endpoint of dimethachlor (technical) PEC

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

Appendix 1 – list of endpoints

Bioconcentration

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{ow}$	2.17	-	-	-
Bioconcentration factor (BCF)[1] ‡	Not relevant	-	-	-
Annex VI Trigger for the bioconcentration factor		-	-	-
Clearance time (days) (CT_{50})	not relevant	-	-	-
(CT_{90})		-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	not relevant	-	-	-

[1] only required if log P_{ow} > 3.

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

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)
as ‡	> 300	> 200
Preparation (µg product/bee)	> 220	> 210
Field or semi-field tests		
Tests are not required as the test substance is of low toxicity for honey bees.		

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

grasses/ dicot weeds

Test substance	Route	Hazard quotient	Annex VI Trigger
as (1500 g /ha)	contact	< 7.5	50
as (1500 g /ha)	oral	< 5.0	50
Preparation (3160 g /ha)	contact	< 15.1	50
Preparation (3160 g /ha)	oral	< 14.4	50

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

Appendix 1 – list of endpoints

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	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	CGA 17020 EC 500 (A-5089F)	Mortality	655 g as/ha
Aphidius rhopalosiphi ‡	CGA 17020 EC 500 (A-5089F)	Mortality	91 g as/ha

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

Crop and application rate: rape and 1500 g as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
CGA 17020 EC 500 (A-5089F)	*Typhlodromus pyri*	655	2.3	0.13	2
CGA 17020 EC 500 (A-5089F)	*Aphidius rhopalosiphi*	91	16.5	0.91	2

[1] 1 m distance assumed, drift rate 2.77 %

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
Chrysoperla carnea	larvae	CGA 17020 EC 500 (A-5089F), glass plate, about 7 wks	1506 g as/ha; initial	Mortality Fecundity	2.5 0	50 %
Pardosa spp	adult	CGA 17020 EC 500 (A-5089F); sand; 14 d	1506 g as/ha; initial	Mortality	6.7	50 %
Typhlodromus pyri	proto-nymphs	CGA 17020 EC 500 (A-5089F); Leaf discs from dwarf French bean plants (Phaseolus vulgaris); 7 + 7 days	1515 g as/ha; initial	Mortality Fecundity	29 5	50 %

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

Appendix 1 – list of endpoints

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
Aphidius rhopalosiphi	adults	CGA 17020 EC 500 (A-5089F); Barley plants; 48 h + 12 - 13 d	3181 g as/ha; initial	Mortality Fecundity	0 12.6	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
Field or semi-field tests are 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[1]
Earthworms			
Eisenia foetida	Dimethachlor ‡	Acute 14 days	LC_{50corr} 70 mg as/kg dw soil
Eisenia foetida	as ‡	Chronic 8 weeks	Not relevant
Eisenia foetida	Preparation (A-5089 F)	Acute 14 days	LC_{50corr} 96 mg as/kg dw soil
Eisenia foetid	Preparation	Chronic	Not relevant
Eisenia foetida	Metabolite CGA 50266	Acute 14 days	LC_{50} > 1000 mg as/kg dw soil
Eisenia foetida	Metabolite CGA 354742	Acute 14 days	LC_{50} > 1000 mg as/kg dw soil
Eisenia foetid	Metabolites	Chronic	Not relevant
Other soil macro-organisms			
Soil mite	as ‡		Not relevant
	Preparation		Not relevant
	Metabolites		Not relevant
Collembola			
	as ‡	Chronic	Not relevant
	Preparation		Not relevant
	Metabolites		Not relevant
Soil micro-organisms			

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

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	End point[1]
Nitrogen mineralisation	Dimethachlor ‡	28 days	2.6 % effect on N_{tot} at day 28 at 10 mg/kg dw soil (7.5 kg/ha)
	Metabolite CGA 50266 + CGA 354742	28 days	1.9 % effect on nitrate at day 28 at 3.8 mg CGA 50266/kg dw soil (2.84 kg/ha) and 2.0 mg CGA 354742/kg dw soil (1.52 kg/ha)
	Preparation (A-5089 F)	29 days	5.1 % effect on nitrate at day 29 at 10 mg as/kg dw soil (7.5 kg as/ha)
Carbon mineralisation	Dimethachlor ‡	28 days	9.8 % effect at day 28 at 10 mg/kg dw soil (7.5 kg/ha)
	Metabolite CGA 50266 + CGA 354742	28 days	2.0 % effect at day 28 at 3.8 mg CGA 50266/kg dw soil (2.84 kg/ha) and 2.0 mg CGA 354742/kg dw soil (1.52 kg/ha)
	Preparation (A-5089 F)	29 days	9.8 % effect at day 29 at 10 mg as/kg dw soil (7.5 kg as/ha)
Field studies[2]			
not relevant			

[1] indicate where endpoint has been corrected due to log P_{ow} > 2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Oil seed rape, application rate 1.5 kg as/ha pre-emergence

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia foetida	Dimethachlor ‡	Acute	2.0 (PEC_i)	35	10
	as ‡	Chronic		Not relevant	5
Eisenia foetida	Preparation (A-5089 F)	Acute	2.0 (PEC_i)	48	10
	Preparation	Chronic		Not relevant	5
Eisenia foetida	Metabolite CGA 50266	Acute	0.6956 (PEC_i)	> 1440	10
	Metabolite CGA 354742	Acute	0.3982 (PEC_i)	> 2510	10
	Metabolite	Chronic		Not relevant	5
Other soil macro-organisms					
Soil mite	As ‡			Not relevant	

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

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
	Preparation			Not relevant	
	Metabolite 1			Not relevant	
Collembola	as ‡			Not relevant	
	Preparation			Not relevant	
	Metabolite 1			Not relevant	

[1] indicate which PEC soil was used (e.g. plateau PEC)

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

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Echinochloa crus-galli	Metabolite CGA 50266	> 2000 (as)	> 2000 (as)	PER 14.5 (as) 5 m buffer	> 138	5
Echinochloa crus-galli	Metabolite CGA 354742	> 2000 (as)	> 2000 (as)	PER 8.3 (as) 1 m buffer	> 242	5
Echinochloa crus-galli	Preparation (A-5089 F)	> 1500 (as)	42.0 (as)	PER 8.6 (as) 5 m buffer	4.9	5
Echinochloa crus-galli	Preparation (A-5089 F)	> 1500 (as)	42.0 (as)	PER 4.4 (as) 10 m buffer	9.7	5

[1] explanation of how exposure has been should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of as or preparation

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

Appendix 1 – list of endpoints

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

Tests with metabolites: In glasshouse tests, exposure to the metabolites CGA 50266 or CGA 354742 at concentrations exceeding the maximum PEC (up to 2000 g/ha) did not have any visible effects on seedling emergence or vegetative vigour. In a separate test with CGA 50266, CGA 354742, CGA 369873, CGA 373464, SYN 528702 and SYN 530561, pre- and post emergence applications were made to 6 plant species at rates between 31 and 1000 g/ha. Plant species (*Digitaria sanguinalis, Setaria faberi, Sinapis arvensis, Galium aparine, Stellaria media, Kochia scoparia)* were selected to include those known to be sensitive to the parent molecule. In the seedling emergence test, 3 metabolites, CGA 50266, CGA 369873 and SYN 528708 had no visible effect on emergence in any species. For the remaining 3 metabolites, CGA 354742, CGA 373464 and SYN 530561, treatment at rates of 250 g/ha or more caused minor effects of up to 30 % in one or two species. In the vegetative vigour test, 5 metabolites, CGA 50266, CGA 369873, CGA 373464, SYN 528702 and SYN 530561 had no visible effect in any species. For the remaining metabolite, CGA 373464, treatment at rates of 500 g/ha or more caused minor effects of up of 30 % in one species.

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

Test type/organism	End point
Activated sludge	EC_{50} > 100 mg as/L, NOEC 100 mg/L
Pseudomonas sp	Not relevant

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

Compartment	
soil	Parent (Dimetachlor)
water	Parent (Dimetachlor)
sediment	Parent (Dimetachlor)
air	Parent (Dimethachlor)
groundwater	Parent (Dimethachlor)

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

Appendix 1 – list of endpoints

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 dangerous to the environment toxic to aquatic organisms, may cause long-term effects

	ECB decision (24th ATP, 27 February 2005)
Active substance	N, R50/R53 dangerous to the environment toxic to aquatic organisms, may cause long-term effects

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

Appendix 2 – abbreviations used in the list of endpoints

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

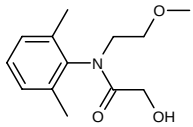
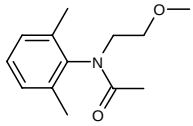
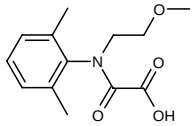
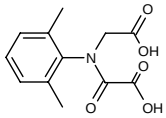
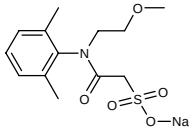
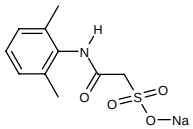
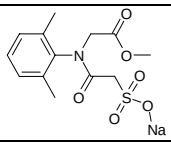
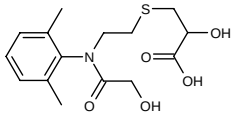
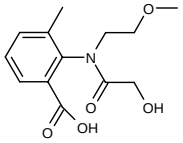
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter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

Appendix 2 – abbreviations used in the list of endpoints

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

Appendix 3 – used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
CGA 39981	N-(2,6-dimethylphenyl)-2-hydroxy-N-(2-methoxyethyl)acetamide	
CGA 42443	N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)acetamide	
CGA 50266	N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)oxalamic acid	
CGA 102935	N-carboxymethyl-N-(2,6-dimethyl-phenyl)oxalamic acid	
CGA 354742	[(2,6-dimethylphenyl)-(2-methoxy-ethyl)carbamoyl]methanesulfonic acid sodium salt	
CGA 369873	(2,6-dimethylphenylcarbamoyl)-methanesulfonic acid sodium salt	
CGA 373464	[(2,6-dimethylphenyl)-(2-sulfo-acetyl)amino]acetic acid sodium salt	
SYN 528702	3-{2-[(2,6-dimethyl-phenyl)-(2-hy-droxyacetyl)amino]ethylsulfanyl}-2-hydroxypropionic acid	
SYN 530561	2-[(2-hydroxyacetyl)-(2-methoxy-ethyl)amino]-3-methylbenzoic acid	
CGA 72649	2,6-dimethylaniline