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

triclopyr

finalised: 14 December 2005

SUMMARY

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

Ireland being the designated rapporteur Member State submitted the DAR on triclopyr in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 21 November 2003. Following a quality check on the DAR, the peer review was initiated on 14 January 2004 by dispatching the DAR for consultation of the Member States and the sole notifier Dow AgroSciences. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in July 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in January – March 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 29 September 2005 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the applicant which comprises broadcast spraying or spot treatment to control a wide spectrum of broad-leaved weeds in pasture, forestry, grassland, railways and set-a-side at application rate up 1.44 kg triclopyr per hectare. Triclopyr can be used only as herbicide.

The representative formulated product for the evaluation was "Garlon 4" ("XRM-4714"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

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

Due to the fact that the butoxyethyl ester (BEE, also refer to butotyl ester), a variant of triclopyr, is used in the formulated product, it should be noted that the evaluated data belong to the variant triclopyr-butoxyethyl ester, unless otherwise specified.

Adequate methods are available to monitor all compounds given in the respective residue definitions for soil and ground water. For food of animal origin not method is available, for air a method for the determination of residues of the butoxyethyl ester is missing. Whether or not sufficient methods are available for surface water depends on the final residue definition.
The methodology used is GC with MS or EC detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.
No analytical method for the determination of triclopyr alone is available, other analytes will always be determined in parallel.

Triclopyr and the ester have shown to be pharmacologically equivalent. Triclopyr is rapidly and extensively absorbed; it is mainly excreted as unchanged in urine (>80%). Only 1-2% of the administered dose is metabolised, to produce 3,5,6-trichloro-2-pyridinol in urine. Four minor metabolites were found in rats: 3,5,6-trichloro-2-pyridinol, glucuronide and sulphate conjugates of pyridinol and triclopyr conjugates. Both triclopyr and BEE are characterised by a moderate acute oral toxicity, they are not acutely toxic via dermal route, the acute inhalation toxicity of BEE is low, while data on triclopyr are not available. Both triclopyr and BEE are not skin irritant; the acid shows irritating potential to the eyes. Both of them are skin sensitiser at the modified Buehler test. Therefore, the following classification is proposed: Xn, R22 (harmful if swallowed), Xi, R36 irritating to eyes, Xi, R43 may cause skin sensitisation by skin contact.
The overall relevant NOAEL from short term toxicity studies is 5 mg/kg bw/day. Neither triclopyr nor its ester have shown genotoxic potential in a battery of *in vitro* and *in vivo* test. The relevant NOAEL for long term studies is 3 mg/kg bw/day. Triclopyr did not show any carcinogenic potential.
The lowest parental NOAEL was 5 mg/kg bw/day, while the reproductive NOAEL was 25 mg/kg bw/day, based on a reduction in mating indices and an increase in time to mating at 250 mg/kg bw/day in rats. The relevant developmental NOAELs were:
rats: ester = 100 mg/kg bw/day (LOAEL 300 mg/kg bw/day); acid = 100 mg/kg bw/day (LOAEL 200 mg/kg bw/day); rabbits: NOAEL ester = 30 mg/kg bw/day (LOAEL = 100 mg/kg bw/day), developmental NOAEL acid = 75 mg/kg bw/day (highest dose tested).
In the rats, retarded ossification of skull bones was observed at 200 mg/kg bw/day and an increased incidence of malformations and skeletal anomalies at 300 mg/kg bw/day. Therefore, Cat 3 R63 was agreed by the experts. The developmental toxic effects in pups in the multigeneration studies are already covered by this classification. Triclopyr did not give any indication of neurotoxic potential. TCP oral LD_{50} is 794 mg/kg bw in rats, 380 in mice, >1000 mg/kg bw in dogs; short term relevant NOAEL is 12 mg/kg bw/day. TCP did not show any genotoxic potential. In the rabbit the maternal NOAEL is 100 mg/kg bw/day and the developmental NOAEL is 25 mg/kg bw/day based on dose-dependent increases in the incidence of foetal and litter CNS malformations at 100 and 250 mg/kg bw/day if compared to controls and historical control incidences. In the rat study the maternal

NOAEL was 50 mg/kg bw/day, while the developmental NOAEL is 150 mg/kg bw/day representing the highest dose tested.
The ADI of triclopyr is 0.03 mg/kg bw/day based on the 2-year oral study in rats with a SF 100.
The AOEL is 0.05 mg/kg bw/day based on the 13-week oral study in rats with a SF 100
An ARfD of 0.3 mg/kg bw/day was set by the experts based on the developmental toxicity study in rabbit, with a NOAEL of 30 mg/kg bw/day and applying a SF 100.
Estimated exposure is above the AOEL both with the German and UK POEM models if no PPE is worn. The AOEL is not exceeded with the German model once appropriate PPE is worn (gloves during mixing/loading, gloves, coveralls and sturdy footwear during application), either for use with boom sprayer or the knapsack application.
AOEL is not exceeded both for re-entry workers (< 3.6%) and bystander (14.8%).

The metabolism of triclopyr and its butoxyethyl ester in plants is adequately elucidated. Triclopyr is the major compound of the residue in vegetal tissues. This is confirmed by supervised residue trials in pasture indicating that the highest potential levels of triclopyr are in the range of 40 mg/kg, while its only identified metabolite, 3,5,6-trichloro-2-pyridinol, never exceeds 10 % of the triclopyr levels. Triclopyr, its conjugates and 3,5,6-trichloro-2-pyridinol are considered as the only significant compounds in terms of toxicological burden present in plants that can be transferred to animals.
In animal metabolism, triclopyr (major residue in milk) and 3,5,6-trichloro-2-pyridinol (major residue in bovine muscle, liver, fat and kidneys) were identified as compounds of toxicological relevance. 3,5,6-trichloro-2-pyridinol is not specific of trichlopyr and can be produced by animal metabolism from other pesticides. This situation makes the establishment of a residue definition quite complex for enforcement reasons. 3 options for residue definition were examined during the peer review process. The first was proposed by the RMS in the DAR and consisted only in triclopyr. This option was considered by the expert meeting (EPCO 19) not protective enough of the consumer because the toxicological burden of the metabolite was not covered and a proposal consisting in the sum of triclopyr, all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates was submitted. This option was also difficult to apply in practice due to the non specificity of the metabolite. A third proposal consisting in dissociating triclopyr on one hand and 3,5,6-trichloro-2-pyridinol on the other hand in 2 separate residue definitions was proposed by EFSA, to allow regulators to consider the potential contribution of other pesticides in setting MRLs for the metabolite 3,5,6-trichloro-2-pyridinol. This last option required the establishment of specific toxicological end points for this metabolite and tentative ADI and ARfD have been set based on the toxicological package submitted for 3,5,6-trichloro-2-pyridinol.
The approaches for residue definition of the expert meeting (EPCO 19) and of the EFSA were further considered for proposing MRLs and conducting the risk assessment for the consumer. These 2 approaches resulted in MRLs proposals in animal commodities which are mainly influenced by the generally higher levels of 3,5,6-trichloro-2-pyridinol in these matrices. The outcome of the risk assessment was also quite similar between the 2 approaches, demonstrating the absence of risk for the consumer.

Sufficient data were available to demonstrate that in soil triclopyr butoxyethyl ester has very low persistence rapidly degrading to triclopyr which exhibits moderate persistence and subsequently degrades further to the major metabolite 3,5,6-trichloro-2-pyridinol which is also moderately persistent. Mineralization of the 2,6-^{14}C radiolabel in the ring accounted for 8-66% of the applied radioactivity (AR) in dark aerobic laboratory studies after 100 days. The formation of unextracted residues in the soil organic carbon was another significant sink (accounting for 22-46% AR at 100 days). Triclopyr butoxyethyl ester is predicted to exhibit low mobility in soil (Quantitative structure activity relationship calculations, measurement not possible due to rapid degradation). In soil triclopyr exhibits very high to high mobility and 3,5,6-trichloro-2-pyridinol high mobility.

In natural surface water systems (dark laboratory studies) mineralization of the 2,6-^{14}C radiolabel in the ring was minimal (maximum 1.6% of the applied radioactivity at 100 days), unextracted residues in the sediment organic carbon were a small sink (accounting for 8-13% AR at 100 days). The major contribution to the mass balance in these studies was the formation of metabolites. Triclopyr butoxyethyl ester exhibited very low persistence degrading (primarily in the water phase) to triclopyr (max 88-95%AR in water, 14-20%AR in sediment) which further degraded with moderate persistence to 3,5,6-trichloro-2-pyridinol which was also moderately persistent (max 5-19%AR in water, 14-23%AR in sediment). The major metabolites 3,6 -dichloro-2-pyridinol (max 8-38%AR in water, 15-26%AR in sediment) and 6 -chloro-2-pyridinol (max 13 %AR in water of only one of the two systems studied) were also identified. In aqueous photolysis experiments with natural water (no sediment present, with simulated summer sunlight conditions) the degradation of triclopyr and 3,6 -dichloro-2-pyridinol was more rapid than in the dark experiments. In these experiments in the presence of light the only major breakdown product produced was oxamic acid (accounting for up to 16%AR).

The environmental exposure assessments available are sufficient to complete appropriate EU level estimates of Predicted Environmental Concentrations (PEC) for the intended uses on Pasture and non-recreational amenity grassland. Assessments are absent for the other intended uses (forestry, railways and set aside). FOCUS groundwater modelling indicates a high potential for groundwater contamination in vulnerable situations over a wide range of geoclimatic conditions across the EU for triclopyr (with 8 out of 9 FOCUS groundwater scenarios indicating annual average concentrations leaving the top 1m soil layer >0.1µg/l.). Modelling also indicates that the major soil metabolite 3,5,6-trichloro-2-pyridinol may also contaminate groundwater but the range of vulnerable geoclimatic conditions where this might happen is less wide spread (2 out of 9 FOCUS groundwater scenarios indicating annual average concentrations leaving the top 1m soil layer >0.1µg/L.). A lysimeter study indicates that when applications are made in the summer to acidic soils under vulnerable north western European conditions groundwater contamination >0.1µg/L (measure annual average leachate concentrations) for triclopyr and 3,5,6-trichloro-2-pyridinol is unlikely. Further data would need to be assessed on the adsorption of triclopyr over a wide soil pH range to confirm whether adsorption of triclopyr is pH dependant or not, before it was possible to confirm if the lysimeter study results could be read across to a larger range of soil pH conditions. Even then the lysimeter study covers summer

application conditions only. Whilst the available data indicate the intended use on grass may be carried out without contaminating vulnerable groundwater, the data also indicate there are a wide range of conditions across Europe under which any authorised use would have to be very strictly managed to safeguard groundwater from contamination with triclopyr above the parametric legal limit (0.1µg/L).

Only a risk assessment for the representative use in pasture is presented in the section on ecotoxicology in the DAR and the addenda. EFSA considers that this risk assessment also covers the ecotoxicological risk assessment necessary for the representative use in non-recreational amenity grassland. No risk assessment is available for the representative uses in forestry, railways and set-a-side.

The risk to bees, soil micro-organisms and biological methods for sewage treatment is considered to be low.

The acute risk to herbivorous and insectivorous birds from exposure to triclopyr is considered to be low. Also the acute risk to herbivorous birds from exposure to triclopyr BEE is low. A high acute risk to insectivorous birds from exposure to triclopyr BEE was identified in the first tier risk assessment and the EPCO experts' meeting did not agree with the presented refined acute risk assessment. Therefore a data requirement was set for the notifier to submit a refined acute risk assessment for insectivorous birds. The short term risk to insectivorous and herbivorous birds from exposure to triclopyr and triclopyr BEE can be considered as low. The long term risk to insectivorous and herbivorous birds is high. Therefore EFSA proposes a data requirement for the notifier to address this risk. The long term risk to birds was only identified by the RMS after revision of the risk assessment as requested by the EPCO experts' meeting and therefore this data requirement was not discussed in an EPCO Expert meeting. A low acute and short term risk to herbivorous and insectivorous birds and a low acute risk to herbivorous mammals from exposure to the metabolite 3,5,6-trichloro-2-pyridinol was identified.

A high acute risk to mammals from exposure to triclopyr BEE and triclopyr was identified. The EPCO experts' meeting decided to set a data requirement for the notifier to submit data to support the assumptions, besides the residue data, used in the presented refined acute risk assessment for herbivorous mammals. It is noted by the EFSA that a second oral acute toxicity study with rats and the formulation Garlon 4 is available which leads to a lower endpoint than the endpoint which was taken into account in the DAR. If the endpoint of this study with the formulation Garlon 4 is expressed in triclopyr BEE equivalents the toxicity is higher than the toxicity from triclopyr BEE alone. Therefore EFSA proposes to take the LD_{50} of 900 mg Garlon 4/kg bw into account when refining the acute risk to herbivorous mammals (see data requirement above). Also a high long term risk to herbivorous mammals is identified. The RMS did not present a refined risk assessment in the addendum of June 2005 as requested by the EPCO experts' meeting but proposes a data requirement for the notifier to address this long term risk to mammals.

A high risk to birds and mammals from consumption of contaminated drinking water was observed in the first tier risk assessment by EFSA (see addendum). Therefore EFSA proposes a data requirement

for the notifier to refine the risk to birds and mammals from exposure to contaminated drinking water. This assessment was neither discussed at the EPCO experts' meeting nor peer reviewed.

A high acute risk to aquatic invertebrates was identified as the TER values (15-434) are below the Annex VI trigger value of 100 for 9 out of 11 FOCUS Step 3 scenario's. EFSA does not find it appropriate to refine a risk, which is based on a flow-through study with *C. virginica,* with a static study which was performed with *D. magna*. Therefore EFSA proposes that risk mitigation measures are taken into account at MS level to address the acute risk to aquatic invertebrates or a static study with *C. virginica* should be requested at MS-level.

A low long term risk to aquatic organisms from exposure to triclopyr but a high long term risk to fish from exposure to triclopyr BEE was observed. The EPCO experts' meeting considered a long term risk assessment for triclopyr BEE necessary because of contamination of surface water by drainage. This was discussed internally in EFSA after the EPCO Expert meeting. EFSA considers that with the intended use of only 2 applications a year with a minimum 6 month interval and the fact that soil and water half lives of the ester are < 1 day, long term exposure to aquatic organisms from drainage to the ester will not occur at least for the notified representative uses. Therefore EFSA proposes that risk mitigation measures should be envisaged at MS level to address the long term risk to fish from exposure to triclopyr BEE if the local conditions are very sensitive to drainage or if local uses have shorter intervals than assessed in the DAR. Furthermore EFSA proposes that also risk mitigation measures are taken into account at MS level to address the long term risk to *D. magna* from exposure to 3,5,6-trichloro-2-pyridinol for the D2 ditch scenario. The acute risk to aquatic organisms from the metabolite 3,5,6-trichloro-2-pyridinol can be regarded as low.

The EPCO experts' meeting set a further data requirement for the notifier to submit at least an algae study with this metabolite 3,6- dichloro-2-pyridinol or to submit the validation of the ECCOSAR model (used by the notifier to address the risk from this metabolite) or another suitable model for this substance class. Furthermore the metabolite 6-chloro-2-pyridinol was identified as a major metabolite by the section on Fate and behaviour. No studies with this metabolite are available. Therefore EFSA proposes a data requirement for the notifier to address the risk to aquatic organisms from exposure to the metabolite 6-chloro-2-pyridinol. The need for this data was not discussed at an EPCO Expert meeting. The metabolite oxamic acid is considered to be not ecotoxicologically relevant by EFSA.

The risk to *Lemna gibba* can be considered as low but the EPCO experts' meeting decided to set a data requirement for the notifier to submit the full study reports of all studies referred to in the DAR regarding dicotyledonous higher aquatic plants as it was questioned that *Lemna gibba* is an appropriate indicator plant. The risk to aquatic higher plants can only be concluded when this data becomes available.

Based on the available studies the risk to non target arthropods is considered to be addressed.

The risk to non-target plants can be considered as low if risk mitigation measures such as a bufferzone of 5 metres are taken into account.

The acute risk to earthworms is considered to be low. The long term risk to earthworms from exposure to the metabolite 3,5,6-trichloro-2-pyridinol is also regarded to be low. The EPCO experts' meeting decided to set a data requirement for the notifier to submit an argumentation if the concentration of 9.6 acid equivalent per kg dry soil, at which the NOEC for earthworms was set, was

reached during the study. The long term risk to earthworms can only be concluded once this argumentation becomes available. At the moment no final conclusion can be drawn regarding the need for a litter bag study with triclopyr due to the outstanding data requirement regarding the long term risk to earthworms. EFSA considers a collembolan reproduction study or a study on gamasid mites with triclopyr necessary given the effects seen on *Aphidius rhopalosiphi* and *Typhlodromus pyri* in the standard laboratory toxicity studies. The need for this data was not discussed at an EPCO Expert meeting.

As 3,5,6- trichloro-2-pyridinol is a major ground water metabolite, a study on the herbicidal activity of this metabolite is considered necessary by EFSA. The need for such a study was not discussed in an EPCO Expert meeting.

Key words: triclopyr, triclopyr-butoxyethyl ester, BEE, triclopyr-butotyl ester, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

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

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Ireland submitted the report of its initial evaluation of the dossier on triclopyr, hereafter referred to as the draft assessment report, to the EFSA on 21 November 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 14 January 2004 to the Member States and the main notifier Dow Agrosciences 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, representatives from Member States identified and agreed in an evaluation meeting on 13 July 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

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

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 29 September 2005 leading to the conclusions as laid down in this report.

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

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

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

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

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 29 September 2005)

Given the importance of the draft assessment report including its addendum (compiled version of August 2005 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Triclopyr is the ISO common name for 3,5,6-trichloro-2-pyridyloxyacetic acid (IUPAC). Due to the fact that the butoxyethyl ester (BEE, also refer to butoyl butotylester[3]), a variant of triclopyr, is used in the formulated product, it should be noted that the evaluated data belong to the variant triclopyr-butoxyethyl ester, unless otherwise specified.

Triclopyr and triclopyr-butoxyethyl ester, respectively, belong to the class of pyridine herbicides such as clopyralid, fluroxypyr and picloram. Triclopyr is taken up via leaves and roots and induces an epinastic response leading to chlorosis, cessation of normal growth and death.

The representative formulated product for the evaluation was "Garlon 4" ("XRM-4714"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

The evaluated representative uses as herbicide comprise broadcast spraying or spot treatment to control a wide spectrum of broad-leaved weeds in pasture, forestry, grassland, railways and set-a-side at application rate up 1.44 kg triclopyr per hectare. Triclopyr can be used only as herbicide.

[3] This is the ISO name for the 2-butoxyethyl radical. However, to minimise the confusion, the term butoxyethyl ester is used to be in line with the DAR.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of triclopyr-butoxyethyl ester as manufactured should not be less than 960 g/kg. At the moment no FAO specification exists. The technical material contains no relevant impurities.

The content of triclopyr and triclopyr-butoxyethyl ester in the representative formulations are 480 g/L (pure) and ca 667 g/L, respectively.

The main data regarding the identity of Triclopyr and triclopyr-butoxyethyl ester, respectively and its physical and chemical properties are given in appendix 1.

The assessment of the data package revealed no particular area of concern, but two data gaps were identified (analytical method for food of animal origin and air).

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of triclopyr-butoxyethyl ester in the technical material and in the representative formulation.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Methods are available to monitor all compounds given in the respective residue definition, i.e. triclopyr and its salts and 3,5,6-trichloro-2-pyridinol in soil and ground water; triclopyr and triclopyr-butoxyethyl ester in air. For surface water the residue definition is not finalised. Due to some out standing data it is unclear whether or not 3,6-dichloro-2-pyridinol and/or 6-chloro-2-pyridinol must be considered for monitoring purposes. However, at the moment no analytical method would be available for these compounds.
At the moment no sufficient enforcement method is available to monitor food of animal origin independent on the final residue definition. At the moment three possible residue definitions are proposed (see 3.2 and 6). None of the submitted methods fulfils the requirements of Annex IIA. The fact that no acceptable method was part of the dossier was already confirmed at the evaluation meeting (June 2004)
The methodology used is GC with MS or EC detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.
No analytical method for the determination of triclopyr alone is available, other analytes will always be determined in parallel. An analytical method for food of plant origin is not required due to the fact that no residue definition is proposed (see 3.1.1).

The discussion in the expert meeting (EPCO 20, March 2005) on identity, physical and chemical properties and analytical methods was limited some physical and chemical properties (outstanding clarification and studies) and the residue analytical methods.

2. MAMMALIAN TOXICOLOGY

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

2.1 ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Triclopyr is rapidly and extensively absorbed in all the treated species, especially in rats. Absorption levels range from 75 to 94% within 72 hours. Triclopyr and the ester have shown to be pharmacologically equivalent.

After entering the body, triclopyr is distributed mainly to the kidneys, with a minor amount found in the liver and fat for rat and dog, and plasma for monkey.

The majority of urinary excretion occurs within 24 hours from administration. Triclopyr is mainly excreted as unchanged in urine (>80%) in all species, with a small amount in faeces (1-3%), increasing as the administered dose increased. No accumulation is expected, except following chronic administration at very high doses.

Only a small proportion (1-2%) of the administered dose is metabolised, to produce 3,5,6-trichloro-2-pyridinol in urine.

Four minor metabolites were found in rats: 3,5,6-trichloro-2-pyridinol, glucuronide and sulphate conjugates of pyridinol and triclopyr conjugates.

2.2 ACUTE TOXICITY

Triclopyr and its butoxyethyl ester (BEE) have been tested in a number of acute toxicity studies.

Both triclopyr and BEE are characterised by a moderate acute oral toxicity (oral LD_{50} 630 mg/kg bw and 803 mg /kg bw for triclopyr and BEE, respectively); they are not acutely toxic via dermal route (LD_{50}>2000 mg/kg bw); the acute inhalation toxicity of BEE is low (LC_{50}> 4.8 mg/L), while data on triclopyr are not available. Both triclopyr and BEE does not have skin irritating properties; the acid shows irritating potential to the eyes. Both of them are skin sensitisers at the modified Buehler test. Therefore, **the following classification is proposed: Xn, R22 (harmful if swallowed); Xi, R36 irritating to eyes; Xi, R43 may cause skin sensitisation by skin contact.**

2.3 SHORT TERM TOXICITY

Toxicity of triclopyr and BEE has been tested after repeated exposures in rats and dogs.

Results seem to indicate that the toxicological patterns of triclopyr and the ester are similar, which was confirmed by the experts during the meeting.

Main effects consist in decreased body weight gain, increased relative kidney weight and renal histopathological changes (degeneration of the proximal tubules). Limited evidence exists on the

occurrence on liver effects in the rats (increased relative weight, histological changes), only in few studies and at high doses.

Dogs have shown a species-specific alteration consisting in a reduced capacity to excrete certain organic acids if compared to other species. Therefore, it cannot be considered a toxic effect.

The overall relevant NOAEL from short term toxicity studies is 5 mg/kg bw/day from the 13-week oral study in rats, based on the diffuse degeneration of the proximal tubule cells in the renal medulla at 20 mg/kg bw/day.

2.4 GENOTOXICITY

Neither triclopyr nor its ester have shown genotoxic potential in a battery of *in vitro* (Ames test, mammalian mutagenicity, two UDS assays in rat hepatocytes) and *in vivo* tests (one mouse micronucleus test and one dominant lethal assay). All the studies gave negative results.

2.5 LONG TERM TOXICITY

Long term effects and carcinogenicity potential of triclopyr have been studied in two 2-year oral studies in rats and in two long term studies in mice.

Main target organ in both species was kidney (increased weight and, occasionally, histopathological changes). Other effects consisted in alterations in haematological parameters at some study points, altered cells in the liver and decreased body weight gain. Rats showed an increased incidence of some tumours (epithelial papillomas, subcutaneous fibromas and adrenal pheocromocytomas) even at the lowest tested dose. However, due to the lack of supporting histopathological evidence and the absence of a dose-response relationship, these tumours were considered not treatment related and of no relevance. The significant increase of the incidence of mammary adenocarcinomas in female rats was not considered sufficient to classify triclopyr as a carcinogen, since they were considered related to the normal spontaneous biological variation, also because, when considered separately, their incidences were within the historical control data.

Mice showed a slight increase in the incidence of mammary tumours in treated animals vs controls; in particular, the incidence of mammary adenocarcinomas slightly exceeded the historical control data, but the weight of evidence indicated the absence of a treatment relation. The significant increase in pulmonary tumours incidence in the study was considered only apparent due to an unusually low incidence in the controls, compared with historical control data.

The relevant NOAEL for long term studies is 3 mg/kg bw/day, from the two-year oral study in rats, based on the occurrence of kidney effects at 12 mg/kg bw/day.

Triclopyr did not show any carcinogenic potential.

2.6 REPRODUCTIVE TOXICITY

Multigeneration studies

In the multigeneration studies in rats, direct adverse effects on reproductive parameters did not occur. The parental NOAEL was 5 mg/kg bw/day, while the reproductive NOAEL was 25 mg/kg bw/day, based on a reduction in mating indices and an increase in time to mating at 250 mg/kg bw/day.

Developmental and teratology studies

In the DAR, the RMS concluded that for triclopyr, the NOAEL for maternal toxicity in rats was 5 mg/kg bw/day as well as the developmental NOAEL, based on visceral and skeletal malformations and anomalies in the litter. Some of the developmental effects were associated with minimal maternal toxicity, therefore the possibility of a treatment related adverse effect on the developing foetus could not be excluded.

In rabbits, the incidence of absent gallbladder was recorded at 75 mg/kg bw/day with a maternal NOAEL of 25 mg/kg bw/day. The developmental NOAEL was 30 mg/kg bw/day based on treatment related skeletal abnormalities at 100 mg/kg bw/day.

No classification was proposed by the RMS.

However, the effects and NOAEL values were discussed at the experts' meeting. In rats the NOAEL of 5 mg/kg bw/day is established by the RMS based on an incidence of thin diaphragm and liver protrusion, which is, however, not reproducible and represents only 1% above controls, and is a minor finding

In rabbits the NOAEL of 25 mg/kg bw/day is based on a single high dose foetus with a missing gallbladder at 75 mg/kg bw/day. No other embryofoetal parameter is affected. The experts agreed on the following values

Rats: NOAEL ester = 100 mg/kg bw/day (LOAEL 300 mg/kg bw/day)
NOAEL acid = 100 mg/kg bw/day (LOAEL 200 mg/kg bw/day)

Rabbits: NOAEL ester = 30 mg/kg bw/day (LOAEL = 100 mg/kg bw/day)
NOAEL acid = 75 mg/kg bw/day (highest dose tested).

Furthermore, the need for classification of triclopyr with R66, R63, R61 and the product with R61 and R63 was discussed during the meeting.

No teratogenic effects were seen in the rabbits. The increased incidence of foetal deaths and skeletal anomalies at 100 mg/kg bw/day was associated with marked maternal toxicity. Therefore, classification was not justified (based on rabbit studies).

However, in the rat, retarded ossification of skull bones was observed at 200 mg/kg bw/day and an increased incidence of malformations and skeletal anomalies at 300 mg/kg bw/day. Therefore, a proposed classification of **Cat. 3, R63** was agreed by the experts. The developmental toxic effects in pups in the multigeneration studies are already covered by this classification.

The classification with R66 was considered as not necessary, since no relevant effects were observed in any of the studies evaluated and there is no indication of skin dryness or cracking from the MSDS. Since this concerns the formulation, it should be dealt with at a MS level.

2.7 NEUROTOXICITY

Triclopyr did not give any indication of neurotoxic potential

2.8 FURTHER STUDIES

The capacity of triclopyr of interfering with some renal functions was investigated, showing that the impairment of the PSP clearance test in dogs was a species-specific phenomenon related to Beagle dogs' reduced excretion of certain organic acid.

Metabolites

Some toxicity studies have been conducted with TCP (3,5,6-trichloro-2-pyridinol):
Oral LD_{50} 794 mg/kg bw in rats, 380 mg/kg bw in mice, >1000 mg/kg bw in dogs.
The short term relevant NOAEL is 12 mg/kg bw/day from the 1-year dog study.
TCP did not show any genotoxic potential. Oral teratology studies were performed in rats and rabbits. In the rabbit study the maternal NOAEL is 100 mg/kg bw/day based on reduced maternal bw gain at 250 mg/kg bw/day and the developmental NOAEL is 25 mg/kg bw/day based on dose-dependent increases in the incidence of foetal and litter CNS malformations at 100 and 250 mg/kg bw/day if compared to controls and historical control incidences.
In the rat study the maternal NOAEL was 50 mg/kg bw/day based on the reduction of body weight gain at 100 mg/kg bw/day and above, while the developmental NOAEL is 150 mg/kg bw/day representing the highest dose tested.
TCP is a relevant metabolite in products of animal origin. The data package for TCP is incomplete with regard to long term studies. Based on the available data, TCP does not show a toxicity higher than the parent compound. But the data package is limited. The short-term NOAEL of 12 mg/kg can be provisionally used to set a tentative ADI of 0.12 mg/kg bw/day. To account for uncertainties due to the lack of long term toxicity, an extra safety factor should be added to set a more reliable value. Adding a SF of 3-5, the reference value is in the same range of Triclopyr ADI (0.04-0.024 mg/kg bw/day vs 0.03 mg/kg bw/day). Therefore, based on these considerations, the use of the ADI of triclopyr to perform a consumer risk assessment is justified. As for the ARfD of TCP, the tentative value of 0.25 mg/kg from the teratogenicity study in rabbit (SF 100) appears to be reliable.

Human studies

Studies in humans show peak plasma levels between 1 and 3 hours from the administration. After 48 hours triclopyr could not be detected any longer; >80% of the administered high and low doses was excreted by 72 hours from the administration.

2.9 MEDICAL DATA

There are no reports on triclopyr related adverse health effects among manufacturing or packaging plant personnel. Some reports refer to irritating symptoms to skin, eyes and upper airways. No epidemiological studies are available.

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

ADI

The experts discussed the most appropriate study to derive the ADI, and agreed on a value of 0.03 mg/kg bw/day based on the 2-year oral study in rats with a SF of 100.

Furthermore, the meeting concluded that there is no relevant difference in toxicology between triclopyr and BEE and thus the same ADI is set for BEE.

AOEL

The AOEL is 0.05 mg/kg bw/day based on the 13-week oral study in rats with a SF of 100

ARfD

Due to the uncertainty regarding malformations occurring at doses where no severe maternal toxicity was observed, the experts concluded that an ARfD was justified.

An ARfD of 0.3 mg/kg bw/day was set by the experts based on the developmental toxicity study in rabbit, with a NOAEL of 30 mg/kg bw/day and applying a SF 100.

2.11 DERMAL ABSORPTION

The issue of dermal absorption was discussed during the meeting.

In the DAR a value of 2% for the concentrate was proposed, based on a study with Garlon 4 in human volunteers and a default value of 10% for the spray. Some MS pointed out that, based on the physical-chemical properties of triclopyr (MW<500, Log Pow >-1 and <4) a default value of 100% should be used for the spray. Therefore a new *in vitro* study with human skin was submitted. Based on this, a value of 18% was agreed for the dilution and 10% for the concentrate.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Operator exposure

Triclopyr representative product is Garlon 4, an emulsifiable concentrate herbicidal formulation, containing 480 g triclopyr/L (corresponding to 62% BEE).

Garlon 4 is intended to be used in pasture, forestry, amenity grassland, railways, set-a-side with application rates ranging from 600 to 1440 g/ha

Estimates of operator exposure were made according to the German model and the UK POEM for boom sprayer and knapsack application. In the addendum, based on the outcomes of the meeting, the operator risk assessment was recalculated with the 10% dermal absorption value, as well as 2%, for the concentrate, from the *in vivo* human study and the *in vitro* study with human skin, respectively. For the spray dilution an 18% value has been applied.

Estimated exposure presented as % of AOEL (0.05 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. Dermal absorption for the concentrate 2%

Model	Method	No PPE	With PPE*
German	Boom sprayer	343	23
	Knapsack	482	62
UK POEM	Boom sprayer	1000	-
	Knapsack	678	120

*PPE (personal protective equipment): gloves, during mixing/loading, gloves, coveralls and sturdy footwear during application

Estimated exposure presented as % of AOEL (0.05 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. Dermal absorption for the concentrate 10%

Model	Method	No PPE	With PPE*:
German	Boom sprayer	501	25
	Knapsack	1157	68
UK POEM	Boom sprayer	1385	-
	Knapsack	1023	155

*PPE (personal protective equipment): gloves, during mixing/loading, gloves, coveralls and sturdy footwear during application

Estimated exposure is above the AOEL both with the German and UK POEM models if no PPE is worn. The AOEL is not exceeded with the German model wearing PPE, i.e. gloves during mixing/loading and gloves, coveralls and sturdy footwear during application, both for use with boom sprayer or knapsack application.

Worker exposure

AOEL is not exceeded (< 3.6%).

Bystander exposure

For the worst case scenario (pasture) bystander exposure represents 15% of the AOEL.

3. RESIDUES

Triclopyr was discussed at the EPCO experts' meeting for residues (EPCO 19) in February 2005.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of triclopyr in plants has been investigated in ryegrass, apples and radish.
These studies demonstrate that triclopyr penetrates rapidly into plants through foliar parts, is absorbed from the soil and is translocated throughout the plant. When applied as butoxyethylester, hydrolysis of the ester bound leads rapidly (within one week) to triclopyr.
Triclopyr is the major compound identified in vegetal tissues and is present as free acid and under a complex mixture of conjugated forms. These conjugated forms can be extracted either readily by neutral solvent or after acid hydrolysis. The free/conjugated triclopyr ratios vary according to the waiting period between application and harvest. Beside triclopyr, the only identified metabolite was 3,5,6-trichloro-2-pyridinol, present at very low level (always less than 10% of the triclopyr level). Other polar, not identified, metabolites are also present in plants but at low levels.

From the information obtained in those 3 crops, covering 3 different crop groups, and 2 modes of application (foliar and soil) no indication is present that the metabolism may be different in other vegetal species.

As none of the representative uses of triclopyr concerns a commodity for human consumption, a residue definition for plant products is not needed. Triclopyr, its conjugates and its metabolite 3,5,6-tricloro-2-pyridinol can be considered as the only significant compounds in terms of toxicological burden in plant metabolism that can be transferred to animals.

Supervised residue trials conform to the representative use on pasture have been submitted. Five of them are valid for the Northern part of EU and three for the Southern part of EU. The method of analysis used for these trials ensures that conjugates of triclopyr are included in their results although this cannot be formally established due to the lack of validation of the methods for conjugates. Results ranged from 1.59 to 25.6 mg/kg grass 7 days after application. Usual statistical tools used for MRL setting applied to that data base suggest that the highest residues to be expected in grass forage should not exceed 40 mg/kg. In some of these trials residues of 3,5,6-trichloro-2-pyridinol were also measured and were found to be very low in comparison with the level of triclopyr, confirming the results of metabolism studies. The reliability of these results is supported by storage stability studies demonstrating the long term stability at -15 to -18°C of residues of triclopyr and 3,5,6,-trichloro-2-pyridinol in field-produced grass and hay substrates, but full details of the validation of the method of analysis used in these storage stability studies were not provided.

Studies on the effects of processing on the nature and the level of residues are not required for the use on pasture.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Limited information is available indicating that residues in succeeding crops established 36 days after application of triclopyr to soil consist in very polar compounds which cannot be identified as triclopyr or its known metabolites.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of triclopyr was investigated in lactating goats and in laying hens.

In lactating goats the absorption and the excretion of the compound is rapid. No sign of accumulation in any organ or tissue is present. The extractability of the residues in the goat edible organs and tissues is high. Triclopyr and its degradation product 3,5,6-trichloro-2-pyridinol were found to be the compounds of relevance and their relative amounts vary according to the tissue. Triclopyr is the predominant compound in milk while 3,5,6-trichloro-2-pyridinol is the major metabolite in liver, kidney, muscle and fat. Conjugates of triclopyr are also present in milk and kidneys. No other metabolite is present at significant level.

In laying hens, triclopyr is the major residue, accounting for about 90% of the total residues in liver, kidneys and skin. In other tissues, the amount of residues present was low and they were not identified.

The residue definition in products of animal origin for both monitoring and risk assessment purposes had been proposed by the RMS as triclopyr only. However the expert meeting (EPCO 19) decided to amend this proposal to the sum of triclopyr and all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates, expressed as triclopyr. In proposing 3,5,6-trichloro-2-pyridinol to be included in the residue definition, the expert meeting recognized this compound as being a hazard, for which a risk assessment for the safety of the consumer needs to be carried out.

However, considering the metabolism data, triclopyr and 3,5,6-trichloro-2-pyridinol are the only 2 compounds to consider in the residue definition, no other metabolite with the intact trichloro-pyridinol moiety is expected to be present. Therefore the residue definition could be focused exclusively on these 2 compounds, without including other potential metabolites. From an analytical point on view, the respective levels of the 2 compounds can be in practice determined separately. The RMS also pointed out that the inclusion of conjugates in the residue definition for monitoring present difficulties related to the validation of the method of analysis. This concern was considered by the EFSA and it appears clearly from the metabolism studies that conjugates contribute to a very limited extend only to the total amount of triclopyr and 3,5,6-trichloro-2-pyridinol present. The interest of the inclusion of conjugates in the residue definition is thus limited, even in term of consumer safety. The residue definition proposed by the expert meeting could therefore be amended as “sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr” if for analytical reason this would be more convenient.

In addition, the RMS indicated that at the enforcement level, legal problems may arise, because 3,5,6-trichloro-2-pyridinol is a metabolite which is not specific to triclopyr. Other pesticides, such as chlorpyriphos and chlorpyriphos-methyl are also metabolized into this compound. Consumption by

animals of feedingstuffs, such as cereal grains, containing residues of chlorpyriphos-methyl may be another source of additional 3,5,6-trichloro-2-pyridinol in commodities of animal origin, potentially resulting in MRL exceedences not due to illegal uses. Further, the choice of the toxicological end points to be considered when assessing the risk resulting from the exposure to 3,5,6-trichloro-2-pyridinol may be confusing. During the peer review of chlopyrifos-methyl, the residue definition for risk assessment was adopted as the sum of chlorpyrifos-methyl, 3,5,6-trichloro-2-pyridinol and their conjugates expressed as chlorpyrifos-methyl. This means that in case of identification of 3,5,6-trichloro-2- pyridinol in animal commodities, 2 sets of toxicological end points should be used, those relating to triclopyr and those relating to chlorpyrifos methyl. This situation is rather incoherent from a scientific point of view, even if it may be understood that these two different approaches were governed by the intention of being as protective as possible of the health of the consumer.

An alternative and pragmatic approach was therefore proposed by the EFSA to the Member States during the evaluation meeting of 28 to 30th September. This proposal consists in fixing 2 residue definitions (triclopyr and 3,5,6-trichloro-2-pyridinol separately) and further in setting independent MRLs and conducting independent risk assessments according to these respective residue definitions. This is possible as the toxicological information on 3,5,6-trichloro-2-pyridinol allows to establish specific tentative values for an ADI (0.03 mg/kg bw/d) and for an ARfD (0.25 mg/kg bw/d) (refer to section 2.8).

As triclopyr does not accumulate is animals, the highest residues present in animal commodities should result from exposure to feedingstuffs contaminated to the highest possible level. The highest expected level of triclopyr and its conjugates in ruminant diet in worst case conditions is around 40 mg/kg as mentioned under point 3.1.1, taking into account that hay is not an industrial product resulting from the mixing of raw material originating from several producers. The possible contribution of 3,5,6-trichloro-2-pyridinol to the dietary exposure of animal is very low.

Feeding studies were submitted with relevant exposure levels and indicated that measurable levels around or above the LOQ may be present in all animal commodities.

3.3. CONSUMER RISK ASSESSMENT

The consumer risk assessment was carried out following 2 approaches: one on the basis of the residue definition and MRLs proposed by the expert meeting (MRLs for the sum of the parent and its metabolite, using the toxicological trigger values of the parent) and one on the basis of the separate residue definitions and MRLs proposed by EFSA (independent MRLs for the parent and its metabolite, using specific toxicological trigger values for both compounds). The calculations related to these 2 approaches for risk assessment are described in the addendum prepared by the EFSA in August 2005. Only residues resulting from the use of triclopyr according to the representative uses supported by the manufacturer were considered.

On chronic level, the potential exposure of the consumers was determined using the WHO Theoretical Maximum Daily Intake (TMDI) calculation model and the WHO European typical diet. This resulted in total intake of residues representing 1% or less of the ADI in all calculation scenarios.

On acute level, potential short term exposures were calculated using the WHO methodology and the large portion consumption data reported for children by GEMS/Food for the Codex Committee of Pesticide Residues. The National Estimated Short Term Intakes were calculated to be around 1 % of the ARfD for cattle meat and cattle milk and around 10% of the ARfD for liver. 3,5,6-trichloro-2-pyridinol is the main contributor to the exhaustion of the ARfD.

There is no indication of any risk for the health of the consumer when triclopyr is used according to the representative uses.

3.4. PROPOSED MRLS

Based on the available data, the following MRLs can be proposed, based on the proposals of the expert meeting and of the EFSA for the residue definition.

Commodity	EFSA proposal		Expert meeting proposal
	Triclopyr (mg/kg)	3,5,6-trichloro-2-pyridinol (mg/kg)	Sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr (mg/kg)
Cattle milk	0.01	0.02	0.03
Cattle meat	< 0.05	0.1	0.2
Cattle liver	< 0.05	2	2
Cattle kidney	0.2	2	2
Cattle fat	< 0.05	0.2	0.2

4. Environmental fate and behaviour

Triclopyr was discussed at the EPCO experts' meeting for fate and behaviour (EPCO 16) in February 2005.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In laboratory (dark aerobic 20°C and 40% maximum water holding capacity (MWHC)) studies carried out on 4 different soils dosed with 2,6-^{14}C-triclopyr butoxyethyl ester, mineralization to CO_2 was variable accounting for between 8 and 66% AR at 100days. Radioactivity not extracted using acidified acetonitrile/water accounted for 22-46%AR at 100 days. In soil extracts chromatography identified there was rapid conversion of triclopyr butoxyethyl ester to triclopyr (accounting for 57-

85% AR) followed by the formation of 3,5,6-trichloro-2-pyridinol (observed maxima 17-33%AR). No other resolved components in extracts were identified, none accounted for more than 3.2%AR at any sampling time. Whilst sterile hydrolysis studies (see section 4.2.1) identify that the chemical hydrolysis of the butoxyethyl ester to triclopyr does occur, the rate of conversion is significantly slower than was measured in these soil studies, indicating microbial enzyme activity as well as chemical hydrolysis is responsible for the rapid loss of the ester side chain. Under dark anaerobic conditions in the laboratory (studied in 2 soils, dosed with 2,6-^{14}C-triclopyr butoxyethyl ester) the route of degradation was the same as observed under aerobic conditions except there was no mineralization to CO_2 and the formation of unextracted residues were minimal. In Laboratory soil photolysis studies where 2,6-^{14}C-triclopyr and 2,6-^{14}-3,5,6-trichloro-2-pyridinol were used as test substances the rates of breakdown of these substances was faster than in dark controls, however no novel breakdown products were identified and no chromatographically resolved breakdown product in soil extracts accounted for > 8.5% AR.

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

In the aerobic laboratory soil degradation studies described at 4.1.1. above, triclopyr butoxyethyl ester degraded to triclopyr with DT_{90} of less than 3 days (the time of the second sample taken), at the first sampling taking within hours of dosing, (nominal time 0 samples), triclopyr already accounted for 10-23%AR. Triclopyr degraded with single first order DT_{50} of 13-52 days (calculated by linear regression).

In laboratory (dark aerobic 20°C and 40% maximum water holding capacity (MWHC)) studies carried out on 4 different soils dosed with ^{14}C-3,5,6-trichloro-2-pyridinol, single first order DT_{50} of 10-67 days were calculated (by linear regression). For two of the soils where triclopyr butoxyethyl was dosed (experiment described at 4.1.1.) it was possible to calculate linear regression single first order degradation DT_{50} for 3,5,6-trichloro-2-pyridinol. These values were 17 and 26 days.

In European bare soil field dissipation studies (Trials sites: 4 Northern European, autumn applications and 1 Southern European, spring application) dosed with triclopyr butoxyethyl ester, DT_{50} and DT_{90} were calculated using residues from all soil depths where residues were detected (only 10cm at some sites but down to 30cm at others) assuming different patterns of degradation calculated by linear regression using the methods of Timme-Frehse. DT_{50} for the conversion of triclopyr butoxyethyl ester to triclopyr could not be estimated due to the interval of sampling (0 and 7 days) at the start of the study. However conversion was rapid as at time 0 sampling, significant levels of triclopyr were determined. The DT50 and DT90 presented in the DAR are summarised below in Table B.4.1.

Table B.4.1. DT50 and DT90 values estimated from bare soil European field dissipation studies where triclopyr butoxyethyl was dosed for triclopyr and 3,5,6-trichloro-2-pyridinol using linear regression.

Trial site	Soil properties	Rate order	DT_{50} (days)	DT_{90} (days)	r^2
Triclopyr					
Nieder Ohmen DE	Loamy silt pH5.1, OC 1.2%	1.5th order	12	64	0.94
Herford DE	Loamy silt pH5.8, OC 1.2%	1st order	54	179	0.95
Norfolk UK	Loamy sand pH6.8, OC 1.2%	1st order	46	154	0.98
Loir-et-Cher North F	Silty clay loam pH7.6, OC 0.9%	1st order	35	117	0.94
St. Nicolas de la Garve South F	Silty clay loam pH6, OC 0.9%	√1st order	6.9	77	0.76
3,5,6-trichloro-2-pyridinol					
Nieder Ohmen DE	Loamy silt pH5.1, OC 1.2%	1st order	68	225	0.97
Herford DE	Loamy silt pH5.8, OC 1.2%	1st order	77	254	0.93
Norfolk UK	Loamy sand pH6.8, OC 1.2%	1st order	63	210	0.99
Loir-et-Cher North F	Silty clay loam pH7.6, OC 0.9%	1st order	58	192	0.97
St. Nicolas de la Garve South F	Silty clay loam pH6, OC 0.9%	√1.5th order	30	281	0.96

The experts' meeting concluded that it could not be excluded that the rate of soil degradation could be pH dependant for triclopyr and 3,5,6-trichloro-2-pyridinol. The EFSA agrees with this statement but also feels that there is no pattern evident when all the available data (laboratory and field) are considered that would suggest that there is pH dependant degradation. Sterile aqueous hydrolysis studies with triclopyr showed this compound was stable to chemical hydrolysis at pH5-9, so differences in the rate of chemical (as opposed to microbial degradation) would not be a reason to expect pH dependant degradation for triclopyr. Whilst in laboratory studies the 2 soils with the longest triclopyr DT50 did have the highest pH, they also had the lowest microbial activity and longer dissipation with higher soil pH is not evident from the field studies. For modelling purposes the EFSA therefore considers it appropriate to use mean / median single first order DT_{50} values for triclopyr as modelling input. Although there is no aqueous hydrolysis data to consider for 3,5,6-trichloro-2-pyridinol, again there is no clear correlation for a pattern relating to soil pH in the

reasonably large data base of 6 laboratory and 5 field values. For modelling purposes the EFSA therefore considers it appropriate to use mean / median single first order DT_{50} values for 3,5,6-trichloro-2-pyridinol as modelling input.

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

K_{doc}, and K_{foc} values for triclopyr and 3,5,6-trichloro-2-pyridinol were determined in batch adsorption studies. The K_{doc} values determined for triclopyr in 4 soils were 41-59 (dimensionless as solute concentrations were determined as µg/g). In 4 different soils K_{foc} values measured for triclopyr were 25-134mL/g, 1/n=0.48-0.81. Because triclopyr water solubility (7.7-8.2g/l) and log Kow 0.42 to -0.96) determinations showed small differences over the pH range 5-9 and it has a pKa of 3.97, some correlation of soil adsorption with pH might be anticipated. However there is no clear pattern relating pH to triclopyr adsorption in the results of the soil adsorption studies available for the 8 different soils. Member state experts discussed the potential pH dependant adsorption of triclopyr. They concluded that for a generic EU wide assessment the use of a mean Koc (i.e. an assessment that excludes the possibility of pH dependant adsorption) in leaching modelling was acceptable to inform decision making at the EU level. However to characterise the risk for specific situations, groundwater leaching assessments at member state level could require further information to assess whether pH dependant adsorption should be introduced into specific leaching assessments or not.

In 5 different soils, K_{foc} values measured for 3,5,6-trichloro-2-pyridinol were 51-149mL/g, 1/n=0.75-0.89. Member state experts discussed the potential pH dependant adsorption of 3,5,6-trichloro-2-pyridinol. They agreed using the available data, adsorption pH dependence could not be completely excluded but that indications for this were limited. It is the EFSA view that because of the lack of evidence of adsorption being affected by pH the use of a mean K_{foc} (i.e. an assessment that excludes the possibility of pH dependant adsorption) in leaching modelling is appropriate.

Reliable batch adsorption data could not be measured for triclopyr butoxyethyl ester as it degraded to triclopyr during the equilibrium time of the study. In a laboratory soil column leaching study (3 different 'Speyer' soils) dosed with 2,6-^{14}C-triclopyr butoxyethyl ester, the ester was not present in the leachate collected, all the radioactivity in leachate was identified as triclopyr.

In a lysimeter study in the UK, 2 undisturbed sandy soil (pH 6.2, 0.6%oc) monoliths of 1m depth were planted with grass , that were dosed with 2,6-^{14}C-triclopyr butoxyethyl ester at 1.89 (1.3N) and 2.2 (1.5N) kg triclopyr equivalents / ha in June when the grass was 20-30cm high. Grass on the lysimeters was cut as required but clippings were returned to the lysimeters. Recharge volumes collected were 26-30% of the precipitation+irrigation of 925-972mm / year. Annual average leachate concentrations were: undetected for triclopyr butoxyethyl ester, 0.03-0.07µg/L for triclopyr and 0.02-0.06µg/L for 3,5,6-trichloro-2-pyridinol. Other radioactivity in leachate (annual average concentrations 0.45-0.58 µg oxamic acid equivalents /L) was characterised as polar broad non descript peaks or tentatively identified as oxamic acid on the basis of comparison of retention time

with a standard. The minor soil metabolite 3,5,6-trichloro-2-methoxypyridine was not detected in leachate samples.

Oxamic acid is a 'degradation product of no concern' as defined by the Guidance document on the assessment of the relevance of metabolites in groundwater SANCO/221/2000-rev.10, 25 February 2003 and is therefore not relevant.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

2,6-^{14}C-triclopyr butoxyethyl ester was hydrolysed in dark sterile buffer solutions at 15 °C to triclopyr with single first order DT_{50} of 209 days (pH 5) 25 days (pH7) and 1.7 days (pH 9). In a natural water in the dark (viable microorganisms present) triclopyr butoxyethyl ester had a single first order DT_{50} of 0.5 days (25°C pH6.7). Triclopyr was stable to aqueous hydrolysis (dark sterile buffers).

In 2 laboratory aerobic natural sediment water systems (20°C in the dark 2-2.5cm sediment depth with 6cm depth overlying water) dosed with 2,6-^{14}C-triclopyr butoxyethyl ester were studied. Mineralisation to CO_2 was minimal, reaching a maximum of 0.3-1.6% AR by 106 days. At study end (106 days) 10-56% of the total applied radioactivity (AR) remained in the water phase with 30-50%AR present in the sediment, 8-13% AR was unextracted from the sediment by acidified acetone. The following identified breakdown products accounted for > 10%AR at any sampling time in either the water or sediment of the systems: triclopyr (max 88-95%AR in water, 14-20%AR in sediment); 3,5,6-trichloro-2-pyridinol (max 5-19%AR in water, 14-23%AR in sediment); 3,6 -dichloro-2-pyridinol (max 8-38%AR in water, 15-26%AR in sediment); 6 -chloro-2-pyridinol (max 13 %AR in water of Italian system only). Using single first order non linear regression between compartments in a multi compartment model, the DT50 outlined in Table B.4.2 were calculated based on the route of degradation triclopyr butoxyethyl ester→triclopy→3,5,6-trichloro-2-pyridinol

Table B.4.2. single first order DT_{50} and DT_{90} values estimated in 20°C aerobic dark laboratory sediment/water studies where triclopyr butoxyethyl ester was dosed.

Trial site	DT_{50} (days)	DT_{90} (days)	r^2
Italian system (water pH 7.9, loam sediment oc 4.9%)			
Water phase			
triclopyr butoxyethyl ester	0.77	2.55	0.98
triclopyr	23.9	79.4	
3,5,6-trichloro-2-pyridinol	27.7	92.1	
Whole system			
triclopyr butoxyethyl ester	0.77	2.55	0.99
triclopyr	23.9	79.4	
3,5,6-trichloro-2-pyridinol	19.8	65.8	

Trial site	DT_{50} (days)	DT_{90} (days)	r^2
French system (water pH 6.2, sand sediment oc 2.4%)			
Water phase			
triclopyr butoxyethyl ester	0.77	2.55	0.92
triclopyr	25.7	85.3	
3,5,6-trichloro-2-pyridinol	18.2	60.6	
Whole system			
triclopyr butoxyethyl ester	0.77	2.55	0.96
triclopyr	34.6	115.1	
3,5,6-trichloro-2-pyridinol	19.8	65.8	

In aqueous photolysis studies where triclopyr butoxyethyl ester was dosed a single first order half life was calculated to be 0.13 days midsummer sunlight at 40°N for the top few cm of a water body (25°C pH 8.4 in a natural river water).

In aqueous photolysis studies where triclopyr was dosed single first order half lives were calculated to be in the range of 0.32-0.92 days midsummer sunlight at 40°N for the top few cm of a water body (25°C in sterile buffer and natural river water).

In aqueous photolysis studies where 3,5,6-trichloro-2-pyridinol was dosed single first order half lives were calculated to be in the range of 0.004-0.083 days midsummer sunlight at 40°N for the top 1m of a water body (25°C in sterile buffer and a natural river water).

In the natural water photolysis studies the major >10%AR photolytic breakdown product was oxamic acid which accounted for 16.4% AR after 2.25 days of natural sunlight at 43°N in an experiment where triclopyr was dosed.

The results of an OECD guideline ready biodegrability test indicate that triclopyr butoxyethyl ester should be classified as ‘not readily biodegradeable’ according to the OECD criteria.

The surface water exposure assessment as presented in the original DAR used FOCUSsw scenarios so includes the routes of entry spray drift, runoff and drainage. This surface water assessment was updated after the experts meeting to provide concentrations for the major metabolites 3,6 -dichloro-2-pyridinol and 6 -chloro-2-pyridinol that were formed in the dark aerobic laboratory sediment water studies. These additional values including the assumptions used in calculations can be found in Appendix 1 (agreed endpoints) of this conclusion. The PECsw and PECsed values for triclopyr butoxyethyl ester, triclopyr and 3,5,6-trichloro-2-pyridinol from the original DAR (also contained in appendix 1) were agreed as appropriate by the peer review completed by member states and EFSA. Note this surface water assessment is considered to only cover the intended uses in pasture, amenity

grassland and set-a-side. The scenarios prescribed by FOCUS were not designed to cover railway or forestry situations and the grassland scenarios certainly don't cover these situations. It is the EFSA's view that further consideration of these uses at member state level is required.

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

Standard FOCUS groundwater modelling using FOCUS guidance for substance property input parameters assuming there was no correlation between soil adsorption and soil properties was presented in an addendum to the DAR dated 2 June 2005. The modelling in the original DAR was disregarded as FOCUS recommendations for normalising soil degradation rates to reference conditions and selection of adsorption values (for 3,5,6-trichloro-2-pyridinol) had not been followed correctly. The EPCO experts' meeting discussed the modelling presented in the addendum and whether or not it was necessary to consider pH dependant adsorption and degradation for triclopyr and 3,5,6-trichloro-2-pyridinol. This is already discussed in sections 4.1.2 and 4.1.3 above. The experts concluded that for a generic EU wide groundwater leaching assessment the use of mean input values for Koc and soil degradation (i.e. an assessment that excludes the possibility of these parameters being pH dependant) was acceptable to inform decision making at the EU level. The EFSA agrees with this conclusion. However to characterise the risk for specific situations, groundwater leaching assessments at member state level could require further information to assess whether pH dependant adsorption for triclopyr should be introduced into specific leaching assessments or not. It is the EFSA opinion that pH dependant adsorption of 3,5,6-trichloro-2-pyridinol and pH dependant soil degradation of both triclopyr and 3,5,6-trichloro-2-pyridinol would not need to be investigated further or incorporated into leaching assessments at the member state level.

The FOCUS groundwater modelling presented in an addendum to the DAR dated 2 June 2005 was carried out using the FOCUS groundwater scenarios with the models FOCUSPELMO 3.3.2 and FOCUSPEARL 2.2.2. at all 9 FOCUS scenarios for the intended use on pasture and amenity grassland. Note this groundwater assessment does not cover the intended uses on railways, set-a-side and in Forestry, as the hydrology in these situations will be significantly different to that simulated for use on grass. Also the mean adsorption value used as input for 3,5,6-trichloro-2-pyridinol (a mean K_{doc} of 174mL/g with a default 1/n of 0.9) still does not represent best modelling practice. It would have been more appropriate (as the data are available) to use the mean K_{foc} calculated for these soils of 91.7mL/g and the mean 1/n of 0.81. However as the main driver for the drinking water standard (0.1µg/L) exceedence is triclopyr and not 3,5,6-trichloro-2-pyridinol this will not change the assessment of the number of scenarios modelled where groundwater contamination > 0.1µg/L is predicted.

When used in accordance with the intended GAP on grassland the modelling predicts that triclopyr butoxyethyl ester will never, leach from the top 1m of vulnerable soil profiles with annual average concentrations as defined by FOCUS above 0.1µg/L. Triclopyr is predicted to leach with

concentrations calculated on this basis above 0.1µg/L at all the FOCUS scenarios except 1 (Porto) when applications are made in the summer and autumn. When applications are made over the winter and spring period 6 (all Northern European scenarios and Piacenza) FOCUS scenarios are still predicted to leach with concentrations calculated on this basis above 0.1µg/L, (in addition to Porto, Sevilla and Thiva are now predicted to be below the limit). 3,5,6-trichloro-2-pyridinol is predicted by the currently available modelling to exceed the drinking water limit at only 2 scenarios (Okehampton and Piacenza). If 3,5,6-trichloro-2-pyridinol K_{foc} of 91.7mL/g and the mean 1/n of 0.81 had been used as modelling input then the number of scenarios exceeding the limit for 3,5,6-trichloro-2-pyridinol could be more than 2.

In the available Lysimeter study (1m depth soil monolith) that represents worst case leaching conditions for north western Europe in terms of climate (recharge volumes collected were 26-30% of the precipitation+irrigation of 925-972mm / year), that was also dosed at 1.3-1.5x the notified intended use rate, annual average leachate concentrations of all chromatographically resolved components (including butoxyethyl ester, triclopyr, 3,5,6-trichloro-2-pyridinol and 3,5,6-trichloro-2-methoxypyridine) were < 0.1µg/l. Therefore there is some experimental evidence that FOCUS modelling may be overestimating leaching potential under certain northern European geoclimatic conditions when a summer application is made (June). It should also be noted that the lysimeter study used a soil monolith of acidic pH and it may be that adsorption of triclopyr might be reduced at higher soil pH. This lysimeter study therefore does not necessarily represent worst case Northern European leaching conditions, as alkaline soil conditions are not covered and experts felt there was currently (July 2005) insufficient data to conclude the adsorption of triclopyr was not pH dependant. The lysimeter study does not cover the situation where applications are made in the Autumn, Winter or Spring.

4.3. FATE AND BEHAVIOUR IN AIR

Triclopyr butoxyethyl ester has a vapour pressure of ca 1.3 x 10-2 Pa at 25 °C and a Henry's law constant of 2.9 x 10-3 Pa m^3/mol In experiments where the volatilisation loss of triclopyr butoxyethyl ester from soil and leaf surfaces following application of GARLON 4 was investigated, no significant evaporation of the active ingredient was found, either from the soil surface (0.58%) nor from plant surface (0.27%) over the 24-hour study period. In addition, the atmospheric half-life of triclopyr butoxyethyl ester (resulting from photochemical oxidative degradation) has been estimated to be 5.6 hours indicating the potential for long range transport via air of any losses to the atmosphere will be minimal.

The vapour pressure of triclopyr $2.0x10^{-4}$ Pa at 25 ºC together with its Henry's Law constant $4.4x10^{-6}$ Pa m3/mol at 20 ºC, pH 7 indicate volatilisation losses for triclopyr should be lower than those measured for triclopyr butoxyethyl ester. The estimated photochemical oxidation half-life in the atmosphere of 26.5 hours indicates the potential for long range transport via air of any losses to the atmosphere should be low.

5. Ecotoxicology

Triclopyr was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 17) in February 2005 in Braunschweig (Germany). Triclopyr will be applied as the triclopyr butoxy ethyl ester (triclopyr BEE) form but this form is rapidly hydrolysed in the environment to the triclopyr form. Triclopyr is considered to be the active substance.

Only a risk assessment for the representative use in pasture is presented in the section on ecotoxicology in the DAR and the addenda. The EFSA considers that this risk assessment also covers the ecotoxicological risk assessment necessary for the representative use in non-recreational amenity grassland. No risk assessment is available for the representative uses in forestry, railways and set-a-side.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals is calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). The risk is calculated for an herbivorous and an insectivorous bird and for an herbivorous mammal. The EPCO experts' meeting agreed that insectivorous mammals are not a standard species for pasture according to SANCO/4145/2000 and herbivorous mammals are more critical in this situation. The meeting could not agree on the relevance of insectivorous mammals for forestry and railways and felt that more guidance for this was needed. The risk assessment was revised by the RMS in the addendum of June 2005.

The acute risk to herbivorous and insectivorous birds from exposure to triclopyr is considered to be low as the TER values (18.81 and 21.8 respectively) are above the Annex VI trigger value. The EPCO experts' meeting agreed that the residue value used to refine the acute risk to herbivorous birds from exposure to triclopyr BEE is worst-case for the whole of Europe, but the RMS was asked to revise the refined acute risk assessment to herbivorous birds based on the 90th percentile residue values instead of the mean values. This was presented in the addendum of June 2005. It was noted by the EFSA that the 90th percentile residue value is expressed in triclopyr and not in triclopyr BEE. Therefore this calculation is revised in an addendum by the EFSA taking into account this correction. The resulting TER value is still above the Annex VI trigger value indicating a low acute risk to herbivorous birds from exposure to triclopyr BEE. A high acute risk to insectivorous birds from exposure to triclopyr BEE was identified in the first tier risk assessment and the EPCO experts' meeting did not agree with the refined acute risk assessment for insectivorous birds from exposure to triclopyr BEE. Therefore a data requirement was set for the notifier to submit a refined risk assessment for insectivorous birds.

The short term risk to birds is calculated for exposure to triclopyr BEE and triclopyr. The long term risk to birds is calculated for exposure to triclopyr only as triclopyr BEE degrades very rapidly in the environment. The short and long term risk to birds was discussed in the EPCO experts' meeting. The meeting asked the RMS to revise these risk assessments using the default conversion factors from the

PPR Panel's opinion on azinphos-methyl[4] to recalculate the endpoints to daily dose values. This was presented in the addendum of June 2005. The EFSA agrees with this revised risk assessment. The short term risk to insectivorous and herbivorous birds from exposure to triclopyr and triclopyr BEE can be considered as low. The long term TER values for insectivorous and herbivorous birds (TER = 0.7 and 1.2 respectively) breach the Annex VI trigger value of 5 indicating a high risk to insectivorous and herbivorous birds from exposure to triclopyr. Therefore the EFSA proposes a data requirement for the notifier to address this risk. The long term risk to birds was only identified by the RMS after revision of the risk assessment as requested by the EPCO experts' meeting and therefore this data requirement was not discussed in an EPCO experts' meeting.

Studies on the acute and short term toxicity of the metabolite 3,5,6-TCP to birds are available. The acute oral LD_{50} of this metabolite exceeds 2000 mg/kg bw for *Colinus virginianus* and the short term dietary LC_{50} value exceeds 5620 mg/kg diet. Also this risk assessment was revised by the RMS in the addendum of June 2005. The EFSA agrees with the revised short term risk assessment for herbivorous and insectivorous birds from exposure to the metabolite 3,5,6-TCP. The resulting TER values are above the Annex VI trigger value indicating a low short term risk to herbivorous and insectivorous birds from exposure to the metabolite 3,5,6-TCP. As the acute risk from this metabolite was not assessed in the DAR, this assessment is presented in the addendum by the EFSA. The resulting TER values indicate a low acute risk to herbivorous and insectivorous birds from exposure to 3,5,6-TCP.

As for birds the RMS was asked during the EPCO experts' meeting to recalculate the refined acute risk to mammals from exposure to triclopyr BEE and triclopyr based on the 90th percentile residue value. This recalculation is available in the addendum of June 2005 and the EFSA agrees with this recalculation. The resulting TER values are still below the Annex VI triggervalue indicating a high acute risk to mammals from exposure to triclopyr BEE and triclopyr. A further refinement of this risk was presented by the notifier which was discussed in the EPCO experts' meeting. The meeting decided to set a data requirement for the notifier to submit data to support the assumptions, besides the residue data, used in the refined acute risk assessment for herbivorous mammals.
It is noted by the EFSA that a second oral acute toxicity study with rats and the formulation Garlon 4 is available. This study leads to a lower endpoint than the endpoint which was taken into account in the DAR. If the endpoint of this study with the formulation Garlon 4 is expressed in triclopyr BEE equivalents the toxicity is higher than the toxicity from triclopyr BEE alone. Therefore EFSA proposes to take the LD50 of 900 mg Garlon 4/kg bw into account when refining the acute risk to herbivorous mammals (see data requirement above).

Also the long term risk to mammals was revised in the addendum of June 2005 as the EPCO experts' meeting did not agree with the long term endpoints used in the addendum of October 2004 as they

[4] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the European Commission's DG for Health and Consumer Protection related to the evaluation of azinphos-methyl. (Question N° EFSA-Q-2003-07). *The EFSA Journal* (2003) 5, 1-20.

were not considered to be the lowest relevant endpoints for a first tier risk assessment. Furthermore the EPCO experts' meeting did not agree with the proposed refinement of the long term risk in this addendum. The revised long term risk assessment for mammals in the addendum of June 2005 is based on the endpoints proposed by the EPCO experts' meeting. A high long term risk to herbivorous mammals is identified. The EPCO experts' meeting suggested to use a more appropriate endpoint and/or to use a time weighted average value based on a measured DT_{50} value to refine this risk. The RMS did not present a refined risk assessment in the addendum of June 2005 as requested but proposes a data requirement for the notifier to address this long term risk to mammals.

The acute risk to mammals from the metabolite 3,5,6-TCP is considered to be low. This was agreed by the EPCO experts' meeting.

The EPCO experts' meeting asked the RMS to revise the risk for earthworm eating mammals for triclopyr BEE. In the addendum of June 2005 the RMS writes that a risk assessment for earthworm eating mammals for triclopyr BEE is not considered appropriate due to the rapid degradation of triclopyr BEE (DT_{50} of 0.77 days in water and DT_{90} less than 7 days in soil) and hence did not revise the risk assessment. The EFSA agrees with the RMS. The logPow of triclopyr is below 3 and therefore the risk from secondary poisoning to birds and mammals is considered to be low. Also the LogPow of the metabolite 3,5,6-TCP is below 3 indicating a low risk from secondary poisoning from this metabolite to birds and mammals. The EFSA does not agree with the assessment of the risk to earthworm eating birds for 3,5,6-TCP presented in the addendum of June 2005 as no conversion of the PEC_{worm} to daily dose was done but the EFSA considers the risk from secondary poisoning from this metabolite low based on the low LogPow.

The EFSA presents in the addendum of 27 July 2005 an assessment of the risk to birds and mammals from exposure to contaminated drinking water as this was not available. A high risk to birds and mammals from consumption of contaminated drinking water was observed in the first tier risk assessment. Therefore EFSA proposes a data requirement for the notifier to refine the risk to birds and mammals from exposure to contaminated drinking water. This assessment was neither discussed at the EPCO experts' meeting nor peer reviewed.

5.2. RISK TO AQUATIC ORGANISMS

Fish, aquatic invertebrates and algae are sensitive and show a similar toxicity on an acute time scale to triclopyr BEE and the lead formulation Garlon 4. Fish are the most sensitive to triclopyr BEE on a chronic time scale and aquatic invertebrates are the most sensitive to the metabolite 3,5,6-TCP on a chronic time scale.

The EPCO experts' meeting decided that the acute risk to aquatic invertebrates should be based on the study of the effects of Garlon 4 to *Crassostrea virginica* as long as it is not proofed that toxicity is enhanced by salt. The acute risk assessment was revised accordingly in the addendum of June 2005. The resulting TER values (15-434) are below the Annex VI trigger value of 100 for 9 out of 11

FOCUS Step 3 scenario's indicating a high acute risk to aquatic invertebrates. To refine this risk the RMS refers to the risk assessment in the original DAR in which the risk was refined by using results from static toxicity tests instead of flow-through tests. The EPCO experts' meeting agreed that static studies could be used in the risk assessment as indicated by the RMS in the addendum of June 2005. However, in the original risk assessment in the DAR the static study with *Daphnia magna* was used to refine the first tier risk assessment which was based on a flow-through study with the same species *D. magna*. In the revised first tier risk assessment (see addendum of June 2005) the risk is based on a flow-through study with *C. virginica* as requested by the EPCO experts' meeting (see above). The EFSA does not find it appropriate to refine a risk, which is based on a flow-through study with *C. virginica*, with a static study which was performed with *D. magna*. The EFSA considers that if a first tier risk assessment based on a flow-through study is refined by basing the higher tier risk assessment on a static study that both studies should be performed with the same species. Therefore the EFSA proposes that risk mitigation measures are taken into account at MS level to address the acute risk to aquatic invertebrates or a static study with *C. virginica* should be requested at MS-level. The need for this data or risk mitigation measures was not discussed at an EPCO experts' meeting.

Also the TER values (21-616) for fish are below the Annex VI trigger value of 100 for 9 out of 11 FOCUS Step 3 scenario's indicating a high acute risk to fish. As 5 different fish species were tested, it was considered appropriate by the RMS and the EPCO experts' meeting to lower the Annex VI trigger value from 100 to 10 as discussed in the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 (final) dated 17 October 2002). During the discussion of another active substance in the same meeting, it was decided to ask the PPR Panel for an opinion on lowering the uncertainty factor by using additional acute species sensitivity data. This generic question was forwarded to the PPR Panel by the EFSA. The opinion of the Panel is still awaited. The EFSA proposes to take this opinion into account at MS-level once it becomes available.

The acute risk to algae can be regarded as low as the TER values for all the FOCUS Step 3 scenario's are above the Annex VI trigger value of 10.

The chronic risk assessment is available in the original DAR. The use of PECtwa values was discussed in the EPCO experts' meeting. The meeting agreed that the risk assessment should be based on initial PEC values until data on the time to onset of effects is available. TER-values based on initial PEC values are available in Table B.9.2.11.2-2 in the DAR. The resulting TER values indicate a low long term risk to aquatic organisms from exposure to triclopyr but a high long term risk to fish from exposure to triclopyr BEE. The EPCO experts' meeting considered a long term risk assessment for triclopyr BEE necessary because of contamination of surface water by drainage. The risk for long term exposure of aquatic organisms to triclopyr BEE from drainage was discussed internally in EFSA after the EPCO Expert meeting. EFSA considers that with the intended use of only 2 applications a year with a minimum 6 month interval and the fact that soil and water half lives of the ester are < 1 day, long term exposure to aquatic organisms from drainage to the ester will not occur at least for the notified representative uses. Therefore EFSA proposes that risk mitigation measures should be

envisaged at MS level to address the long term risk to fish from exposure to triclopyr BEE if the local conditions are very sensitive to drainage or if local uses have shorter intervals than assessed in the DAR.

Triclopyr and the metabolites 3,5,6-TCP and 3,6-DCP was found in concentrations above 10% of the applied amount in a water/sediment study. Therefore the risk to sediment dwelling organisms from exposure to these substances needs to be addressed. A full life cycle study is available investigating the toxicity of triclopyr BEE to *Chironomus riparius*. No studies on sediment dwelling organisms with triclopyr and the metabolites 3,5,6-TCP and 3,6-DCP are available but triclopyr and 3,5,6-TCP were formed extensively during the study with triclopyr BEE and their impact on sediment dwelling organisms are therefore taken into account during the risk assessment for triclopyr BEE. The analytically verified concentrations during the study for triclopyr and 3,5,6-TCP were far above the maximum FOCUS step 3 PEC_{SED} values. The EPCO experts' meeting considered the risk to sediment dwelling organisms addressed although the meeting did not agree with the use of PECtwa values in the risk assessment. The need for a study on sediment dwelling organisms with the metabolite 3,6-DCP is discussed below.

Furthermore acute toxicity studies on fish, aquatic invertebrates, algae and chronic studies on fish and aquatic invertebrates with the metabolite 3,5,6-TCP are available. It is noted by EFSA that for 3,5,6-TCP a lower endpoint for aquatic invertebrates (an EC_{50} of 9.3 mg/L for *Crassostrea virginica*) is available in the DAR than the value for *D. magna* of 10.4 mg/L which is mentioned in the list of endpoints and which was used to calculate the risk. Due to the limited available time EFSA did not revise this risk assessment in an addendum as the acute risk to aquatic organisms from 3,5,6-TCP is driven by the toxicity to algae and hence the outcome of the risk assessment would not change. The acute risk to aquatic organisms from the metabolite 3,5,6-TCP can be regarded as low as the TER-values respect the Annex VI trigger value. The chronic TER value for *Daphnia magna* for the D2 ditch scenario (TER = 7 based on a Focus step 3 PEC value) is below the Annex VI triggervalue indicating a high risk to aquatic invertebrates in the D2 ditch scenario. The use of PEC_{twa} values was not accepted by the EPCO experts' meeting, because no data to support the time to onset of effects is available, therefore the EFSA proposes that risk mitigation measures are taken into account at MS level to address the long term risk to *D. magna* from exposure to 3,5,6-TCP for the D2 ditch scenario. The chronic TER values for the other 10 scenarios respect the Annex VI trigger value. The risk to aquatic organisms, including sediment dwelling organisms, from the metabolite 3,6-DCP was discussed in the EPCO experts' meeting. In the addendum of October 2004 an argumentation from the notifier is presented to address this issue. This argumentation is based on the ECCOSAR model. The EPCO experts' meeting was afraid that the ECCOSAR model does not take into account the specific mode of action of this substance. As the EPCO experts' meeting did not think that a suitable model for this substance class is available at the moment, a further data requirement was set for the notifier to submit at least an algae study with this metabolite 3,6-DCP or to submit the validation of the ECCOSAR model or another suitable model for this substance class. Furthermore the metabolite 6-chloro-2-pyridinol was identified as a major metabolite (see section 4.2). No studies with this

metabolite are available. Therefore the EFSA proposes a data requirement for the notifier to address the risk to aquatic organisms from exposure to the metabolite 6-chloro-2-pyridinol. The need for this data was not discussed at an EPCO experts' meeting.
It is noted by the EFSA that also oxamic acid is considered a major metabolite in groundwater and surface water (see section 4.2). This metabolite is not considered to be ecotoxicological relevant and no studies with this metabolite on aquatic organisms are considered necessary. Oxamic acid is an organic compound of aliphatic structure with a chain length of less than 4 which contains only C, H and O atoms and has no structures or functional groups which are known to be of ecotoxicological concern. This was not discussed in an EPCO experts' meeting.

As triclopyr is an herbicide studies on aquatic plants are considered necessary. Studies on the effects of triclopyr BEE and the metabolite 3,5,6-TCP on *Lemna gibba* are available. The TER values based on the endpoints from these studies and FOCUS Step 2 PEC values respect the Annex VI triggervalue. The need for additional toxicity studies with higher aquatic plants was discussed at the EPCO experts' meeting as it was questioned that *Lemna gibba* is an appropriate indicator plant given the mode of action and known specificity of the compound. Some additional data on the effects on dicotyledonous aquatic higher plants is mentioned in the DAR but no full study reports are available. Therefore the EPCO experts' meeting decided to set a data requirement for the notifier to submit the full study reports of all studies referred to in the DAR regarding dicotyledonous higher aquatic plants. The risk to aquatic higher plants can only be concluded when this data becomes available.

As the logPow is below 3 for triclopyr and the metabolite 3,5,6-TCP, the risk for bioconcentration in fish for these substances can be considered low. This is confirmed by the available bioconcentration studies in fish with triclopyr and the metabolite 3,5,6-TCP (BCF = 0.77 and 3.21 respectively). As the LogPow exceeds 3 for triclopyr BEE a study on bioconcentration in fish was made available. The resulting BCF factor is 110. The EPCO experts' meeting agreed that the trigger is 100 as the substance is not biodegradable. Nevertheless, because of the rapid depuration, the EPCO experts' meeting concluded that the risk from bioconcentration from triclopyr BEE is addressed.

5.3. RISK TO BEES

Acute contact and oral toxicity studies with triclopyr, triclopyr BEE and the lead formulation Garlon 4 are available. All resulting HQ values do not breach the appropriate Annex VI trigger value indicating a low risk to bees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The RMS made a revised risk assessment for non-target arthropods using the new studies, which were summarised in the addendum of October 2004, available in the addendum of June 2005 as requested by the EPCO experts' meeting. In addition to this the RMS made a clarification available to EFSA which is added to the final addendum.
A high risk to the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* was observed in the laboratory studies on glass plates. An extended laboratory study with *A. colemani* was made available

in which effects on mortality were 11% at 2.656 L product/ha which is slightly below the representative use rate of 3 L product/ha. The EPCO experts' meeting agreed to use the extended laboratory study with *A. colemani* as a higher tier study for *A. rhopalosiphi*. Several extended laboratory studies with *T. pyri* were made available. In the extended laboratory studies on leaf discs the observed LR_{50} is 4.085 L product/ha which is higher than in the in-field use rate of 3 L product/ha. Also an extended lab study on whole plants with *T. pyri* is available. The observed mortality in this study was 61% at 2.5 L product/ha and 68% at 5 L product/ha. Effects on fecundity in this study were below 15%. The observed mortality at the lower dose rate is not in line with the observations in the extended laboratory studies on leaf disks. The RMS feels that it is the most appropriate to base the risk assessment for *T. pyri* on the LR_{50} of 4.085 L product/ha which is higher than in the in-field use rate of 3 L product/ha and hence considers the risk to *T. pyri* addressed. Furthermore laboratory studies were made available with *Poecilus cupreus*, *Chrysoperla carnea*, *Pardosa amentata* and *Episyrphus balteatus* in which effects were below 50% at the in-field dose rate.

Based on the available studies the risk to non target arthropods is considered to be addressed.

5.5. RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from triclopyr BEE, triclopyr, the lead formulation Garlon 4 and the metabolite 3,5,6-TCP are available. The endpoint for triclopyr BEE and the lead formulation Garlon 4 were corrected for the organic content of the test soil as the LogPow exceeds 2 for triclopyr BEE and the active substance is applied as triclopyr BEE in the formulation. The logPow of triclopyr and the metabolite 3,5,6-TCP is < 2 and therefore no correction factor is required for these compounds. The corresponding TER-values do not breach the Annex VI trigger value, indicating a low acute risk to earthworms.

Studies on the long term toxicity to earthworms from the lead formulation and the metabolite 3,5,6-TCP are available. The TER-value for 3,5,6-TCP does not breach the Annex VI trigger value, indicating a low long term risk to earthworms from exposure to 3,5,6-TCP. The use of a correction factor for the long term toxicity study with Garlon 4 was discussed in the EPCO experts' meeting. The meeting decided to set a data requirement for the notifier to submit an argumentation if the concentration of 9.6 acid equivalent per kg dry soil, at which the NOEC was set, was reached during the study as some concerns were raised that the ester could have been bound to the organic matter before it was transformed to acid. The long term risk to earthworms can only be concluded once this argumentation becomes available.

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

The DT_{90f} for triclopyr BEE is short (< 7 days) but could not be reliably estimated due to the sampling intervals utilised in the available field dissipation studies. The DT_{90f} for triclopyr is 178.89 days and for 3,5,6-TCP 281.5 days. As the DT_{90f} for triclopyr BEE is below 100 days, no studies on other soil non-target macro-organisms are considered necessary. As the risk to soil micro-organisms

and earthworms from exposure to 3,5,6-TCP is considered to be low, also no studies on other soil non-target macro-organisms are considered necessary for this metabolite.

As the risk to micro-organism from triclopyr is considered to be low, no litterbag study is trigger based on these data. At the moment no final conclusion can be drawn regarding the need for a litter bag study with triclopyr as there is still an outstanding data requirement regarding the long term risk to earthworms. EFSA considers a collembolan reproduction study or a study on gamasid mites with triclopyr necessary given the effects seen on *Aphidius rhopalosiphi* and *Typhlodromus pyri* in the standard laboratory toxicity studies. The need for this data was not discussed at an EPCO Expert meeting.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of the lead formulation Garlon 4 and the soil metabolite 3,5,6-TCP were tested on soil microbial respiration and nitrogen transformation. No deviations of more than 25 % after 100 days at concentrations above the PEC_{soil} were observed (i.e. no breaching of the Annex VI trigger value) and hence the risk to soil non-target micro-organisms from Garlon 4 and 3,5,6-TCP is considered to be low. Furthermore a study is available in which the basic microbial functions of nitrogen fixation, nitrification and degradation of cellulose, starch, protein and leaf material were examined in soil spiked with triclopyr BEE. No effects above 25% were observed after 35 days at concentrations above the PEC_{soil}. In addition the effect of triclopyr on growth of *Aerobacter aerogenes*, *Pseudomonas aeruginosa*, *Salmonella typhosa*, *Staphylococcus aureus*, *Aspergillus terreus* and *Pullularia pullulans*. No inhibition of growth was observed. Based on these two studies and the study on soil microbial respiration and nitrogen transformation with Garlon 4, the risk to soil micro-organisms from exposure to triclopyr BEE and triclopyr is considered to be low. No further studies are considered necessary.

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

A study on the effects of the lead formulation on non-target terrestrial plants is available and the risk assessment for non-target plants is presented in the addendum of October 2004. The risk to non-target plants can be considered as low if a bufferzone of 5 metres is taken into account. This was agreed by the EPCO experts' meeting.

Furthermore a study is available which shows that 3,5,6-TCP has no insecticidal activity. The EFSA noted that no study on the herbicidal activity of this metabolite is available. As 3,5,6-TCP is a major metabolite in groundwater such as study is considered necessary by the EFSA. The need for such a study was not discussed in an EPCO experts' meeting.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The 3 hour EC_{50} for inhibition of respiration of sewage sludge micro-organisms is 659.9 mg/L. Based on this study the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: Triclopyr butoxyethyl ester; triclopyr; 3,5,6-trichloro-2-pyridinol
Definitions for monitoring: Triclopyr and *3,5,6-trichloro-2-pyridinol

Water

Ground water

Definitions for exposure assessment: Triclopyr butoxyethyl ester; triclopyr and its salts; 3,5,6-trichloro-2-pyridinol; oxamic acid.
Definitions for monitoring: Triclopyr and its salts and *3,5,6-trichloro-2-pyridinol

Surface water

Definitions for risk assessment:

Surface water and sediment: Triclopyr and its salts; 3,5,6-trichloro-2-pyridinol; 3,6 -dichloro-2-pyridinol

Surface water only: Triclopyr butoxyethyl ester; 6 -chloro-2-pyridinol; oxamic acid

Definitions for monitoring: At least Triclopyr and its salts and *3,5,6-trichloro-2-pyridinol.

There are gaps in the available ecotoxicological data for 3,6-dichloro-2-pyridinol and 6 -chloro-2-pyridinol that need to be filled, before these compounds could be excluded as not requiring consideration in monitoring programs.

*Note 3,5,6-trichloro-2-pyridinol is also a breakdown product of other plant protection product active substances (examples are chlorpyrifos and chlorpyrifos-methyl). It is therefore not a good 'marker' compound for monitoring / identifying use or misuse of tricopyr.

Air

Definitions for risk assessment: Triclopyr butoxylethyl ester; triclopyr
Definitions for monitoring: Triclopyr butoxyethyl ester and triclopyr

Food of plant origin

Definitions for risk assessment: no residue definition required as no use on crops for human consumption
Definitions for monitoring: no residue definition required as no use on crops for human consumption

Food of animal origin

Expert meeting (EPCO 19 proposal):

Definitions for risk assessment: Sum of triclopyr and all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates, expressed as triclopyr (or sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr)

Definitions for monitoring: Sum of triclopyr and all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates, expressed as triclopyr (or sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr)

EFSA proposal:

Definitions for risk assessment: Triclopyr; 3,5,6-trichloro-2-pyridinol

Definitions for monitoring: Triclopyr; 3,5,6-trichloro-2-pyridinol

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
triclopyr butoxyethyl ester	Very low persistence (DT_{90} lab (20°C) < 3 days)	See 5.5, 5.6 and 5.7.
triclopyr	Moderately persistent (DT_{50} lab (20°C) 13-52 days, field 7-54 days)	See 5.5, 5.6 and 5.7.
3,5,6-trichloro-2-pyridinol	Moderately persistent (DT_{50} lab (20°C) 10-67 days, field 30-77 days)	Relevant because of the higher toxicity and risk to earthworms than the parent.

Ground water

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative grassland uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological relevance**
triclopyr butoxyethyl ester	Not measured due to fast degradation [5]QSAR software estimated K_{oc} 560mL/g low mobility	No all 9 FOCUS scenarios No UK Lysimeter	Yes	Yes	See 5.2.

[5] Quantitative structure activity relationship

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative grassland uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
triclopyr	Very high to high mobility Koc 25-134mL/g	Yes 8 FOCUS scenarios No UK Lysimeter	Yes	Yes	See 5.2.
3,5,6-trichloro-2-pyridinol	high mobility Koc 51-149mL/g	Yes 2 FOCUS scenarios No UK Lysimeter	No insecticidal activity. No information on herbicidal activity available.	Yes	Relevant because of the higher long term toxicity and risk to aquatic invertebrates than the parent.
oxamic acid		Yes UK lysimeter	'Degradation product of no concern'	'Degradation product of no concern'	Not considered to be of ecotoxicological relevance.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
triclopyr butoxyethyl ester	See 5.2.
triclopyr	See 5.2.
3,5,6-trichloro-2-pyridinol	Relevant because of the higher long term toxicity and risk to aquatic invertebrates than the parent.
3,6-dichloro-2-pyridinol	No data available.

Compound (name and/or code)	Ecotoxicology
6 -chloro-2-pyridinol	No data available.
oxamic acid	Not considered to be of ecotoxicological relevance.

Air

Compound (name and/or code)	Toxicology
triclopyr butoxyethyl ester	Not acutely toxic via inhalation
triclopyr	No data available

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

- An enforcement method for food of animal origin (refer to chapter 1 and 6). It should be noted that the RMS has received recently a method for food of animal origin, but not evaluated.
- Depending on the final residue definition for surface water, it could be necessary to require more data (refer to chapter 1 and 6).
- An enforcement method for the determination of triclopyr-butoxyethylester in air (date of submission unknown, data gap identified during the expert meetings, refer to chapter 1 and 6)
- Submission of full details of the validation of the method ACR 77.4 used for determining the storage stability of triclopyr in hay (relevant for representative use in pasture; date of submission unknown; refer to point 3.1.1).
- Further soil adsorption data for triclopyr over a wider pH range to confirm whether adsorption and leaching in soil is pH dependant for use in specific groundwater exposure assessments at the member state level (proposed by EPCO experts' meeting, date of submission unknown; refer to points 4.1.3 and 4.2.2).
- Submission of a refined acute risk assessment for insectivorous birds (relevant for all representative uses evaluated; the notifier has indicated that they are committed to carry out a residue decline study in insects to validate the conclusion on the risk assessment to insectivorous birds. This will be available in early 2007; refer to point 5.1)
- Submission of a refinement of the long term risk to herbivorous and insectivorous birds (proposed by EFSA, not peer reviewed; relevant for all representative uses evaluated, date of submission unknown; refer to point 5.1)
- Submission of a refinement of the risk to birds and mammals from exposure to contaminated drinking water. (proposed by EFSA, not peer reviewed; relevant for all representative uses evaluated, data made available by the notifier but not evaluated by the RMS nor peer reviewed; refer to point 5.1)
- Submission of data to support the assumptions, besides the residue data, used in the refined acute risk assessment for herbivorous mammals. This refined risk assessment should be based on the lowest endpoint from the study with Garlon 4. (relevant for all representative uses evaluated, date of submission unknown; refer to point 5.1)
- Submission of a refinement of the long term risk to herbivorous mammals (proposed by RMS in addendum of June 2005, not peer reviewed; relevant for all representative uses evaluated, date of submission unknown; refer to point 5.1)
- Submission of at least an algae study with the metabolite 3,6-dichloro-2-pyridinol or to submit the validation of the ECCOSAR model or another suitable model for this substance class. (relevant for all representative uses evaluated, the notifier has indicated that the following studies will be complete by Summer 2006: Test substance: 3,6-dichloropyridinol : Full life cycle toxicity test with sediment swelling midge (*Chironimus riparius*) under static conditions (OECD guidline 219), Acute toxicity to water fleas, *Daphnia magna*, under static conditions

following OECD guideline 202 EC, Growth inhibition test with freshwater diatom *Navicula pelliculos.* and 7 day growth inhibition test with Duckweed (*Lemna gibba*); refer to point 5.2).

- Notifier to address the risk to aquatic organisms from exposure to the metabolite 6-chloro-2-pyridinol. (proposed by EFSA, not peer reviewed; relevant for all representative uses evaluated, date of submission unknown; refer to point 5.2)
- Submission of the full study reports of all studies referred to in the DAR regarding dicotyledonous higher aquatic plants. (relevant for all representative uses evaluated, the notifier submitted the study reports after the EPCO expert meeting. These have not been evaluated nor peer reviewed; refer to point 5.2)
- Submission of an argumentation if the concentration of 9.6 acid equivalent per kg dry soil, at which the long term NOEC for earthworms was set for Garlon 4, was reached during the study. (relevant for all representative uses evaluated, Notifier will submit a long term earthworm study by the summer of 2006; refer to point 5.5)
- Submission of a collembolan reproduction study or a study on gamasid mites with triclopyr. (proposed by EFSA, not peer reviewed; relevant for all representative uses evaluated, date of submission unknown; refer to point 5.6)
- Submission of a study on the herbicidal activity of the ground water metabolite 3,5,6-TCP (proposed by EFSA, not peer reviewed; relevant for all representative uses evaluated, date of submission unknown; refer to point 5.8)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the applicant which comprises broadcast spraying or spot treatment to control a wide spectrum of broad-leaved weeds in pasture, forestry, grassland (non-recreational), railways and set-a-side at application rate up 1.44 kg triclopyr per hectare. Triclopyr can be used only as herbicide.

The representative formulated product for the evaluation was "Garlon 4" ("XRM-4714"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

Due to the fact that the butoxyethyl ester (BEE, also refer to butotyl ester), a variant of triclopyr, is used in the formulated product, it should be noted that the evaluated data belong to the variant triclopyr-butoxyethyl ester, unless otherwise specified.

Adequate methods are available to monitor all compounds given in the respective residue definitions for soil and ground water. For food of animal origin not method is available, for air a method for the determination of residues of the butoxyethyl ester is missing. Whether or not sufficient methods are available for surface water depends on the final residue definition.

The methodology used is GC with MS or EC detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.

No analytical method for the determination of triclopyr alone is available, other analytes will always be determined in parallel.

Triclopyr and the ester have shown to be pharmacologically equivalent. Triclopyr is rapidly and extensively absorbed; it is mainly excreted as unchanged in urine (>80%). Both triclopyr and BEE are characterised by a moderate acute oral toxicity, they are not acutely toxic via dermal route, the acute inhalation toxicity of BEE is low, while data on triclopyr are not available. Both triclopyr and BEE are not skin irritant; the acid shows irritating potential to the eyes. Both of them are skin sensitiser at the modified Buehler test. Therefore, **the following classification is proposed: Xn, R22 (harmful if swallowed), Xi, R36 irritating to eyes, Xi, R43 may cause skin sensitisation by skin contact.**

The overall relevant NOAEL from short term toxicity studies is 5 mg/kg bw/day. Neither triclopyr nor its ester have shown genotoxic potential. The relevant NOAEL for chronic toxicity is 3 mg/kg bw/day. Triclopyr did not show any carcinogenic potential.

In rats, retarded ossification of skull bones was observed at 200 mg/kg bw/day and an increased incidence of malformations and skeletal anomalies at 300 mg/kg bw/day. Therefore, **Cat 3 R63 was agreed**. Triclopyr did not give any indication of neurotoxic potential.

The ADI of 0.03 mg/kg bw/day based on the 2-year oral study in rats with a SF 100 was agreed on.

The AOEL is 0.05 mg/kg bw/day based on the 13-week oral study in rats with a SF 100.

An ARfD of 0.3 mg/kg bw/day was set by the experts based on the developmental toxicity study in rabbit, with a NOAEL of 30 mg/kg bw/day and applying a SF 100.

Estimated exposure is above the AOEL both with the German and UK POEM models if no PPE is worn. The AOEL is not exceeded with the German model wearing appropriate PPE (gloves during mixing/loading, gloves, coveralls and sturdy footwear during application), either for use with boom sprayer or the knapsack application.

AOEL is not exceeded both for re-entry workers (< 3.6%) and bystander (14.8%).

The metabolism of triclopyr and its butoxyethyl ester in plants is adequately elucidated. Triclopyr is the major compound of the residue in vegetal tissues. This is confirmed by supervised residue trials in pasture indicating that the highest potential levels of triclopyr are in the range of 40 mg/kg, while its only identified metabolite, 3,5,6-trichloro-2-pyridinol, never exceeds 10 % of the triclopyr levels. Triclopyr, its conjugates and 3,5,6-trichloro-2-pyridinol are considered as the only significant compounds in terms of toxicological burden present in plants that can be transferred to animals.

In animal metabolism, triclopyr (major residue in milk) and 3,5,6-trichloro-2-pyridinol (major residue in bovine muscle, liver, fat and kidneys) were identified as compounds of toxicological relevance. 3,5,6-trichloro-2-pyridinol is not specific of trichlopyr and can be produced by animal metabolism from other pesticides. This situation makes the establishment of a residue definition quite complex for enforcement reasons. 3 options for residue definition were examined during the peer review process. The first was proposed by the RMS in the DAR and consisted only in triclopyr. This option was considered by the expert meeting (EPCO 19) not protective enough of the consumer because the toxicological burden of the metabolite was not covered and a proposal consisting in the sum of triclopyr, all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates was submitted. This option was also difficult to apply in practice due to the non specificity of the metabolite. A third proposal consisting in dissociating triclopyr on one hand and 3,5,6-trichloro-2-

pyridinol on the other hand in 2 separate residue definitions was proposed by EFSA, to allow regulators to consider the potential contribution of other pesticides in setting MRLs for the metabolite 3,5,6-trichloro-2-pyridinol. This last option required the establishment of specific toxicological end points for this metabolite and tentative ADI and ARfD have been set based on the toxicological package submitted for 3,5,6-trichloro-2-pyridinol.
The approaches for residue definition of the expert meeting (EPCO 19) and of the EFSA were further considered for proposing MRLs and conducting the risk assessment for the consumer. These 2 approaches resulted in MRLs proposals in animal commodities which are mainly influenced by the generally higher levels of 3,5,6-trichloro-2-pyridinol in these matrices. The outcome of the risk assessment was also quite similar between the 2 approaches, demonstrating the absence of risk for the consumer.

The information and assessments available on the environmental fate and behaviour of triclopyr (when applied as triclopyr butoxyethyl ester) are sufficient to complete an appropriate EU level environmental exposure assessment for the intended uses on pasture and non-recreational amenity grassland. Assessments are absent for the other intended uses (forestry, railways and set aside). FOCUS groundwater modelling indicates a high potential for groundwater contamination in vulnerable situations over a wide range of geoclimatic conditions across the EU for triclopyr (with 8 out of 9 FOCUS groundwater scenarios indicating annual average concentrations leaving the top 1m soil layer >0.1µg/l.). Modelling also indicates that the major soil metabolite 3,5,6-trichloro-2-pyridinol may also contaminate groundwater but the range of vulnerable geoclimatic conditions where this might happen is less wide spread (2 out of 9 FOCUS groundwater scenarios indicating annual average concentrations leaving the top 1m soil layer >0.1µg/L.). A lysimeter study indicates that when applications are made in the summer to acidic soils under vulnerable north western European conditions groundwater contamination >0.1µg/L for triclopyr and 3,5,6-trichloro-2-pyridinol is unlikely. Further data would need to be assessed on the adsorption of triclopyr over a wide soil pH range to confirm whether adsorption of triclopyr is pH dependant or not, before it was possible to confirm if the lysimeter study results could be read across to a larger range of soil pH conditions. Even then the lysimeter study covers summer application conditions only. Whilst the available data indicate the intended use on grass may be carried out without contaminating vulnerable groundwater, the data also indicate there is a wide range of conditions across Europe under which any authorised use would have to be very strictly managed to safeguard groundwater from contamination with triclopyr above the parametric legal limit (0.1µg/L).

Only a risk assessment for the representative use in pasture is presented in the section on ecotoxicology in the DAR and the addenda. EFSA considers that this risk assessment also covers the ecotoxicological risk assessment necessary for the representative use in non-recreational amenity grassland. No risk assessment is available for the representative uses in forestry, railways and set-a-side.
The risk to bees, soil micro-organisms and biological methods for sewage treatment is considered to be low.

The acute risk to herbivorous and insectivorous birds from exposure to triclopyr is considered to be low as the TER values (18.81 and 21.8 respectively) are above the Annex VI trigger value. Also the acute risk to herbivorous birds from exposure to triclopyr BEE is low. A high acute risk to insectivorous birds from exposure to triclopyr BEE was identified in the first tier risk assessment and the EPCO experts' meeting did not agree with the refined acute risk assessment for insectivorous birds from exposure to triclopyr BEE. Therefore a data requirement was set for the notifier to submit a refined risk assessment for insectivorous birds. The short term risk to insectivorous and herbivorous birds from exposure to triclopyr and triclopyr BEE can be considered as low. The long term TER values for insectivorous and herbivorous birds (TER = 0.7 and 1.2 respectively) breach the Annex VI trigger value of 5 indicating a high risk to insectivorous and herbivorous birds. Therefore EFSA proposes a data requirement for the notifier to address this risk. The long term risk to birds was only identified by the RMS after revision of the risk assessment as requested by the EPCO experts' meeting and therefore this data requirement was not discussed in an EPCO Expert meeting. A low acute and short term risk to herbivorous and insectivorous birds and a low acute risk to herbivorous mammals from exposure to the metabolite 3,5,6- trichloro-2-pyridinol was identified.

A high acute risk to mammals from exposure to triclopyr BEE and triclopyr was identified. A further refinement of this risk was presented by the notifier which was discussed in the EPCO experts' meeting. The meeting decided to set a data requirement for the notifier to submit data to support the assumptions, besides the residue data, used in the refined acute risk assessment for herbivorous mammals. It is noted by the EFSA that a second oral acute toxicity study with rats and the formulation Garlon 4 is available which leads to a lower endpoint than the endpoint which was taken into account in the DAR. If the endpoint of this study with the formulation Garlon 4 is expressed in triclopyr BEE equivalents the toxicity is higher than the toxicity from triclopyr BEE alone. Therefore EFSA proposes to take the LD_{50} of 900 mg Garlon 4/kg bw into account when refining the acute risk to herbivorous mammals (see data requirement above). Also a high long term risk to herbivorous mammals is identified. The RMS did not present a refined risk assessment in the addendum of June 2005 as requested by the EPCO experts' meeting but proposes a data requirement for the notifier to address this long term risk to mammals.

A high risk to birds and mammals from consumption of contaminated drinking water was observed in the first tier risk assessment by EFSA (see addendum). Therefore EFSA proposes a data requirement for the notifier to refine the risk to birds and mammals from exposure to contaminated drinking water. This assessment was neither discussed at the EPCO experts' meeting nor peer reviewed.

A high acute risk to aquatic invertebrates was identified as the TER values (15-434) are below the Annex VI trigger value of 100 for 9 out of 11 FOCUS Step 3 scenario's. EFSA does not find it appropriate to refine a risk, which is based on a flow-through study with *C. virginica,* with a static study which was performed with *D. magna*. Therefore EFSA proposes that risk mitigation measures are taken into account at MS level to address the acute risk to aquatic invertebrates or a static study with *C. virginica* should be requested at MS-level.

A low long term risk to aquatic organisms from exposure to triclopyr but a high long term risk to fish from exposure to triclopyr BEE was observed. The EPCO experts' meeting considered a long term risk assessment for triclopyr BEE necessary because of contamination of surface water by drainage.

This was discussed internally in EFSA after the EPCO Expert meeting. EFSA considers that with the intended use of only 2 applications a year with a minimum 6 month interval and the fact that soil and water half lives of the ester are < 1 day, long term exposure to aquatic organisms from drainage to the ester will not occur at least for the notified representative uses. Therefore EFSA proposes that risk mitigation measures should be envisaged at MS level to address the long term risk to fish from exposure to triclopyr BEE if the local conditions are very sensitive to drainage or if local uses have shorter intervals than assessed in the DAR. Furthermore EFSA proposes that also risk mitigation measures are taken into account at MS level to address the long term risk to *D. magna* from exposure to 3,5,6- trichloro-2-pyridinol for the D2 ditch scenario. The acute risk to aquatic organisms from the metabolite 3,5,6- trichloro-2-pyridinol can be regarded as low.

The EPCO experts' meeting was afraid that the ECCOSAR model, presented to address the risk to aquatic organisms from the metabolite 3,6-dichloro-2-pyridinol, does not take into account the specific mode of action of this substance. A further data requirement was set for the notifier to submit at least an algae study with this metabolite 3,6-dichloro-2-pyridinol or to submit the validation of the ECCOSAR model or another suitable model for this substance class. Furthermore the metabolite 6-chloro-2-pyridinol was identified as a major metabolite by the section on Fate and behaviour. No studies with this metabolite are available. Therefore EFSA proposes a data requirement for the notifier to address the risk to aquatic organisms from exposure to the metabolite 6-chloro-2-pyridinol. The need for this data was not discussed at an EPCO Expert meeting. The metabolite oxamic acid is considered to be not ecotoxicologically relevant by EFSA. The risk to *Lemna gibba* can be considered as low but the EPCO experts' meeting decided to set a data requirement for the notifier to submit the full study reports of all studies referred to in the DAR regarding dicotyledonous higher aquatic plants as it was questioned that *Lemna gibba* is an appropriate indicator plant. The risk to aquatic higher plants can only be concluded when this data becomes available.

Based on the available studies the risk to non target arthropods is considered to be addressed.

The risk to non-target plants can be considered as low if a bufferzone of 5 metres is taken into account.

The acute risk to earthworms is considered to be low. The long term risk to earthworms from exposure to the metabolite 3,5,6-trichloro-2-pyridinol is also regarded to be low. The EPCO experts' meeting decided to set a data requirement for the notifier to submit an argumentation if the concentration of 9.6 acid equivalent per kg dry soil, at which the NOEC for earthworms was set, was reached during the study. The long term risk to earthworms can only be concluded once this argumentation becomes available. At the moment no final conclusion can be drawn regarding the need for a litter bag study with triclopyr due to the outstanding data requirement regarding the long term risk to earthworms. EFSA considers a collembolan reproduction study or a study on gamasid mites with triclopyr necessary given the effects seen on *Aphidius rhopalosiphi* and *Typhlodromus pyri* in the standard laboratory toxicity studies. The need for this data was not discussed at an EPCO Expert meeting.

As 3,5,6-TCP is a major ground water metabolite, a study on the herbicidal activity of this metabolite is considered necessary by EFSA. The need for such a study was not discussed in an EPCO Expert meeting.

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

- An exceedence of the AOEL for operators exposed to triclopyr was identified. Therefore, the use of PPE is needed both during mixing/loading (gloves) as well as during application (gloves, coveralls and sturdy footwear) in order to have estimated exposure level below the AOEL.
- A high risk to aquatic invertebrates was identified as the TER values (15-434) are below the Annex VI trigger value of 100 for 9 out of 11 FOCUS Step 3 scenario's. EFSA does not find it appropriate to refine a risk, which is based on a flow-through study with *C. virginica*, with a static study which was performed with *D. magna*. Therefore EFSA proposes that risk mitigation measures are taken into account at MS level to address the acute risk to aquatic invertebrates or a static study with *C. virginica* should be requested at MS-level (refer to point 5.2).
- EFSA proposes that risk mitigation measures should be envisaged at MS level to address the long term risk to fish from exposure to triclopyr BEE if the local conditions are very sensitive to drainage or if local uses have shorter intervals than assessed in the DAR. EFSA proposes that also risk mitigation measures are taken into account at MS level to address the long term risk *D. magna* from exposure to 3,5,6-TCP for the D2 ditch scenario (refer to point 5.2).
- Risk mitigation measure have to be taken into account at MS level to address the risk to non-target plants, e.g. a buffer zone of 5 metres (refer to point 5.8).

Critical areas of concern

- The operator exposure assessment indicated that the AOEL is expected to be exceeded if no PPE is worn. Therefore, the use of PPE, i.e. gloves during mixing/loading and gloves, coveralls and sturdy footwear during application is necessary and recommended.
- Potential for groundwater contamination of triclopyr in vulnerable situations over a large geoclimatic area in Europe.
- Potential for groundwater contamination of 3,5,6-trichloro-2-pyridinol in vulnerable situations in situation represented by the Piacenza and Okehampton FOCUS groundwater scenarios (although any local risk management measures that would be necessary for triclopyr should also prevent contamination by 3,5,6-trichloro-2-pyridinol).
- In terms of environmental fate and behaviour exposure assessments, those available in the DAR and its addenda do not cover the intended uses in forestry and on railways and set aside.
- Only a risk assessment for the representative use in pasture is presented in the section on ecotoxicology in the DAR and the addenda. EFSA considers that this risk assessment also covers the ecotoxicological risk assessment necessary for the representative use in non-recreational amenity grassland. No risk assessment is available for the representative uses in forestry, railways and set-a-side.
- A high acute risk to insectivorous birds from exposure to triclopyr BEE was observed. Furthermore a high long term risk to insectivorous and herbivorous birds from exposure to triclopyr was observed. The need for further addressing the acute risk to insectivorous birds as

well as the long term risk to birds was identified. Furthermore a high risk to birds from exposure to contaminated drinking water was observed by the EFSA for which submission of a refinement is proposed.

- A high acute risk to herbivorous mammals from exposure to triclopyr BEE and triclopyr was observed. Data to support the assumptions used to refine this acute risk to herbivorous mammals (besides the residue data) need to be submitted. EFSA proposes to take the LD_{50} of 900 mg Garlon 4/kg bw into account when refining the acute risk to herbivorous mammals as this endpoint is lower than the endpoint used in the present risk assessment. Furthermore, a high long term risk to mammals was identified for which the submission of a refined risk assessment is proposed. Also a high risk to mammals from exposure to contaminated drinking water was observed by the EFSA for which submission of a refinement is proposed.
- A high acute risk to aquatic invertebrates was identified for 9 out of 11 FOCUS Step 3 scenario's. The EFSA does not find it appropriate to refine a risk, which is based on a flow-through study with *C. virginica*, with a static study which was performed with *D. magna*. Therefore, the EFSA proposes risk mitigation measures are taken into account to address this risk or a static study with *C. virginica* should be requested.
- Also a high long term risk to aquatic organisms was observed. Therefore, EFSA proposes that risk mitigation measures should be envisaged to address the long term risk to fish and the long term risk to *D. magna* (refer to section of particular conditions proposed).
- A high risk to non-target plants was identified. Risk mitigation measures, such as a bufferzone of 5 metres, are proposed to address this risk.

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

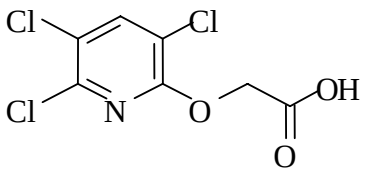
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Triclopyr
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	Ireland
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3,5,6-trichloro-2-pyridyloxyacetic acid
Chemical name (CA) ‡	None provided
CIPAC No ‡	376
CAS No ‡	055335-06-3
EEC No (EINECS or ELINCS) ‡	265-024-8
FAO Specification ‡ (including year of publication)	No FAO Specification
Minimum purity of the active substance as manufactured ‡ (g/kg)	960g/kg as Butoxyethyl Ester
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None identified
Molecular formula ‡	$C_7H_4Cl_3NO_3$
Molecular mass ‡	256.47
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

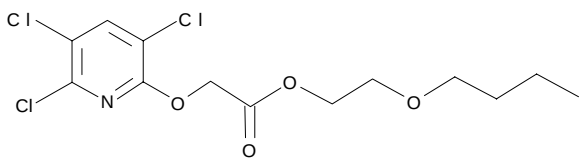
Melting point (state purity) ‡	150.5 ºC (99.8%)
Boiling point (state purity) ‡	Product decomposed at 208 ºC
Temperature of decomposition	208 ºC (99.8%)
Appearance (state purity) ‡	Granular white solid (99.5%)
Relative density (state purity) ‡	1.85 at 21 ºC (D^{21}_4) (99.8%)
Surface tension	71.6±0.3mN/m at 21 ºC (99.4%)
Vapour pressure (in Pa, state temperature) ‡	$2.0x10^{-4}$ Pa at 25 ºC (99.8%)
Henry's law constant (Pa m^3 mol^{-1}) ‡	4.7×10^{-6} Pa m^3/mol at pH 5 4.4×10^{-6} Pa m^3/mol at pH 7 4.4×10^{-6} Pa m^3/mol at pH 9 8.8×10^{-5} Pa m^3/mol unbuffered at 20 ºC
Solubility in water ‡ (g/l or mg/l, state temperature)	pure water 0.408 g/L pH 5 7.69 g/L pH 7 8.10 g/L pH 9 8.22 g/L at 20 ºC (99.8%)
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	Hexane 0.09 g/L Toluene 19 g/L Methylene chloride 25 g/L Methanol 665 g/L Acetone 582 g/L Acetonitrile 92.2 g/L Ethyl acetate 272 g/L
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH 5 log K_{ow}= 0.42 pH 7 log K_{ow}= -0.45 pH 9 log K_{ow}= –0.96 at 20-25 °C. (all 99.8%)
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	pH 5 stable, no hydrolysis (24 °C) pH 7 stable, no hydrolysis (24 °C) pH 9 stable, no hydrolysis (24 °C)
Dissociation constant ‡	pKa = 3.97 at 21 ºC (99.8%)
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	Absorption observed at λ 295, 232 & 203 nm with corresponding Extinction Coefficient ε values of $8.10x10^3$, $1.07x10^4$ & $2.26x10^4$ (10% 1M HCl in MeOH). Absorption observed at λ 297 & 234nm with corresponding Extinction Coefficient ε values of $6.77x10^3$ & $1.03x10^4$ (10% 1M NaOH in MeOH) Absorption observed at λ 298, 235 & 205nm with corresponding Extinction Coefficient ε values of $6.86x10^3$, $1.07x10^4$ & $1.98x10^4$(in MeOH)

Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	Average $t_{1/2}$ = 0.5 days (sterile water buffered at pH 7, 25 ºC) Average $t_{1/2}$ = 1.2 days (River water)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Φ = 0.034 for sterile water at pH 7 Φ = 0.012 for natural river water
Flammability ‡	Not flammable
Explosive properties ‡	Not explosive

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

Active substance (ISO Common Name) ‡	Triclopyrbutotyl ester Another name (not ISO) in use is: Triclopyr Butoxyethyl ester

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3,5,6-trichloro-2-pyridyloxy-2-butoxyethyl ester
Chemical name (CA) ‡	None provided
CIPAC No ‡	376.222
CAS No ‡	064700-56-7
EEC No (EINECS or ELINCS) ‡	265-024-8
FAO Specification ‡ (including year of publication)	No FAO Specification
Minimum purity of the active substance as manufactured ‡ (g/kg)	960g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None identified
Molecular formula ‡	$C_{13}H_{16}Cl_3NO_4$
Molecular mass ‡	356.64
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-32ºC (241ºK) (99%)
Boiling point (state purity) ‡	Product decomposed at 210 ºC
Temperature of decomposition	210 ºC (99%)
Appearance (state purity) ‡	1.3 at 21ºC (D^{21}_4) (99%)
Relative density (state purity) ‡	Clear colourless liquid (99%)
Surface tension	62.9±0.2mN/m at 21 ºC (97.6%)
Vapour pressure (in Pa, state temperature) ‡	$1.0x10^{-4}$ Pa at 25 ºC (99%)
Henry's law constant (Pa m^3 mol^{-1}) ‡	2.9 x 10^{-3} Pa m^3 /mol at 20 ºC
Solubility in water ‡ (g/l or mg/l, state temperature)	Destilled H_2O 5.8 g/L pH 5 5.9 g/L pH 7 5.9 g/L pH 9 3.9 g/L at 20 ºC (99%)
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	Miscible in all proportions with Hexane, Toluene, Methylene chloride, Methanol, Acetone, Acetonitrile and Ethyl acetate
Partition co-efficient (log POW) ‡ (state pH and temperature)	log K_{ow}= 4.75, 4.62 and 4.31 at pH 5, 7 & 9, respectively (22 °C) (all 99%).
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	$T_{1/2}$ = 84 days, 8.7 days and 0.3 days at PH 5, 7 & 9, respectively (25 °C).
Dissociation constant ‡	Not available
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	Absorption observed at λ 295, 232 & 203nm with corresponding Extinction Coefficient ε values of $7.2x10^3$, $1.02x10^4$ and $2.1x10^4$(10% 1M HCl in MeOH, pH= 0.89). Absorption observed at λ 297, 234 & 217nm with corresponding Extinction Coefficient ε values of $6.83x10^3$, $1.06x10^4$ and $8.43x10^3$ (10% 1M NaOH in MeOH, pH= >14) Absorption observed at λ 295, 232 & 204nm with corresponding Extinction Coefficient ε values of $5.09x10^3$, $7.8x10^3$ and 1.45 $x10^4$(in MeOH, pH = 8.25)
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	Predicted 3.1hr. (40ºN, 25 ºC)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Φ = 0.493
Flammability ‡	Not flammable
Explosive properties ‡	Not explosive

List of representative uses evaluated*

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	g ae/hL min max	water (L/ha) min max	g ae/ha min max	(l)	(m)
Pasture Non-recreational amenity grassland Forestry Railways Set-a-side	EU	Garlon 4 Formulation code XRM-4714	F	Broad leaf weeds Brush control Cut stump	EC	Triclopyr 480 g ae/L ae =acid equivalent	Overall foliar treatment applied with a hydraulic boom sprayer Spot treatment with Knappsack sprayer	All year	Min 1 max 2 per year*	0.5 years	Overall min 200 max 360 Spot treatment min 75 max 96	Overall min 300 max 400 Spot** treat-ment min 800 max 1500	Overall min 600 max 1440 Spot treat-ment min 600 max 1440	7	*total dose in any one year must not exceed 1440gae/ha **spot treatment typical water volumes range from 800-1500 l/ha depending on the morphology of the target species. Obviously by its very nature a spot treatment is not applied to the whole area, the 1500 l/ha is a theoretical value.

In fate and behaviour the uses on railways, forestry and set aside have not been adequately covered by the available assessment relating to potential ground water contamination.
In ecotoxicology no risk assessment is available for the uses on railways, forestry and set aside.
In fate and behaviour the uses on railways and forestry have not been adequately covered by the available assessment relating to potential surface water exposure.

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(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)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

Appendix 1.2: Methods of Analysis

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

Technical as (principle of method)	A sample of technical material containing triclopyr butoxyethyl ester is analysed by GLC with FID detection.
Impurities in technical as (principle of method)	A sample of technical material analysed by GLC with FID detection. The method is applicable to the analysis of triclopyr butoxyethyl ester and related impurities (see Appendix1 of Annex C)
Plant protection product (principle of method)	A sample of the preparation was analysed using HPLC with UV detection.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	There is no need for an analytical method for the determination of residues in food of plant origin, based on the evaluated representative uses.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	A new method incl. ILV is required.
Soil (principle of method and LOQ)	Residues of triclopyr and 3,5,6-TCP were extracted from soil with in a solution of acetone/aqueous HCl. The extract was purified on a C18 SPE column using acetonitrile/aqueous HCl as eluant. The analytes were partitioned into 1-chlorobutane, which was then evaporated. After the addition of acetone, triclopyr and TCP[6] were reacted with MTBSTFA (*N*-tert-butyldimethylsilyl-*N*-methyltrifluoroactamide) to form the *t*-butyl dimethylsilyl derivatives and analysed by capillary GC/MSD. Triclopyr tertiary butyl dimethylsilyl ester was quantified at 254.0 m/z and the 312.0 m/z ion used for confirmation, TCP tertiary butyl dimethylsilyl ester was quantified at 254 m/z and confirmed at 256 m/z. LOQ = 0.01mg/kg
Water (principle of method and LOQ)	Residues of Triclopyr and 3,5,6-Trichloro-2-Pyridinol were extracted with 1-chlorobutane from acidified water, saturated with NaCl. The chlorobutane extracts were concentrated and appropriate internal standards (fluroxypyr analogs) dissolved in acetone, were added. The sample were reacted with *N*-methyl-*N*-(*tert*-butyldimethylsilyl)-trifluoroacetamide (MTBSTFA) to form the *tert*-

[6] TCP: 3,5,6-trichloro-2-pyridinol

	butyldimethylsilyl derivatives of triclopyr and 3,5,6-TCP and analysed by capillary gas chromatography with mass selective detection (GC/MSD). LOQ = 0.1µg/L (drinking-, surface water)
Air (principle of method and LOQ)	Air was drawn through a Tenax two bed configured tube. After sampling for 8 hr. (total air volume 480 L) both tubes were desorbed by shaking in acetone. The extract was treated with MSTFA (*N*-methyl-*N*-trimethylsilyl trifluoroacetamide) to produce the trimethylsilyl ester of triclopyr which was analysed by GLC/ECD. LOQ = 1.7µg/m^3 (based on a 30 L air sample); 0.1µg/m^3 (based on a 480L air sample) *A method for triclopyr-butoxyethyl ester is required.*
Body fluids and tissues (principle of method and LOQ)	Not required [substance is not classified as toxic (T) or very toxic (T+)]

Classification and proposed labelling (Annex IIA, point 10)

With regard to physical/chemical data	No classification required.

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Rapid and extensive (75- 94% in 72 h – incl. humans)
Distribution ‡	Mainly kidneys
Potential for accumulation ‡	None, except following chronic administration at very high doses (>50mg/kg in rat and ~20mg/kg in dog)
Rate and extent of excretion ‡	Rapid (89-95% in urine within 72h in the rat); (>80% unchanged PM in human urine). In the dog (specifically) at doses > 5mg/kg, excretion becomes non-linear.
Metabolism in animals ‡	3,5,6-trichloro-2-pyridinol and its glucuronide and sulphate conjugates and possible triclopyr conjugates (1-2% in rat urine; <1% in humans)
Toxicologically significant compounds ‡ (animals, plants and environment)	Triclopyr, and 3,5,6-trichloro-2-pyridinol (TCP)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	630 mg triclopyr acid /kg bw 803 mg triclopyr BEE[7] /kg bw **R22**
Rat LD_{50} dermal ‡	> 2000 mg triclopyr acid /kg bw (male & female rat) > 2000 mg triclopyr BEE /kg bw (male & female rat)
Rat LC_{50} inhalation ‡	> 4.8 mg triclopyr BEE /L air (max. attainable conc)
Skin irritation ‡	Triclopyr acid: Non-irritant (rabbit) Triclopyr BEE: Non-irritant (rabbit)
Eye irritation ‡	Triclopyr acid: Irritant (rabbit) **R36** Triclopyr BEE: Non-irritant (rabbit)
Skin sensitization ‡ (test method used and result)	Both triclopyr and BEE sensitiser (modified Buehler) **R43**

[7] Triclopyr BEE: triclopyr butoxyethyl ester

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Very slight to slight diffuse degeneration of proximal tubule cells in the descending part of the renal medulla (male and female rats)
Lowest relevant oral NOAEL / NOEL ‡	5 mg triclopyr /kg bw/day (13-week dietary study in rats)
Lowest relevant dermal NOAEL / NOEL ‡	1000 mg triclopyr BEE/kg bw/day (21-day rabbit). Dermal irritation was observed in females from 100 mg/kg bw day.
Lowest relevant inhalation NOAEL / NOEL ‡	No data, not required

Genotoxicity ‡ (Annex IIA, point 5.4)

No genotoxic potential

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

Target/critical effect ‡	Increased relative kidney weight combined with and microscopic degenerative changes in the descending part of the proximal tubule
Lowest relevant NOAEL / NOEL ‡	3 mg triclopyr /kg bw/day (male rat; 2-year dietary rat study)
Carcinogenicity ‡	No evidence of carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Reduction in mating indices and an increase in the time-to-mating (rat)
Lowest relevant reproductive NOAEL / NOEL ‡	25 mg triclopyr acid/kg bw/day (rat); Maternal NOAEL = 5 mg/kg bw/day. Reproductive NOAEL = 25 mg/kg bw/day
Developmental target / critical effect ‡	Increased foetal deaths (resorptions and post implantation loss) and increased foetal skeletal variants (incidences of additional sternebral centres, reduced digital bone ossification and extra rib in rabbit); incidences of unossified and variant sternebrae and extra thoracolumbar ribs in rats (Triclopyr BEE) **Cat. 3 R63***

** In the rabbits the increased incidence of foetal deaths and skeletal anomalies at 100 mg/kg bw/day was associated with marked maternal toxicity. Therefore, classification was not justified.*
However, in the rat, retarded ossification of skull bones was observed at 200 mg/kg bw/day and an increased incidence of malformations and skeletal anomalies at 300 mg/kg bw/day. Therefore, a classification of Cat. 3, R63 was agreed on. The developmental toxic effects in pups in the multigeneration studies are already covered by this classification.

Lowest relevant developmental NOAEL / NOEL ‡	Developmental = 75 mg triclopyr acid/kg bw/day (rabbit); Maternal = 25 mg triclopyr acid/kg bw/day) Developmental = 30 mg triclopyr BEE/kg bw/day (rabbit); Maternal = 30 mg triclopyr BEE/kg bw/day

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

Target / critical effects	No data, not required
Lowest relevant NOAEL / NOEL	No data, not required

Other toxicological studies ‡ (Annex IIA, point 5.8)

Renal Function Assay (Triclopyr BEE)	NOAEL < 5 mg/kg bw/day (beagle dogs), based on a reduced rate of PSP excretion in Beagle dogs at 5 mg/kg bw/day, the top dose tested. NOAEL > 20 mg/kg bw/day (monkeys) - triclopyr at doses up to 20 mg/kg bw daily did not have an effect on renal function in rhesus monkeys as measured by PSP excretion or inulin and PAH clearance.
PSP Excretion and Creatinine Clearance in Dogs	The decrease in PSP excretion in beagle dogs at doses as low as 5 mg/kg bw/day is consistent with competition between PSP and triclopyr for excretion by tubular secretory mechanisms. The recovery of PSP excretory capacity 73 hours after triclopyr treatment, in combination with stable GFR levels as demonstrated by normal values for endogenous creatinine clearance, supports the hypothesis that suppression of PSP following concomitant administration of PSP and triclopyr is a physiologic event rather than a consequence of renal injury.
Metabolites	
Oral LD_{50} TCP	794 mg/kg (male rat) 380 mg/kg bw (male mouse) > 1000 m/kg bw (beagle dogs)
1-year oral (Dog) TCP	NOAEL = 12 mg/kg bw/day (beagle dogs), based on perturbations in clinical chemistry parameters (both sexes), perturbations in haematology parameters (females) and reductions in body weight (females) at 48 mg/kg bw/day.

90-day oral (Rat) TCP	NOAEL = 30 mg/kg bw/day (rat), based on increased relative liver and kidney weights at 100 mg/kg bw/day.
Genotoxicity TCP	All three in-vitro tests (reverse mutation; unscheduled DNA synthesis; CHO/HGPRT forward mutation) were negative. Both of the in-vivo tests (mouse micronucleus) were negative.
Teratology, gavage (Rabbit) TCP	$NOAEL_{maternal}$ = 100 mg/kg bw/day (rabbits) based on reduced maternal body weight gain at 250 mg/kg bw/day $NOAEL_{developmental}$ = 25 mg/kg bw/day (rabbits) based on dose-dependent increases in the incidence of foetal and litter CNS malformations at 100 and 250 mg/kg bw/day compared to concurrent control. The incidences of these malformations were substantially increased compared to historical control incidences.
Teratology, gavage (Rat) TCP	$NOAEL_{maternal}$ = 50 mg/kg bw/day (rats) based on the reductions in body weight gain from 100 mg/kg bw/day. $NOAEL_{developmental}$ = 150 mg/kg bw/day, the highest dose tested.
Human studies	
In vitro dermal absorption, human (spray dilution)	Triclopyr was slowly absorbed through human skin. Based on blood and urinary data, an average of 1.58% of triclopyr applied to the skin as Garlon 4 was absorbed over 96 hours.
	Studies in humans show peak plasma levels between 1 and 3 hours from the administration. After 48 hours triclopyr could not be detected any longer; more than 80% of the administered doses was excreted by 72 hours from the administration

Medical data ‡ (Annex IIA, point 5.9)

	No product related adverse health effects among manufacturing or packaging plant personnel. The majority of alleged human health effects associated with triclopyr reported to the U.S. EPA by Dow AgroScience involved skin, eye, or respiratory irritation related to alleged exposure either by handling or spray drift. No epidemiological studies.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.03 mg triclopyr acid/kg bw/day	2-year dietary study in rats	100
AOEL ‡	0.05 mg triclopyr acid/kg bw/day	13-week dietary study in rats	100
ARfD ‡ (acute reference dose)	0.3 mg triclopyr BEE/kg bw/day	Rabbit teratology study	100

Dermal absorption (Annex IIIA, point 7.3)

Garlon 4 *In vitro* dermal absorption, human (spray dilution)	10% for the concentrate and 18% for the dilution over 24 hours (8 hour exposure)

Acceptable exposure scenarios (including method of calculation)

Operator	Estimated exposure is below the AOEL only with the German model and wearing PPE, both for boom sprayer and knapsack application (25% and 68%, respectively)
Workers	Exposure is below the AOEL (<3.6%).
Bystanders	Exposure is below the AOEL (15%, pasture)

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Xn, Xi;	harmful, irritant
	R22	harmful if swallowed;
	R36	irritating to eyes;
	R43	may cause skin sensitisation by skin contact;
	Cat. 3, R63	possible risk of harm to the unborn child

Appendix 1.4: Residues

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

Plant groups covered	Ryegrass, apples and radish
Rotational crops	Wheat, turnip, green beans and lettuce
Plant residue definition for monitoring	Not needed as no representative use on plant commodities for human consumption
Plant residue definition for risk assessment	Not needed as no representative use on plant commodities for human consumption
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	Goat, Hen
Animal residue definition for monitoring	Expert meeting (EPCO 19) proposal: Sum of triclopyr, all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates, expressed as triclopyr (or sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr) EFSA proposal: Triclopyr; 3,5,6-trichloro-2-pyridinol
Animal residue definition for risk assessment	**Expert meeting (EPCO 19) proposal:** Sum of triclopyr, all metabolites containing the 3,5,6-trichloro-2-pyridinol moiety and their conjugates, expressed as triclopyr (or sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr) **EFSA proposal:** Triclopyr; 3,5,6-trichloro-2-pyridinol
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No. Log K_{ow}= 0.42, -0.45 and-0.96 at PH 5, 7 & 9, respectively at 20-25°C.

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

Very polar residues that could not be identified as triclopyr or its known metabolites.

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

Triclopyr and 3,5,6-trichloro-2-pyridinol stable for more than one year in grass samples Triclopyr stable for up to one year in milk and animal products

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes, 200 mg/kg DM for dairy and beef cattle	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)	Yes	-	-
	Feeding studies (100 and 300 mg/kg) Residue levels in matrices : mg/kg		
Muscle	Triclopyr: ND and ND TCP: <0.05 and 0.11	Not required	Not required
Liver	Triclopyr: <0.05 and <0.05 TCP: 0.78 and 1.89	Not required	Not required
Kidney	Triclopyr: <0.05 and 0.22 TCP: 0.58 and 1.35	-	Not required
Fat	Triclopyr: ND and <0.05 TCP: 0.07 and 0.22	Not required	Not required
Milk	Triclopyr: <0.01 and 0.01 TCP: 0.01 and 0.02	-	-
Eggs	-	Not required	-

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

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (results in mg triclopyr/kg)	Recommendation/comments	MRL	STMR (b)
Ryegrass	Northern	1.59, 2.50, 13.00, 15.51, 25.6	Conjugates included	Not applicable	13.0mg/kg
Ryegrass	Southern	19.0,19.3, 21.0	Conjugates included	Not applicable	19.3mg/kg

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

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

ADI	Triclopyr : 0.03 mg/kg bw/day 3,5,6-trichloro-2-pyridinol : 0.03 mg/kg bw/d (tentative)	
TMDI (European Diet) (% ADI)	**EFSA proposal**	**Expert meeting proposal**
	Triclopyr alone : <1% of triclopyr ADI 3,5,6-trichloro-2-pyridinol alone : <1% of 3,5,6-tricloro-2-pyridinol ADI	Sum of triclopyr and 3,5,6-trichloro-2-pyridinol : 1% of triclopyr ADI
NEDI (% ADI)	Not applicable	
Factors included in NEDI	Not applicable	
ARfD	Triclopyr : 0.3 mg/kg bw/day 3,5,6-trichloro-2-pyridinol : 0.25 mg/kg bw/d (tentative)	
NESTI (% ARfD) according to National large portion consumption data	**EFSA proposal**	**Expert meeting proposal**
	Cattle liver : 9% of 3,5,6-trichloro-2-pyridinol ARfD for French children Other commodities : ≤1% of ARfD of triclopyr and 3,5,6-trichloro-2-pyridinol	Cattle liver : 9% of triclopyr ARfD for French children Other commodities : ≤1% of triclopyr ARfD

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not applicable	Not applicable	Not applicable	Not applicable

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

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

	EFSA proposal		**Expert meeting proposal**
	Triclopyr (mg/kg)	3,5,6-trichloro-2-pyridinol (mg/kg)	Sum of triclopyr and 3,5,6-trichloro-2-pyridinol expressed as triclopyr (mg/kg)
Milk	0.01	0.02	0.03
Meat	< 0.05	0.1	0.2
Liver	< 0.05	2	2
Kidney	0.2	2	2
Fat	< 0.05	0.2	0.2

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	8.2-65.8% AR after 100 d (n = 4 soils)
Non-extractable residues after 100 days ‡	22.3-45.7% AR after 100 d (n = 4 soils)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	Aerobic conditions at 20 °C and 40% Moisture Holding Capacity (MHC) , n = 4 soils, Triclopyr: Maximum levels = 57.1-85.3% AR (Time of maximum occurrence = 3 d) TCP: Maximum levels = 17.5-33.1% AR (Time of maximum occurrence = 16-100 d)

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

Anaerobic degradation ‡	n = 2 soils Mineralisation: 0% at 365 d Non extractable residues: essentially zero Triclopyr: 96.4-99% AR on day 0, and 75-83% AR on day 365 (soil + water) TCP: Maximum levels = 18-25.9% at day 365 (soil + water)
Soil photolysis ‡	n = 1 soil Light exposed samples: Triclopyr: 96.7% AR on day 0, 48% AR on day 31 TCP: 1.2% AR by day 31 CO_2:15.5% AR by day 31 NER: 25.3% by day 31 Dark control samples: Triclopyr: 94.3% AR on day 0, 80.5% AR on day 31 TCP: 4.6% AR by day 31 CO_2: 4.4% by day 31 NER: 7.2% by day 31

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

Method of calculation	Laboratory : Aerobic study on triclopyr BEE: Simple first-order kinetics for triclopyr, except for Faringdon sandy clay soil where root first-order Timme-Frehse was calculated. Aerobic study on TCP: Simple first order kinetics Anaerobic study: rates not calculated (see below) Soil photolysis studies: Simple first-order kinetics, accounting for the effect of non photolytic degradation Field studies: First-order kinetics along with different Timme-Frehse kinetic models were used for triclopyr BEE, triclopyr and TCP.
Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50lab} (20 °C, aerobic): Triclopyr BEE: << 3 days (level ≤ 4.4% AR by day 3) Triclopyr: (16√1st order), 13, 51, and 52 days; (r^2 = 0.96-0.99), -10kPa normalised mean first order for use in FOCUS modelling = 31.5 days TCP (20 °C, aerobic-derived values): 17, 26 days (r^2 = 0.93-0.95), mean = 21.5 days; (20 °C, aerobic - direct experimental values): 67, 10, 12, 61 days; (r^2 = 0.890-0.988) mean = 37.5 days -10kPa normalised mean first order for use in FOCUS modelling = 31.2 days
	DT_{90lab} (20 °C, aerobic): Triclopyr BEE: < 3 days Triclopyr: (35), 44, 170, and 171 days; (r^2 = 0.96-0.99), mean = 105 days TCP (20 °C, aerobic-derived values): 56, 86 days (r^2 = 0.93-0.95), mean = 71 days; (20 °C, aerobic - direct experimental values): 221, 35, 40, 203 days; (r^2 = 0.890-0.988), mean = 125 days [Overall TCP mean = 107 days (n = 6)]
	DT_{50lab} (10 °C, aerobic): Triclopyr BEE: not determined Triclopyr: 67.1 days (calculated*) TCP: 129 days; Marcham sandy clay loam soil (r^2 = 0.900) *by multiplying the mean 20 ºC degradation rate by the FOCUS default of 2.2

	DT_{50lab} (20 °C, anaerobic): < 1 day for conversion of triclopyr BEE to triclopyr; triclopyr degradation slow over 365 days under study conditions, rate not calculated.
	Soil photolysis Triclopyr DT_{50lab}: 39.8 days (n = 1 soil) TCP DT_{50lab}: 16.35 days (n = 1 soil)
	degradation in the saturated zone: Not determined and no data required.
Field studies ‡ (state location, range or median with n value)	DT_{50f} Crimplesham, Norfolk, UK: Triclopyr BEE $DT_{50field}$: could not be determined reliably due to rapid degradation, (at t=0 < 2% of theoretical dose was measured as the ester in soil). Triclopyr $DT_{50field}$: 46.32 days (n = 1, First order Timme-Frehse, r^2 = 0.9829) TCP $DT_{50field}$ 63.09 days (n = 1, First order Timme-Frehse, r^2 = 0.9853) St. Nicolas De La Grave, Southern France: Triclopyr BEE $DT_{50field}$: could not be determined due to rapid degradation. Triclopyr $DT_{50field}$: 6.94 days (n = 1, Square root 1st order Timme-Frehse, r^2 = 0.7597) TCP $DT_{50field}$ 30.24 days (n = 1, Square root 1.5th order Timme-Frehse, r^2 = 0.9615) Muche/Kirschgarten, Nieder Ohmen, Germany: Triclopyr BEE $DT_{50field}$: could not be determined due to rapid degradation. Triclopyr $DT_{50field}$: 12.19 days (n = 1, 1.5th order Timme-Frehse, r^2 = 0.9433) TCP $DT_{50field}$ 67.83 days (n = 1, First order Timme-Frehse, r^2 = 0.9688) Herford, Germany: Triclopyr BEE $DT_{50field}$: could not be determined due to rapid degradation. Triclopyr $DT_{50field}$: 53.85 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9545) TCP $DT_{50field}$ 76.51 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9324)

St. Amand Longpre, Loir-et-Cher, Northern France: Triclopyr BEE $DT_{50field}$: could not be determined due to rapid degradation. Triclopyr $DT_{50field}$: 35.08 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9428) TCP $DT_{50field}$ 57.89 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9747)
DT_{90f} Crimplesham, Norfolk, UK Triclopyr BEE $DT_{90field}$: could not be determined reliably due to rapid degradation, (at t=0 < 2% of theoretical dose was measured as the ester in soil). Triclopyr $DT_{90field}$: 153.90 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9829) TCP $DT_{90field}$ 209.6 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9853) St. Nicolas De La Grave, Southern France: Triclopyr BEE $DT_{90field}$: could not be determined due to rapid degradation. Triclopyr $DT_{90field}$: 76.57 days (n = 1, Square root 1st order Timme-Frehse, r^2 = 0.7597) TCP $DT_{90field}$ 281.5 days (n = 1, Square root 1.5th order Timme-Frehse, r^2 = 0.9615) Muche/Kirschgarten, Nieder Ohmen, Germany: Triclopyr BEE $DT_{90field}$: could not be determined due to rapid degradation. Triclopyr $DT_{90field}$: 63.64 days (n = 1, 1.5th order Timme-Frehse r^2 = 0.9433) TCP $DT_{90field}$ 225.3 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9688)

	Herford, Germany: Triclopyr BEE $DT_{90field}$: could not be determined due to rapid degradation. Triclopyr $DT_{90field}$: 178.89 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9545) TCP $DT_{90field}$ 254.1 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9324) St. Amand Longpre, Loir-et-Cher, Northern France: Triclopyr BEE $DT_{90field}$: could not be determined due to rapid degradation. Triclopyr $DT_{90field}$: 116.53 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9428) TCP $DT_{90field}$ 192.3 days (n = 1, 1st order Timme-Frehse, r^2 = 0.9747)
Soil accumulation and plateau concentration ‡	Triclopyr BEE and metabolites will not accumulate in soil.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡	Triclopyr BEE: It was not possible to calculate meaningful sorption data for triclopyr BEE because of very rapid degradation in soil. Triclopyr in European soils: K_f: not determined K_{foc}: not determined 1/n: not applicable K_d: 0.45-1.3 (mean = 0.91, 4 soils) K_{oc}: 40.55-59.3 (mean = 47.65, 4 soils, appropriate for use in FOCUS modelling) Triclopyr in USA soils: K_f: 0.165-0.975 mL/g (mean = 0.61 mL/g, 4 soils) K_{foc}: 24.6-134.5 mL/g (mean = 59.4 mL/g, 4 soils) 1/n: 0.481-0.806 (mean = 0.628, 4 soils) K_d: not reported K_{oc}:not reported [K_{foc} = K_f normalised to organic carbon content, K_{oc} = K_d normalised to organic carbon content]

	TCP in European soils K_f: 0.683-6.40 mL/g (mean = 2.36 mL/g, 5 soils) K_{foc}: 50.9-148.8 mL/g (mean = 91.7 mL/g, 5 soils, appropriate for use in FOCUS modelling) 1/n: 0.75-0.89 (mean = 0.81, 5 soils, appropriate for use in FOCUS modelling) K_d: 1.21-13.6 mL/g (mean = 4.55 mL/g, 5 soils) K_{oc}: 68.0-316.3 mL/g (mean = 172.38 mL/g, 5 soils)
pH dependence ‡ (yes / no) (if yes type of dependence)	No soil pH dependence identified in TCP studies. No clear soil pH dependence identified in triclopyr studies, though pKa indicates some dependence might be expected

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

Column leaching ‡	A laboratory column leaching study showed that triclopyr BEE did not leach after application. Triclopyr was found in the leachate.
Aged residues leaching ‡	Guideline: German BBA. Aged for (d): up to 124 days Triclopyr was found in the leachate (4.5%) after 124 days. TCP and another unknown component, in addition to non-extractable radioactivity, were also found in the aged leachate samples (≤ 2.8% of leachate radioactivity).
Lysimeter/ field leaching studies‡	Location: Dow AgroSciences Letcombe laboratory, UK Study type: lysimeter Number of applications: 1 (2 lysimeters, numbered 23 and 24) made in June in the first year only. Application rate: 2.63 kg a.s./ha and 3.06 kg a.s./ha (triclopyr BEE), or 1.89 kg a.e./ha and 2.20 kg a.e./ha (triclopyr) were achieved for lysimeters 23 and 24, respectively. Average annual rainfall (mm): Total precipitation (natural and artificial) was 925 mm and 972 mm for year 1 and 2 respectively. Average annual leachate volume (L): Volume of representative combined sample for year 1 was 3.45 L for lysimeter 23 and 4.32 L for lysimeter 24, volume of representative combined sample for year 2 was 3.42 L for lysimeter 23 and 3.58 L for lysimeter 24.

	% radioactivity in leachate (maximum/year): Lysimeter 23 (composition of representative leachates): Triclopyr BEE: year 1 and 2, not detected Triclopyr: year 1 0.07 µg/L, year 2 0.07 µg/L TCP: year 1 0.06 µg/L, year 2 0.03 µg/L Oxamic acid+short chain acids year 1 0.51 µg/L, year 2 0.46 µg/L Lysimeter 24 (composition of representative leachates): Triclopyr BEE: year 1 and 2, not detected Triclopyr: year 1 0.03 µg/L, year 2 0.03 µg/L TCP: year 1 0.02 µg/L, year 2 0.02 µg/L Oxamic acid+short chain acids year 1 0.45 µg/L, year 2 0.58 µg/L

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Triclopyr BEE (applied substance) Method of calculation	Kinetics: first order DT_{50}: 1 day (inferred from laboratory soil metabolism and field dissipation studies) Soil depth: 5 cm
Application rate	Crop: grass/ % plant interception: none (application to bare ground assumed as worst case) Number of applications: 1 Application rate: 2002 g/ha (lumped application)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.67	na	na	na
Short term 4h	1.33	1.93	na	na
2d	0.667	1.44	na	na
4d	0.167	0.903	na	na
Long term 7d	0.0209	0.546	na	na
28d	<0.0001	0.138	na	na
50d	<0.0001	0.0770	na	na
100d	<0.0001	0.0385	na	na

Triclopyr (active substance) Method of calculation	Kinetics: first order DT_{50}: 54 days (longest value from field studies) Soil depth: 5 cm
Application rate	Crop: grass/ % plant interception: none (application to bare ground assumed as worst case) Number of applications: 1 Application rate: 2002 g/ha of triclopyr BEE (with 100% conversion to triclopyr assumed) [Effective application rate of 1440 g/ha for triclopyr.]

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.92	na	na	na
Short term 24h	1.90	1.91	na	na
2d	1.87	1.90	na	na
4d	1.82	1.87	na	na
Long term 7d	1.76	1.84	na	na
28d	1.34	1.61	na	na
50d	1.01	1.42	na	na
100d	0.532	1.08	na	na

Metabolites

TCP (metabolite) Method of calculation	Kinetics: first order DT_{50}: 77 days (longest value from field studies) Soil depth: 5 cm
Application rate	Crop: grass % plant interception: none (application to bare ground assumed as worst case) Number of applications: 1 Application rate: 2002 g/ha of triclopyr BEE (with TCP assumed to form at a maximum of 33% of the applied dose) [Effective application rate of 367.6 g/ha for TCP.]

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.490	na	na	na
Short term 24h	0.486	0.488	na	na
2d	0.481	0.486	na	na
4d	0.473	0.481	na	na
Long term 7d	0.460	0.475	na	na
28d	0.381	0.433	na	na
50d	0.312	0.395	na	na
100d	0.199	0.323	na	na

[An absolute worst-case PEC_S value for TCP can be calculated by assuming 100% conversion of triclopyr BEE to triclopyr and 100% conversion of triclopyr to TCP. Using these assumptions, an application of triclopyr BEE corresponding to the yearly maximum dose of 2.002 kg/ha would give a TCP concentration of 1.49 mg/kg soil, based on a soil depth of 5 cm, a soil bulk density of 1.5 g/cm^3 and molecular weights (g/mole) of 356.6 for triclopyr BEE, 256.5 for triclopyr and 198.4 for TCP.]

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	Triclopyr BEE (pH 5.0) DT_{50} (15 °C): 208.8 days (first-order, r^2 = 0.94) DT_{50} (25 °C): 84.0 days (first-order, r^2 = 0.99) DT_{50} (35 °C): 25.9 days (first-order, r^2 = 0.99)
	Triclopyr BEE (pH 7.0) DT_{50} (15 °C): 25.5 days (first-order, r^2 = 0.99) DT_{50} (25 °C): 8.7 days (first-order, r^2 = 0.99) DT_{50} (35 °C): 2.3 days (first-order, r^2 = 0.99)
	Triclopyr BEE (pH 9.0) DT_{50} (15 °C): 1.7 days (first-order, r^2 = 0.99) DT_{50} (25 °C): 0.3 days (first-order, r^2 = 0.99) DT_{50} (35 °C): 0.06 days (first-order, r^2 = 0.99) Triclopyr BEE (pH 6.7) DT_{50} (25 °C): 0.5 days (natural water, hydrolysis at 25 °C only) (first-order, r^2 = 0.99)
	The relevant metabolite, triclopyr, is hydrolytically stable in sterile aqueous solutions between pH 4 and pH 9 at ambient environmental temperatures. TCP is assumed to be similarly stable.

Photolytic degradation of active substance and relevant metabolites ‡	Triclopyr BEE DT_{50} = 6.6 days (autumn, 37.5 °N, 24.5 °C, sterile pH 5 buffer solution) (first order, r^2 = 0.99) or 4 hours in natural river water (corrected for hydrolysis, summer, 40 °N, 25 °C or 3.1 hours, including hydrolysis, pH 8.4 unbuffered). Triclopyr DT_{50} = 0.32 days (summer, 40 °N, 25 °C, sterile pH 7 phosphate buffer) (first order); 0.92 days (summer, 40 °N, 25 °C, natural water). In natural water oxamic acid was formed at a maximum 16%AR. TCP DT_{50} = 5.4 minutes (summer, 40 °N, 25 °C, sterile pH 7 phosphate buffer, 1 m depth); 2.0 hours (summer, 40 °N, 25 °C, river water, 1 m depth). (Published, non GLP study)
Readily biodegradable (yes/no)	Not readily biodegradable (modified test available)
Degradation in water/sediment - DT_{50} water ‡	A non-linear, first order exponential regression was used to model the decline of triclopyr BEE and the rise and decline of total triclopyr and TCP. Triclopyr BEE DT_{50} 0.77 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.923-0.980) Triclopyr DT_{50} 23.90 to 25.67 days (mean = 24.785) (non-linear first order fit, n = 2, r^2 = 0.923 to 0.980) TCP DT_{50} 18.24 to 27.72 days (mean = 22.98) (non-linear first order fit, n = 2, r^2 = 0.923 to 0.980)
- DT_{90} water ‡	Triclopyr BEE DT_{90} 2.55 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.923-0.980) Triclopyr DT_{90} 79.39 to 85.28 days (mean = 82.335) (non-linear first order fit, n = 2, r^2 = 0.923 to 0.980) TCP DT_{90} 60.59 to 92.10 days (mean = 76.345) (non-linear first order fit, n = 2, r^2 = 0.923 to 0.980)

- DT_{50} whole system ‡	Triclopyr BEE DT_{50} 0.77 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.958-0.988) Triclopyr DT_{50} 23.90 to 34.65 days (mean = 29.275) (non-linear first order fit, n = 2, r^2 = 0.958 to 0.988) TCP DT_{50} 19.8 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.958 to 0.988)
- DT_{90} whole system ‡	Triclopyr BEE DT_{90} 2.55 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.958-0.988) Triclopyr DT_{90} 79.39 to 115.12 days (mean = 97.255) (non-linear first order fit, n = 2, r^2 = 0.958 to 0.988) TCP DT_{90} 65.78 days (individual and mean) (non-linear first order fit, n = 2, r^2 = 0.958 to 0.988)
Mineralization	0.3% AR to 1.6% AR CO_2
Non-extractable residues	7.8 % AR to 13.0% AR at 106 days (most in fulvic acid)
Distribution in water / sediment systems (active substance) ‡	>90% triclopyr BEE degraded by day 3; most triclopyr BEE in the aqueous phase during the conversion.
Distribution in water / sediment systems (metabolites) ‡	Water phase: Triclopyr, max of 94.9% AR (7 days, n = 2 systems) TCP, max of 19.0% AR (59 days, n = 2 systems) 3,6-dichloro-2-pyridinol, max of 37.8% AR (106 days, n = 2 systems) 6-chloro-2-pyridinol, max of 13.4% AR (59 days, n = 2 systems) Sediment phase: Triclopyr, max of 20.3% AR (59 days, n = 2 systems) TCP, max of 23.2% AR (106 days, n = 2 systems) 3,6-dichloro-2-pyridinol, max of 26.1% AR (59 days, n = 2 systems)

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

Parent

Method of calculation	FOCUS surface water modelling tools: Step 1 and Step 2 calculations performed for triclopyr BEE, triclopyr and TCP (FOCUS_STEPS_ONE_TWO_1.1). Step 3 calculations for triclopyr BEE, triclopyr and TCP (FOCUS_SWASH_1.1, FOCUS_MACRO_4.4.2, FOCUS_PRZM_SW_1.1.1 and FOCUS_TOXWA_1.1.1). Calculations based on average DT_{50} values for soil (determined from aerobic laboratory studies at 20 °C, corrected to pF2 moisture), average water/sediment whole-system DT_{50} values (first order) and averaged sorption data. Calculation of 3,6-dichloro-2-pyridinol in surface water is based on TCP PEC_{max} values in surface water at each FOCUS step corrected for maximum formation of 3,6-dichloro-2-pyridinol in water (37.8%), and molecular weight difference between TCP and 3,6-dichloro-2-pyridinol (MW = 173.984). Calculation of 6-chloro-2-pyridinol in surface water is based on TCP PEC_{max} values in surface water at each FOCUS step corrected for maximum formation of 6-chloro-2-pyridinol in water (13.4%), and molecular weight difference between TCP and 6-chloro-2-pyridinol (MW = 142.563).
Application rate	Spray application to grass/ (winter period used for all calculations) Number of applications: 1 per year Application rate: 2002 g/ha of triclopyr BEE Inputs of triclopyr BEE, triclopyr and TCP were simulated separately as direct application of the substance concerned. Effective application rates for triclopyr and TCP were respectively 1440 g/ha and 372 g/ha.
Main routes of entry	Drainage and runoff (using FOCUS assumptions for Steps 1-2 and relevant FOCUS scenarios for Step 3) Spray drift (2.759% for 1 application to grass in Steps 1-2, automatically supplied by SWASH drift calculator in Step 3).

Maximum and 21-day TWA PEC_{SW} values from Step 1 and Step 2 for triclopyr BEE, triclopyr, TCP, 3,6-dichloro-2-pyridinol, and 6-chloro-2-pyridinol.

Simulation	Compound	Maximum PEC_{SW} (µg/L)	21-day TWA PEC_{SW} (µg/L)
Step 1	Triclopyr BEE	400.5	21.8
	Triclopyr	464.6	364.7
	TCP	104.1	73.5
	3,6-dichoro-2-pyridinol*	34.35	24.25
	6-chloro-2-pyridinol*	10.03	7.08
Step 2 (southern Europe, October-February)	Triclopyr BEE	18.4	1.32
	Triclopyr	110.1	86.4
	TCP	24.7	17.4
	3,6-dichoro-2-pyridinol*	8.15	5.74
	6-chloro-2-pyridinol*	2.38	1.68
Step 2 (northern Europe, October-February)	Triclopyr BEE	18.4	1.43
	Triclopyr	134.8	105.8
	TCP	30.2	21.3
	3,6-dichoro-2-pyridinol*	9.97	7.03
	6-chloro-2-pyridinol*	2.91	2.05

TWA = time-weighted average
Each substance was modelled separately as if it was the applied material.
* Calculated from TCP maximum PECsed values determined at STEPS 1&2 using the FOCUS-SW modelling scheme.

Maximum and 21-day TWA PEC_{SED} values from Step 3 for triclopyr BEE, triclopyr and TCP

Simulation	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
Triclopyr BEE		
1 (D1-ditch)	6.444	2.395
2 (D1-stream)	3.788	0.532
3 (D2-ditch)	4.858	0.898
4 (D2-stream)	0.373	0.033
5 (D3-ditch)	3.511	0.440
6 (D4-pond)	0.271	0.109

Simulation	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
7 (D4-stream)	0.553	0.052
8 (D5-pond)	0.256	0.095
9 (D5-stream)	0.200	0.018
10 (R2-stream)	0.534	0.039
11 (R3-stream)	2.253	0.243
Triclopyr		
12 (D1-ditch)	15.131	14.579
13 (D1-stream)	8.263	8.025
14 (D2-ditch)	23.526	22.522
15 (D2-stream)	11.878	11.416
16 (D3-ditch)	1.227	0.358
17 (D4-pond)	0.674	0.670
18 (D4-stream)	0.580	0.461
19 (D5-pond)	7.854	7.815
20 (D5-stream)	4.002	2.981
21 (R2-stream)	0.290	0.030
22 (R3-stream)	0.836	0.157
TCP		
23(D1-ditch)	8.231	8.016
24 (D1-stream)	4.816	4.419
25 (D2-ditch)	6.263	5.938
26 (D2-stream)	3.049	2.725
27 (D3-ditch)	0.568	0.159
28 (D4-pond)	0.165	0.164
29 (D4-stream)	0.097	0.064
30 (D5-pond)	1.457	1.435
31 (D5-stream)	0.852	0.646
32 (R2-stream)	0.280	0.067
33 (R3-stream)	0.367	0.078

TWA = time-weighted average
Step 3 calculations were not required for triclopyr but were carried out for the sake of completeness.
Each substance was modelled separately as if it was the applied material.
Values expressed on a dry weight basis.

Maximum and 21-day TWA PEC_{SW} values for 3,6-dichloro-2-pyridinol and 6-chloro-2-pyridinol based on maximum percentage formation in surface water from highest step 3 TCP PEC_{SW} value.

Metabolite	TCP scenario and concentration	PECsw maximum µg/L)	TCP scenario and concentration	PECsw 21-day TWA (µg/L)
3,6-dichloro-2-pyridinol*	D2 – ditch (7.996 µg/L)	2.64	D1 – ditch (3.520 µg/L)	1.16
6-chloro-2-pyridinol*	D2 – ditch (7.996 µg/L)	0.77	D1 – ditch (3.520 µg/L)	0.34

* Calculated from TCP maximum PEC_{sw} values determined at STEP 3 using the FOCUS-SW modelling scheme.

Method of calculation	FOCUS surface water modelling tools: Step 1 and Step 2 calculations performed for triclopyr BEE, triclopyr and TCP (FOCUS_STEPS_ONE_TWO_1.1). Step 3 calculations for triclopyr BEE, triclopyr and TCP (FOCUS_SWASH_1.1, FOCUS_MACRO_4.4.2,FOCUS_PRZM_SW_1.1.1 and FOCUS_TOXWA_1.1.1). Entry routes: drainage and runoff (using FOCUS assumptions for Steps 1-2 and relevant FOCUS scenarios for Step 3) Spray drift (2.759% for 1 application to grass in Steps 1-2, automatically supplied by SWASH drift calculator in Step 3). Calculations based on average DT_{50} values for soil (determined from aerobic laboratory studies at 20 °C, corrected to pF2 moisture), average water/sediment whole-system DT_{50} values (first order) and averaged sorption data. Calculation of 3,6-dichloro-2-pyridinol in sediment is based on TCP PEC_{max} values in sediment at each FOCUS step corrected for maximum formation of 3,6-dichloro-2-pyridinol in sediment (26.1%), and molecular weight difference between TCP and 3,6-dichloro-2-pyridinol.

Application rate	Spray application to grass/ (winter period used for all calculations) Number of applications: 1 per year Application rate: 2002 g/ha of triclopyr BEE Inputs of triclopyr BEE, triclopyr and TCP were simulated separately as direct application of the substance concerned. Effective application rates for triclopyr and TCP were respectively 1440 g/ha and 372 g/ha.

Maximum and 21 day TWA PEC_{SED} values from Step 1 and Step 2 for triclopyr BEE, triclopyr, TCP, and 3,6-dichloro-2-pyridinol.

Simulation	Compound	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
Step 1	Triclopyr BEE	2.14×10^3	119.5
	Triclopyr	214.8	173.4
	TCP	175.1	127.7
	3,6-dichoro-2-pyridinol*	39.90	29.10
Step 2 (southern Europe, October-February)	Triclopyr BEE	33.3	1.89
	Triclopyr	51.1	40.2
	TCP	41.4	30.3
	3,6-dichoro-2-pyridinol*	9.43	6.90
Step 2 (northern Europe, October-February)	Triclopyr BEE	41.4	2.35
	Triclopyr	62.5	49.2
	TCP	51.1	37.1
	3,6-dichoro-2-pyridinol*	11.64	8.45

TWA = time-weighted average
Each substance was modelled separately as if it was the applied material.
Values expressed on a dry weight basis.
* Calculated from TCP maximum PECsed values determined at STEPS 1&2 using the FOCUS-SW modelling scheme.

Maximum and 21-day TWA PEC_{SED} values from Step 3 for triclopyr BEE, triclopyr and TCP

Simulation	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
Triclopyr BEE		
1 (D1-ditch)	6.444	2.395
2 (D1-stream)	3.788	0.532
3 (D2-ditch)	4.858	0.898
4 (D2-stream)	0.373	0.033
5 (D3-ditch)	3.511	0.440
6 (D4-pond)	0.271	0.109
7 (D4-stream)	0.553	0.052
8 (D5-pond)	0.256	0.095
9 (D5-stream)	0.200	0.018
10 (R2-stream)	0.534	0.039
11 (R3-stream)	2.253	0.243
Triclopyr		
12 (D1-ditch)	15.131	14.579
13 (D1-stream)	8.263	8.025
14 (D2-ditch)	23.526	22.522
15 (D2-stream)	11.878	11.416
16 (D3-ditch)	1.227	0.358
17 (D4-pond)	0.674	0.670
18 (D4-stream)	0.580	0.461
19 (D5-pond)	7.854	7.815
20 (D5-stream)	4.002	2.981
21 (R2-stream)	0.290	0.030
22 (R3-stream)	0.836	0.157
TCP		
23(D1-ditch)	8.231	8.016
24 (D1-stream)	4.816	4.419
25 (D2-ditch)	6.263	5.938
26 (D2-stream)	3.049	2.725
27 (D3-ditch)	0.568	0.159
28 (D4-pond)	0.165	0.164
29 (D4-stream)	0.097	0.064

Simulation	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
30 (D5-pond)	1.457	1.435
31 (D5-stream)	0.852	0.646
32 (R2-stream)	0.280	0.067
33 (R3-stream)	0.367	0.078

TWA = time-weighted average
Step 3 calculations were not required for triclopyr but were carried out for the sake of completeness.
Each substance was modelled separately as if it was the applied material.
Values expressed on a dry weight basis.

Maximum and 21-day TWA PEC_{SED} values for 3,6-dichloro-2-pyridinol based on maximum percentage formation from highest step 3 TCP PEC_{SED} value.

Metabolite	TCP scenario and concentration	PECsw maximum µg/kg)	TCP scenario and concentration	PECsw 21-day TWA (µg/kg)
3,6-dichloro-2-pyridinol*	D1 – ditch (8.231 µg/L)	1.88	D1 – ditch (8.016 µg/L)	1.83

* Calculated from TCP maximum PECsed values determined at STEP 3 using the FOCUS-SW modelling scheme.

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Modelling runs with the FOCUS-PELMO and FOCUS-PEARL models. The effect of different monthly and seasonal application dates was examined for all nine European standard scenarios using a grass crop. Triclopyr BEE was assumed to convert to triclopyr on a one-to-one molar basis, which was in turn converted to TCP (PELMO one-to-one molar basis, PEARL 1-to-0.26 molar basis) which subsequently converted to CO_2 and other minor products. The temperature correction factor, Q10, was set to the recommended values of 2.2. For triclopyr BEE, triclopyr and TCP, the normalized (20°C, -10 kPa (pF2) DT_{50} values used were 1, 31.5 and 31.2 days, respectively. The recommended Walker equation moisture correction factor of 0.7 was used for all the simulations. The Koc used were 560mL/g, 47.6 mL/g and 174 mL/g for triclopyr BEE, triclopyr and TCP, respectively. The FOCUS default Freundlich isorption isotherm exponent of 0.9 was used.

Application rate	2.002 kg triclopyr BEE/ha with 90% crop interception assumed (i.e. 0.2002kg triclopyr BEE to soil/ha) Application regime: single lumped application each year for 20 consecutive years. Time of application: Since application can be made at any time of year, application in each month (15th) was simulated separately for each scenario in PELMO, i.e. 12 independent simulations for each scenario. For PEARL simulations were conducted for each season on the 15th of each month for spring (Apr.), summer (Jul.), autumn (Oct.), and winter (Jan.), i.e. 4 independent simulations for each scenario.
$PEC_{(gw)}$	
Maximum concentration	The 80th percentile annual average concentrations based upon 20 years of applications were calculated. FOCUS-PELMO: The maximum occurred for the September Piacenza scenario (1.317 µg triclopyr/L). FOCUS-PEARL: The maximum occurred for the autumn (October) Piacenza scenario (1.749 µg triclopyr/L).
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	In all simulations triclopyr BEE annual average concentrations were <0.1µg/L. FOCUS-PELMO: From January to May, and December annual average concentrations from each month for all 9 scenarios yielded concentrations <0.1 µg/L for Triclopyr. For July to November annual average concentrations from each month for all 9 scenarios yielded concentrations >0.1 µg/L for Triclopyr. For all months, except September, annual average concentrations from each of the 11 months for all 9 scenarios yielded concentrations <0.1 µg/L for TCP. FOCUS-PEARL: For each season simulated using PEARL, annual average concentrations from each month (Jan., Apr., Jul., and Oct.) for all 9 scenarios yielded concentrations >0.1 µg/L for Triclopyr For each month (Jan., Apr., Jul., and Oct.) representing each season, annual average concentrations from each month for all 9 scenarios yielded concentrations <0.1 µg/L for TCP.

Annual average 80th percentile PEC_{GW} values (µg/L) for triclopyr and TCP calculated using FOCUS_PELMO_3.3.2

Scenario	January 15		February 15		March 15		April 15	
	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP
Châteaudun (irrigated)	0.018	0.005	0.011	0.004	0.017	0.006	0.019	0.006
Hamburg	0.017	0.007	0.020	0.009	0.036	0.013	0.032	0.014
Jokioinen	0.003	0.001	0.003	0.001	0.015	0.004	0.047	0.012
Kremsmünster	0.031	0.009	0.025	0.011	0.067	0.021	0.077	0.024
Okehampton	0.099	0.042	0.087	0.028	0.135	0.044	0.147	0.047
Piacenza (irrigated)	0.208	0.110	0.160	0.072	0.199	0.083	0.214	0.083
Porto	0.002	0.001	0.001	0.000	0.001	0.000	0.001	0.000
Sevilla (irrigated)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Thiva (irrigated)	0.005	0.002	0.002	0.001	0.001	0.001	0.003	0.001
Number ≤0.1 µg/L	8	8	8	9	7	9	7	9

Scenario	May 15		June 15		July 15		August 15	
	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP
Châteaudun (irrigated)	0.024	0.009	0.028	0.011	0.041	0.016	0.044	0.017
Hamburg	0.051	0.022	0.098	0.039	0.122	0.038	0.203	0.067
Jokioinen	0.071	0.018	0.103	0.026	0.143	0.037	0.191	0.054
Kremsmünster	0.110	0.037	0.169	0.044	0.210	0.069	0.210	0.067
Okehampton	0.167	0.056	0.201	0.081	0.252	0.094	0.439	0.129
Piacenza (irrigated)	0.269	0.101	0.373	0.118	0.798	0.228	1.146	0.350
Porto	0.001	0.000	0.001	0.000	0.002	0.001	0.006	0.001
Sevilla (irrigated)	0.000	0.000	0.001	0.000	0.001	0.000	0.005	0.001
Thiva (irrigated)	0.005	0.002	0.014	0.005	0.024	0.010	0.057	0.027
Number ≤0.1 µg/L	6	8	5	8	4	8	4	7

Scenario	September 15		October 15		November 15		December 15	
	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP
Châteaudun (irrigated)	0.058	0.022	0.049	0.021	0.037	0.015	0.024	0.011
Hamburg	0.232	0.063	0.200	0.063	0.146	0.044	0.079	0.022
Jokioinen	0.205	0.058	0.140	0.042	0.060	0.017	0.008	0.002
Kremsmünster	0.210	0.082	0.174	0.056	0.084	0.041	0.050	0.023
Okehampton	0.504	0.172	0.557	0.189	0.398	0.116	0.323	0.087
Piacenza (irrigated)	1.317	0.486	0.665	0.356	0.377	0.201	0.276	0.173
Porto	0.017	0.004	0.023	0.005	0.015	0.004	0.007	0.002
Sevilla (irrigated)	0.005	0.001	0.009	0.002	0.011	0.002	0.001	0.001
Thiva (irrigated)	0.107	0.047	0.180	0.059	0.047	0.019	0.018	0.006
Number ≤0.1 µg/L	3	7	3	7	6	7	7	8

Hamburg values were recalculated by the notifier using application mode 1 (application to soil), with an application input of 0.2002 kg/ha of triclopyr BEE.

Annual average 80th percentile PEC_{GW} values (µg/L) for triclopyr and TCP calculated using FOCUS_PEARL_2.2.2

Scenario	January 15		April 15		July 15		October 15	
	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP	Triclopyr	TCP
Châteaudun (irrigated)	0.194	0.015	0.163	0.013	0.221	0.018	0.287	0.025
Hamburg	0.455	0.036	0.358	0.032	0.642	0.058	1.036	0.093
Jokioinen	0.160	0.010	0.156	0.009	0.290	0.018	0.422	0.024
Kremsmünster	0.242	0.021	0.226	0.021	0.399	0.034	0.462	0.036
Okehampton	0.481	0.034	0.345	0.030	0.602	0.042	1.059	0.093
Piacenza (irrigated)	1.083	0.127	0.614	0.069	1.122	0.089	1.749	0.209
Porto	0.007	0.000	0.002	0.000	0.011	0.000	0.055	0.003
Sevilla (irrigated)	0.060	0.005	0.054	0.003	0.108	0.006	0.314	0.023
Thiva (irrigated)	0.089	0.006	0.063	0.004	0.155	0.013	0.535	0.080
Number ≤0.1 µg/L	3	8	3	9	1	9	1	8

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

Direct photolysis in air ‡		Not determined – no data requested.
Quantum yield of direct phototransformation		Not determined in air
Photochemical oxidative degradation in air ‡		Triclopyr BEE DT_{50}: 5.6 hours (Atkinson method, AOP v. 1.89), OH radical concentration 1.5×10^6 radicals/cm^3 (12 h concentration) Triclopyr DT_{50}: 26.5 hours (Atkinson method, AOP v. 1.89), OH radical concentration 1.5×10^6 radicals/cm^3 (12 h concentration)
Volatilizatio:	from plant surfaces:	Experimental data suggest a volatilisation loss of triclopyr BEE from leaf surfaces of approximately 0.27% over a 24-hour period.
	from soil:	Experimental data suggest a volatilisation loss of triclopyr BEE from the soil surface of approximately 0.58% over a 24-hour period. For triclopyr, the volatilisation loss from soil was estimated to 0.031% of the applied amount within 24 hours after treatment (Dow method).

PEC (air)

Method of calculation	Expert judgement based on vapour pressure, Henry's Law Constant, photochemical oxidative half-life in air, experimental data on volatilisation loss for triclopyr BEE and, for triclopyr, "Dow method" estimation of volatilisation loss.

$PEC_{(a)}$

Maximum concentration	Not calculated since no agreed method available. Not used in the assessment

Definition of the Residue (Annex IIA, point 7.3)

	Soil Triclopyr BEE, Triclopyr and its salts, and TCP Surface water Triclopyr BEE, Triclopyr and its salts, TCP, 3,6-dichloro-2-pyridinol, and 6-chloro-2-pyridinol, Oxamic acid Sediment Triclopyr and its salts, TCP, and 3,6-dichloro-2-pyridinol. Ground water Triclopyr and its salts and TCP Air Triclopyr BEE and Triclopyr

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

Soil (indicate location and type of study)	No monitoring studies have been conducted for triclopyr BEE, however, Dow AgroSciences contracted with WRc plc Medmenham to survey the available water information.
Surface water (indicate location and type of study)	Not detected in 300 surface water monitoring samples in Germany. The UK surface water monitoring program reported 85 detections out of 3833 samples and 2 out of 1249 drinking water samples.
Ground water (indicate location and type of study)	Not found in over 500 groundwater samples in Germany. UK data show 11 detections out of 1683 total groundwater samples (from >4 sites) with only one sample >0.1 µg/L (maximum concentration of 0.36 µg/L).
Air (indicate location and type of study)	No monitoring data.

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	R53 proposed (May cause long-term adverse effects in the aquatic environment)

Appendix 1.6: Effects on non-target Species

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

Acute & Long-term toxicity to mammals	Rat: Triclopyr BEE → LD_{50} 803 mg/kg Triclopyr → LD_{50} 630 mg a.s./kg 3,5,6-TCP → LD_{50} 794 mg/kg Garlon 4 → LD_{50} 842 mg triclopyr BEE/kg Triclopyr BEE → NOAEL 5 mg/kg bw/day Triclopyr → NOAEL 25 mg as/kg bw/day 3,5,6-TCP → NOAEL 30 mg/kg bw/day
Acute toxicity to birds	Mallard Duck : Triclopyr BEE → LD_{50} > 4640 mg/kg bw Triclopyr → LD_{50} 1698 mg a.s./kg bw
	Bobwhite Quail: Triclopyr BEE → LD_{50} 735 mg/kg bw 3,5,6-TCP → LD_{50} >2000 mg/kg bw Garlon 4 → LD_{50} 849 mg triclopyr BEE /kg bw
Dietary toxicity to birds	Mallard Duck : Triclopyr BEE → LC_{50} >5401mg/kg diet Triclopyr → LC_{50} >5620mg a.s./kg diet 3,5,6-TCP → LC_{50} >5620mg/kg diet (>1027 mg/kg bw/day)
	Bobwhite Quail: Triclopyr BEE → LC_{50} 5401 mg/kg diet (1890 mg/kg bw/day) Triclopyr → LC_{50} 2935 mg a.s./kg diet (1027 mg/kg bw/day)
Reproductive toxicity to birds	Triclopyr → NOEC 200 mg a.s./kg diet (Mallard Duck) (30 mg/kg bw/day)
	Triclopyr → NOEC 500 mg a.s./kg diet (Bobwhite Quail)

Acute Toxicity/exposure ratios for Birds (Annex IIIA, points 10.1 and 10.3)

Food type	ETE (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Triclopyr BEE			
Short grass	125.08	735	5.88
Insects	108.26	735	6.79
Triclopyr			
Short grass	89.97	1698	18.87
Insects	77.88	1698	21.80

Acute Refined Risk Assessment for herbivorous Birds (Triclopyr BEE)

Food type	ETE (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Short grass	144.68*	735	11.5

* 90^{th} percentile residue concentration

Short-term toxicity risk for birds

Food type	ETE (mg/kg bw)	LD_{50} (mg/kg bw)	TERst
Triclopyr BEE			
Short grass	66.95	1890	28
Insects	60.38	1890	31
Triclopyr			
Short grass	48.15	1027	21
Insects	43.43	1027	24
3,5,6-TCP			
Short grass	12.44	>1967	158
Insects	11.22	>1967	175

Long-term toxicity risk (Triclopyr) for birds

Food type	ETE (mg ae/kg diet)	NOEC (mg as/kg bw/day)	TER_{LT}
Short grass	25.52	30	1.2
Insects	43.43	30	0.7

Acute toxicity exposure ratios for mammals

Food type	ETE (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Triclopyr BEE			
Short grass	395.16	803	2.03
Triclopyr			
Short grass	284.23	630	2.22

Refined* Acute Toxicity exposure ratios

Food type	ETE (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Triclopyr BEE			
Short grass	201.1	803	3.99
Triclopyr			
Short grass	144.68	630	4.35

* based on levels of measured residues from field trials

Long-term toxicity exposure ratios for mammals exposed to triclopyr BEE and Triclopyr acid.

Food type	ETE (mg/kg bw/day)	NOAEL (mg/kg bw/day)	TER_{LT}
Triclopyr			
Short grass	80.62	25	0.31
Triclopyr BEE			
Short grass	112.09	5	0.04

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

Acute Toxicity Endpoints (µg/L)				
Test compound	Fish	Inverts	Algae	Aquatic Plants
Triclopyr BEE	310	660	193	2200
Triclopyr	117000	>131000	75800	-
3,5,6-TCP	12500	10400*	610	8750
Garlon 4	441	300	1104	-

Chronic Toxicity Endpoints (µg/L)				
Test Compound	Fish	Inverts	Algae	Aquatic Plants
Triclopyr BEE	26.3	1600	-	-
Triclopyr	46300	48500	-	-
3,5,6-TCP	80.8	58	-	-

* A lower value of 9.3 mg 3,5,6-TCP/L for *Crassostrea virginica* is available in the DAR.

Toxicity to Sediment Dwelling Organisms (Triclopyr BEE)

Midge *Chironomus riparius*	NOEC = 23mg as/L

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

Location Compound	PECsw (µg/L)	Acute Toxicity Endpoint µg/l				Acute TER				Critical TER
		Fish	Inverts	Algae	Plants	Fish	Inverts	Algae	Plants	
Step 1										
Southern and Northern Europe										
Triclopyr BEE	400.5	270	190	193	2200	0.7	0.47	0.48	5.49	100 or 10 [a]
Triclopyr	464.6	117000	>131000	75800	-	251.8	>282	163.15	-	100 or 10 [a]
TCP	104.1	12500	10400	610	8750	120.1	100	99.9	84.05	100 or 10 [a]
Step 2										
Northern Europe → October – February										
Triclopyr BEE	18.4	270	190	193	2200	14.7	10.32	10.49	119.56	100 or 10 [a]
Triclopyr	134.8	117000	>131000	75800	-	131.4	>972	562.31	-	100 or 10 [a]
TCP	30.2	12500	10400	610	8750	413.8	344.3	20.19	289.74	100 or 10 [a]
Southern Europe → October – February										
Triclopyr BEE	18.4	270	190	193	2200	14.7	10.32	10.49	119.56	100 or 10 [a]
Triclopyr	110.1	117000	>131000	75800	-	1062.4	>1190	688.47	-	100 or 10 [a]
TCP	24.7	12500	10400	610	8750	506.5	421.4	24.69	354.25	100 or 10 [a]

Location Compound	PECsw (µg/L)	Acute Toxicity Endpoint µg/l				Acute TER				Critical TER
		Fish	Inverts	Algae	Plants	Fish	Inverts	Algae	Plants	
Step 3										
Triclopyr BEE										
D1 - Ditch	12.836					21	15	15.0	171.39	
D1 - Stream	11.225					24	17	17.2	195.99	
D2 - Ditch	12.719					21	15	15.2	172.97	
D2 - Stream	9.830					27	19	19.6	223.80	
D3 - Ditch	12.635	270	190	193	2200	24	15	15.3	174.12	100 or 10 [a]
D4 - Pond	0.438					616	434	440.6	5022.8	
D4 - Stream	10.234					26	19	18.9	214.97	
D5 - Pond	0.438					616	434	440.6	5022.8	
D5 - Stream	9.611					28	20	20.1	228.90	
R2 - Stream	10.900					25	17	17.7	201.83	
R3 - Stream	11.814					23	16	16.3	186.22	
Triclopyr										
D1 - Ditch	15.556					7521	>8421	4872.7	-	
D1 - Stream	9.789					11952	>13382	7743.4	-	
D2 - Ditch	94.095					1243	>1392	805.6	-	
D2 - Stream	60.123					1946	>2179	1260.8	-	
D3 - Ditch	9.115	117000	>131000	75800	-	12836	>14372	8316.0	-	100 or 10 [a]
D4 - Pond	0.467					250535	>281	16213	-	
D4 - Stream	7.389						>17729	10259	-	
D5 - Pond	7.732					15834	>16943	9803.4	-	
D5 - Stream	17.748					15132	>7381	4270.9	-	
R2 - Stream	7.846					6592	>16696	9661.0	-	
R3 - Stream	8.505					14912	>15402	9812.4	-	
						13757				
TCP										
D1 - Ditch	4.302					2906	2417	141.8	2034	
D1 - Stream	2.689					4649	3868	226.9	3254	
D2 - Ditch	7.996					1563	1301	76.3	1094.3	
D2 - Stream	5.301					2358	1962	115.1	1650.6	
D3 - Ditch	2.349	12500	10400	610	8750	5321	4427	259.7	3724.9	100 or 10 [a]
D4 - Pond	0.081					154321	128395	7530.9	108024	
D4 - Stream	1.904						5462	320.4		
D5 - Pond	0.806					6565	12903	756.8	4595.5	
D5 - Stream	1.906					15509	5456	320.0	10856	
R2 - Stream	2.028					6558	5128	300.8	4590.8	
R3 - Stream	2.198					6164	4732	277.5	4314.6	
						5687			3980.9	

Longterm toxicity exposure ratios for Triclopyr BEE, Triclopyr and TCP

Substance Triclopyr BEE		Chronic Endpoint		Critical TER
		Fish	Invertebrate	
		Critical Endpoints (µg/L)		
		26.3	1600	
Location	Global Max (µg/L)	TERlt (Global Max Basis)		
D1 - Ditch	12.836	2	125	10
D1 - Stream	11.225	2	143	10
D2 - Ditch	12.719	2	126	10
D2 - Stream	9.830	3	163	10
D3 - Ditch	12.635	2	127	10
D4 - Pond	0.438	60	3653	10
D4 - Stream	10.234	3	156	10
D5 - Pond	0.438	60	3653	10
D5 - Stream	9.611	3	166	10
R2 - Stream	10.900	2	147	10
R3 – Stream	11.814	2	135	10
Triclopyr		Chronic Endpoint		Critical TER
		Fish	Invertebrate	
		Critical Endpoints (µg/L)		
		46300	48500	
Location	Global Max (µg/L)	TERlt (Global Max Basis)		
D1 - Ditch	15.556	2976	3118	10
D1 - Stream	9.789	4730	4955	10
D2 - Ditch	94.095	492	515	10
D2 - Stream	60.123	770	807	10
D3 - Ditch	9.115	5080	5321	10
D4 - Pond	0.467	99143	103854	10
D4 - Stream	7.389	6266	6564	10
D5 - Pond	7.732	5988	6273	10
D5 - Stream	17.748	2609	2733	10
R2 - Stream	7.846	5901	6181	10
R3 – Stream	8.505	5444	5703	10

TCP		Chronic Endpoint		Critical TER
		Fish	Invertebrate	
		Critical Endpoints (µg/L)		
		80.8	58	
Location	Global Max (µg/L)	TER (Global Max Basis)		
D1 - Ditch	4.302	19	13	10
D1 - Stream	2.689	30	22	10
D2 - Ditch	7.996	10	7	10
D2 - Stream	5.301	15	11	10
D3 - Ditch	2.349	34	25	10
D4 - Pond	0.081	998	716	10
D4 - Stream	1.904	42	30	10
D5 - Pond	0.806	100	72	10
D5 - Stream	1.906	42	30	10
R2 - Stream	2.028	40	29	10
R3 - Stream	2.198	37	26	10

Bioconcentration

Bioconcentration factor (BCF) ‡	Triclopyr BEE → BCF = 110 Triclopyr → BCF = 0.77 3,5,6-TCP → BCF = 3.21
Annex VI Trigger:for the bioconcentration factor	BCF <100
Clearance time (CT_{50}) (CT_{90})	CT_{50}: Triclopyr BEE → 6 hours Triclopyr → 14 days 3,5,6-TCP → ~ 1 day
Level of residues (%) in organisms after the 14 day depuration phase	Triclopyr BEE → 0.014 after 54hours depuration Triclopyr → not detected after 1 day depuration 3,5,6-TCP → not detected after 3 days

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

	Triclopyr BEE
Acute oral toxicity	>110 µg/bee
Acute contact toxicity	>100 µg/bee

	Triclopyr
Acute contact toxicity	>100 µg a.s./bee
Acute contact toxicity	>100 µg a.s./bee
	Garlon 4
Acute contact toxicity	>100 µg a.s./bee
Acute contact toxicity	>100 µg a.s./bee

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

Route of exposure	Application rate	LD_{50}	Hazard Quotients	
			Q_{HO}	Q_{HC}
Triclopyr BEE				
Oral	2002 g as/ha	>110 µg/bee	<18	-
Contact	2002 g as/ha	>100 µg/bee	-	<20
Triclopyr				
Oral	1440 g ae/ha	>100 µg ae/bee	<14	-
Contact	1440 g ae/ha	>100 µg ae/bee	-	<14
Garlon 4				
Oral	1440 g ae/ha	>100 µg ae/bee	<14	-
Contact	1440 g ae/ha	>100 µg ae/bee	-	<14

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

Test species	Study type	Rate (L product /ha)	g triclopyr BEE/ha	Results
Typhlodromus pyri	Laboratory (glass plate)	2.5	1668	Mortality = 100%
		5.0	3335	Mortality = 100%
	Extended laboratory (leaf disc)	0.5	333.5	Mortality = 11% Fecundity = -19%
		5.0	3335	Mortality = 56% Fecundity = -27%
	Extended laboratory (whole plant)	2.5	1668	Mortality = 61% Fecundity = 8%
		5.0	3330	Mortality = 68% Fecundity = 14%

Test species	Study type	Rate (L product /ha)	g triclopyr BEE/ha	Results
Typhlodromus pyri	Dose response extended laboratory study (leaf disks)	0.4155	277.25	Mortality = 5% Fecundity = 9%
		3.0	2002	Mortality = 1% Fecundity = 11%
	Dose response extended laboratory study (leaf disks)	1.5, 3, 4.5 & 6	1001, 2002, 3003 & 4004	LR50 = 4.085L product/ha Up to 39% effect on reproduction
Aphidius rhopalosiphi	Laboratory (glass plate)	3.0	2002	Mortality = 100%
Aphidius colemani	Extended laboratory (French bean plants)	2.656	1800	Mortality = 11% Fecundity = -23%
		5.313	3600	Mortality =95% Fecundity was not assessed due to level of mortality
Poecilus cupreus	Laboratory (Quartz sand)	3.0	2002	Mortality = 10.3%
Chrysoperla carnea	Laboratory (glass plate)	2.5	1668	Mortality = 26.7% Fecundity: no effects
		5.0	3330	Mortality = 50% Fecundity: no effects
Pardosa armentata	Laboratory (Quartz sand)	3.0	2002	Mortality = 0%
Episyrphus balteatus	Laboratory (glass plate)	3.0	2002	Mortality = 32%
		6.0	4004	Mortality = 39%

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

Test substance	LC_{50} / NOEC value (mg /kg dry soil)
Acute Toxicity	
Triclopyr BEE	>521*
Triclopyr	>983
3,5,6-TCP	9.8
Garlon 4	555* mg as/kg dry soil
Long-term Toxicity	
3,5,6-TCP	4.60
Garlon 4	9.60 mg as/kg dry soil

*All values have been corrected for Log Pow

Risk to Earthworms

Test substance	Maximum application (g as/ha)	Mass of soil per hectare (kg)	PEC_S (mg as/kg)	LD_{50} or NOEC (mg as/kg)	TER_A TER_{lt}
Acute Risk					
Triclopyr BEE	2,002	7.5×10^5	2.67	>521*	>195
Triclopyr	1,440	7.5×10^5	1.92	>983	>512
3,5,6-TCP	368	7.5×10^5	0.49	9.8	20
Garlon 4	1440	7.5×10^5	1.92	555*	289
Long-term Risk					
3,5,6-TCP	368	7.5×10^5	0.490	4.60	9.38
Garlon 4	1440	7.5×10^5	1.92	9.60	5.00

*All values have been corrected for Log Pow

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

Nitrogen mineralization	Triclopyr BEE → No effect up to 8.5 mg/kg soil after 35 days 3,5,6-TCP → At 4.15 mg/kg soil effects were <25% after 100 days Garlon 4 → effects were <25% at 15 L product/ha after 100 days

Carbon mineralization	Triclopyr BEE → No effect up to 8.5 mg/kg soil after 35 days 3,5,6-TCP → At 4.15 mg/kg soil effects were <25% after 29 days Garlon 4 → effects were <25% at 15 L product/ha after 28 days
Growth of micro-organisms	Triclopyr: 0% growth inhibition at 500 mg as/kg agar

Effects on Non-target plants

Species	EC_{50} (g as/ha)	PEC (g/ha)*	TER
Avena sativa	>1440	8.21	>175
Lolium perenne	>1440	8.21	>175
Brassica napus	56.7	8.21	6.9
Pisum sativum	75.2	8.21	9.2
Daucus carota	64.6	8.21	7.9
Beta vulgaris	43.5	8.21	5.3

* representing drift at a 5 metres buffer zone

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R52 Harmful to aquatic organisms

Appendix 2 – Abbreviations used in the list of endpoints

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

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