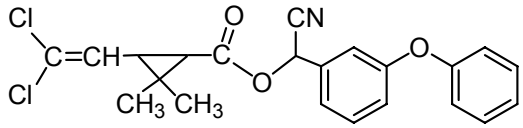
CYPERMETHRIN

This EQS dossier was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive).

The dossier was reviewed by the Scientific Committee on Health and Environmental Risks (SCHER), which made several comments. Responses to the detailed comments are provided at the end of the dossier. In addition, clearer explanation has been given in the dossier regarding the use of an additional assessment factor of 10 for the marine EQS.

NOTE: This dossier is accompanied by an Excel data table.

1 CHEMICAL IDENTITY

Common name	Cypermethrin[1]
Chemical name (IUPAC)	cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate;
Synonym(s)	
Chemical class (when available/relevant)	Pyrethroid insecticide
CAS number	52315-07-8
EU number	257-842-9
Molecular formula	$C_{22}H_{19}Cl_2NO_3$
Molecular structure	
Molecular weight ($g.mol^{-1}$)	416.3 g/mol
Classification and labelling	T; R25 - Xn; R48/22 - Xi; R37 - N; R50-53

[1] Isomer mixture of cypermethrin, alpha-cypermethrin (CAS 67375-30-8), beta-cypermethrin (CAS 65731-84-2), theta-cypermethrin (CAS 71691-59-1) and zeta-cypermethrin (52315-07-8). No significant differences in toxicity between isomers were found in the literature studied.

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Annex III EQS Dir. (2008/105/EC)	Not Included
Existing Substances Reg. (793/93/EC)	Not applicable
Pesticides(91/414/EEC)	Included in Annex I
Biocides (98/8/EC)	Included in Annex I; PT8: Wood preservatives
PBT substances	Not likely, since BCF < 2000. However not investigated by the PBT working group under TC-NES
Substances of Very High Concern	No

(1907/2006/EC)	
POPs (Stockholm convention)	No
Other relevant chemical regulation (veterinary products, medicament, ...)	Veterinary use
Endocrine disrupter	Limited evidence for anti-androgenic properties in *in-vitro* system (Sun et al., 2007)

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

QS for ecotoxicity is the "critical QS" for derivation of an Environmental Quality Standard

The applied assessment factors for both fresh surface water and sediment are 50. The uncertainty for freshwater is related to many low EC50s or NOECs for species from sensitive taxa, that were either unassignable or had exposure concentrations that were likely not maintained during the course of the experiments. The residual uncertainty in the data for benthic organisms is due to the fact that only two species were available.

	Value	Comments
Proposed AA-EQS for [freshwater] [µg.L^{-1}]	0.000082	**Critical QS is QS$_{freshwater, eco.}$**
Proposed AA-EQS for [marine waters] [µg.L^{-1}]	0.0000082	**See section 7**
Proposed MAC-EQS for [freshwater] [µg.L^{-1}]	0.00058	**See section 7.1**
Proposed MAC-EQS for [marine waters] [µg.L^{-1}]	0.000058	

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective*	Unit	Value	Comments
Pelagic community (freshwater)	[µg.l^{-1}]	0.000082	**See section 7.1**
Pelagic community (marine waters)	[µg.l^{-1}]	0.0000082	
Benthic community (freshwater)	[µg.kg^{-1} $_{dw}$]	0.033	**see section 7.1**
	[µg.l^{-1}]	-	
Benthic community (marine)	[µg.kg^{-1} $_{dw}$]	0.0033	
	[µg.l^{-1}]	-	
Predators (secondary poisoning)	[mg.kg^{-1} $_{biota\ ww}$]	3.33	**See section 7.7**
	[µg.l^{-1}]	2.77 (freshwater) 2.77 (marine waters)	
Human health via consumption of fishery products	[mg.kg^{-1} $_{biota\ ww}$]	3.04	**See section 7.8**
	[µg.l^{-1}]	2.53	
Human health via consumption of water	[µg.l^{-1}]	0.1	

* Please note that as recommended in the Technical Guidance for deriving EQS (drat version), "EQSs [...] are not reported for 'transitional and marine waters', but either for freshwater or marine waters". If justified by substance properties or data available, QS for the different protection objectives are given independently for transitional waters or coastal and territorial waters.

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

Plant protection product; pyrethroid insecticide. Biocidal uses. Veterinary uses.

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility (mg.l^{-1})	0.004 at 20°C, pH 7	(Anonymous2002)
Volatilisation		
Vapour pressure (Pa)	1.9*10^{-7} at 20°C	(EC, 2006)
Henry's Law constant (Pa.m^3.mol^{-1})	2.0*10^{-2} (calculated)	(Tomlin, 2002)
Adsorption	**The range - is used for derivation of quality standards.**	
Organic carbon – water partition coefficient (K_{OC})	K_{OC} = 350000	(Maund et al. 2002)
Suspended matter – water partition coefficient($K_{susp-water}$)	35000 (calculated)	
Bioaccumulation	**The BCF value - on fish is used for derivation of quality standards.**	
Octanol-water partition coefficient (Log Kow)	6.6	(Tomlin, 2002)
BCF (measured)[a]	1204 L/kg	(EC, 2006)
BMF (default for BCF<2000)	1	

[a] Detailed data in Annex I.

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	DT_{50} = 92-1302 d at pH 3, depending on isomer ratio DT_{50} = 136-221 d at pH 7, depending on isomer ratio DT_{50} = 23-38 min at pH 11, depending on isomer ratio River water DT_{50} = 5.1–21.1 d at pH 8, depending on isomer ratio	(EC, 2006)

	Sea water DT_{50} = 7.2-24 d at pH 8, depending on isomer ratio	
Photolysis	DT_{50}= 2.6-3.6 d, depending on isomer ratio	(EC, 2006)
Biodegradation	DT_{50} = 17 d	(EC, 2006)

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment	Predicted environmental concentration (PEC)	Master reference
Freshwater		
Marine waters (coastal and/or transitional)		
Sediment		
Biota (freshwater)		
Biota (marine)		
Biota (marine predators)		

6.2 MEASURED CONCENTRATIONS

Compartment	Measured environmental concentration (MEC)	Master reference
Freshwater	Mean: 0.01 µg.l^{-1} [a] 90th percentile: 0.02 µg.l^{-1} [a]	Data collected for EC priority substances review
	Mean: 0.02 µg.l^{-1} [b] 90th percentile: 0.05 µg.l^{-1} [b]	Data collected for EC priority substances review
	<0.01 - <0.1 µg.l^{-1} [c]	http://www.bestrijdingsmiddelenatlas.nl/
Marine waters (coastal and/or transitional)		
WWTP effluent		
Sediment	Mean: 21.78 µg.kg$^{-1}_{dw}$ [d] 90th percentile: 50 µg.kg$^{-1}_{dw}$ [d]	Data collected for EC priority substances review
Biota		
Biota (marine predators)		

[a] Data from Spain (2002-2006), Germany (2003-2005), Italy (2005), UK (2003-2006). Whole water with no separation of liquid and SPM phases. Range 0-0.2 µg.l^{-1}. Most measurements show concentrations below the LOQ.

[b] Data from France (2000-2007). Whole water with determination on each separate phase (sum of all phases). Range 0.01-0.1 µg.l^{-1}. Most measurements show concentrations below the LOQ.

[c] Data from the Netherlands (2006-2008): 641 samples on 97 sampling points. All data below detection LOQ, LOQ varied from 0.01 - 0.1 µg/L. Most measurements show concentrations below the LOQ.

[d] Data from France (2000-2007). Whole sediment fraction below 2 mm. Range 0.01-50 µg.kg$^{-1}_{dw}$. Most measurements show concentrations below the LOQ.

7 EFFECTS AND QUALITY STANDARDS

Many data are available for cypermethrin. All studies have been evaluated and rewarded a reliability index according to Klimisch *et al.* The physico-chemical properties of cypermethrin (low water solubility, high log K_{ow}) result in strong sorption to sediment and suspended matter and a non-homogenous distribution of the substance in the aqueous phase. These characteristics put special demands on the way toxicity tests are performed. Based on the properties of the substance, studies lacking chemical analyses were considered invalid. In chapter 7, only the results of studies assessed as valid (Klimisch code 1 or 2) are presented. Detailed toxicity data (including the non-valid studies) are presented in Annex II.

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

ACUTE EFFECTS			**Master reference**
Algae & aquatic plants (µg.l^{-1})	**Freshwater**	*Pseudokirchneriella subcapitata* / 96 h EC_{50} : > solubility	(EC, 2006)
	Marine	not available	
Invertebrates (µg.l^{-1})	**Freshwater**	*Asellus aquaticus* / 24 h EC_{50} : 0.02[a]	(Stephenson, 1982)
	Freshwater	*Daphnia magna* / 48 h EC_{50} : 0.40[b]	(EC, 2006; EC, 2003; EC, 1999)
	Freshwater	***Gammarus pulex* / 96 h** **EC_{50} : 0.0013[c]**	**(EC, 2006)**
	Freshwater	*Paratya australiensis* / 96 h LC_{50} : 0.09	(EC, 2006; Davies et al. 1994)
	Marine	*Acartia clausi* / 48 h EC_{50} : 1.1	(Willis and Ling, 2004)
	Marine	*Acartia tonsa* / 96 h EC_{50} : 0.1288	(Barata et al. 2002)
	Marine	*Oithona similis* / 48 h EC_{50} : 0.14	(Willis and Ling, 2004)
	Marine	*Pseudocalanus elongatus* / 48 h EC_{50} : 1.37	(Willis and Ling, 2004)
	Marine	*Temora longicornis* / 48 h EC_{50} : 0.12	(Willis and Ling, 2004)
	Sediment	*Ampelisca abdita* / 10 d LC_{50} : 3006 µg.kg^{-1}	(Anderson et al. 2008)
	Sediment	*Eohaustorius estuarius* / 10 d LC_{50} : 70.5 µg.kg^{-1}	(Anderson et al. 2008)
	Sediment	*Palaemonetes pugio* / 10 d LC_{50} : 2700 µg.kg^{-1}	(Clark et al. 1987)
Insects (µg.l^{-1})	**Freshwater**	*Aedes aegypti* / 24 h EC_{50} : 0.31[d]	(Van de Plassche and Linders, 1991; Stephenson, 1982)
	Freshwater	*Chaoborus crystallinus*/ 24 h EC_{50} : 0.03[a]	(Stephenson, 1982)
	Freshwater	*Chironumus thummi* / 24 h EC_{50} : 0.2[a]	(Stephenson, 1982)
	Freshwater	*Cloeon dipetrum* / 24 h EC_{50} : 0.07[a]	(Stephenson, 1982)

	Freshwater	*Corixa punctata*/ 24 h EC_{50} : 0.7[a]	(Stephenson, 1982)
	Freshwater	*Gyrinus natator* / 24 h EC_{50} : 0.07[a]	(Stephenson, 1982)
	Freshwater	*Cloeon dipterum* / 96 h EC_{50} : 0.020	(Shell, 1980)
	Marine	not available	
	Sediment	Not available	
Fish **(µg.l^{-1})**	**Freshwater**	*Cnesterodon decemmaculatus* / 96 h LC_{50} : 0.43	(Carriquiriborde et al. 2007)
	Freshwater	*Cyprinus carpio* / 96 h LC_{50} : 0.99[e]	(EC, 2006)
	Freshwater	*Galaxius maculaus* / 240 h LC_{50} : 1.47	(Davies et al. 1994)
	Freshwater	*Heteropneustes fossilis* / 72 h LC_{50} : 0.67	Saha and Karivaj 2003
	Freshwater	*Lepomis macrochirus* / 96 h LC_{50} : 1.78	(ICI, 1980)
	Freshwater	*Oncorhynchus mykiss* / 96 h LC_{50} : 1.04[f]	(EC, 2006)
	Freshwater	*Oreochromis niloticus* / 96 h LC_{50} : 2.1[g]	(Stephenson, 1982) and Stephenson et al 1984
	Freshwater	*Pseudoraphritis urvilii* / 240 h LC_{50} : 1.98	(Davies et al. 1994)
	Freshwater	*Salmo trutta* / 96 h LC_{50} : 1.2	(Stephenson, 1982)
	Freshwater	*Scardinius erythrophthalmus* / 96 h EC_{50} : 0.4	(EC, 2006)
	Marine	*Cyprinodon variegatus* / 96 h EC_{50} : 2.86[h]	(EC, 2006)
	Sediment	Not available	
Other taxonomic groups		*Piona carnea* /Freshwater spider/ 24 h LC_{50} : 0.05	(Stephenson, 1982)

[a] Endpoint immobility

[b] Geometric mean of 0.3, 1.25, 3.14, 0.3, 0.141 and 0.085 µg/L

[c] Endpoint immobility; test duration 96 hours

[d] Geometric mean of 1, 1 and 0.03 µg/L

[e] Geometric mean of 0.9 and 1.1 µg/L

[f] Geometric mean of 2.8, 1, 0.7, 2.8, 0.69, 0.9, 1.3, 0.5, 0.5 and 1.47 µg/L

[g] Geometric mean of 2.2 and 2 µg/L

[h] Geometric mean of 2.37 and 3.45 µg/L

CHRONIC EFFECTS			**Master reference**
Algae & aquatic plants ($\mu g.l^{-1}$)	**Freshwater**	*Pseudokirchneriella subcapitata* / 96 h EC_{50} : > solubility	(EC, 2006)
	Marine	Not available	
Invertebrates ($\mu g.l^{-1}$)	**Freshwater**	*Daphnia magna* / 21 d NOEC : 0.009[a]	(EC, 2006)
	Marine	***Acartia tonsa* / 32 d** **NOEC : 0.0041**	**(Barata et al. 2002)**
	Sediment	*Hyalella azteca* / 10 d NOEC : 1.63[b] $\mu g.kg^{-1}$	(Maund et al. 2002)
Insects ($\mu g.l^{-1}$)	**Freshwater**	Not available	
	Marine	Not available	
	Sediment	*Chironomus tentans* / 10 d NOEC : 25.8[c] $\mu g.kg^{-1}$	(Maund et al. 2002)
Fish ($\mu g.l^{-1}$)	**Freshwater**	*Oryzias latipes* / 24 d NOEC : 2.79	(Gonzalez-Doncel et al. 2004)
	Freshwater	*Pimephales promelas* / 34 d NOEC : 0.03[d]	(EC, 2006)
	Marine	Not available	
Other taxonomic groups		Not available	

[a] Endpoint growth

[b] Geometric mean of 3.83 and 0.69 µg/kg

[c] Geometric mean of 38, 83.3 and 5.4 µg/kg

[d] Test duration 34 days

7.2 TREATMENT OF FRESHWATER AND MARINE ECOTOXICITY DATA

According to the guidance, ecotoxicity data for pesticides can be pooled unless evidence exists that sensitivity of organisms and/or behaviour of the compound differs between freshwater and marine environments. The available data do not point at such a difference, and the data are pooled.

7.3 FIELD EXPERIMENTS

Several cosm studies have been performed for cypermethrin. The main findings of these studies are reported in the annexes. Copies of the study summaries in the DAR are reported in the annexes as well.

Based on the fast decline of cypermethrin concentrations in water, test organisms in the mesocosm studies are exposed by acute peak exposure. Since the AA-QS is derived to protect the environment from effects caused by chronic exposure, the results of these studies can solely be used as indicative.

The studies which are considered valid have NOEC values ranging from < 0.02 to < 0.4 µg/L for the most sensitive taxonomic groups.

When cypermethrin is monitored, it should be taken into account that the physico-chemical properties of cypermethrin (low water solubility, high log Kow) will result in strong sorption to sediment and suspended matter and a non-homogenous distribution of the substance in the aqueous phase. This causes difficulties for the determination of the cypermethrin concentrations in the water phase in a field (or cosm) situation (e.g. the concentration of cypermethrin in a sample taken 4 cm below the water surface can differ significantly from the concentration in a sample taken at a depth of 80 cm). Therefore, the most conservative NOEC value (< 0.035 µg/L) derived from the cosm studies is used as indicative value.

7.4 DERIVATION OF THE MAC-QS$_{WATER}$

7.4.1 Freshwater environment

The acute base-set (algae, *Daphnia* and fish) is complete and additional acute toxicity data are available for invertebrates, insects and fish. Based on the available data, an assessment factor of 10 is used on the lowest L(E)C_{50} value (*Gammarus pulex,* 0.0013 µg/L) for the freshwater environment, resulting in a MAC-QS $_{water\ AF}$ of 0.0013 µg/L / 10 = 0.13 ng/L.
However, based on the specific mechanism of action of cypermethrin, it is clear that insects and crustaceans form the most sensitive groups. Since acute toxicity data for a wide range of these species are available, the MAC-QS can be derived using a species sensitivity distribution (SSD).

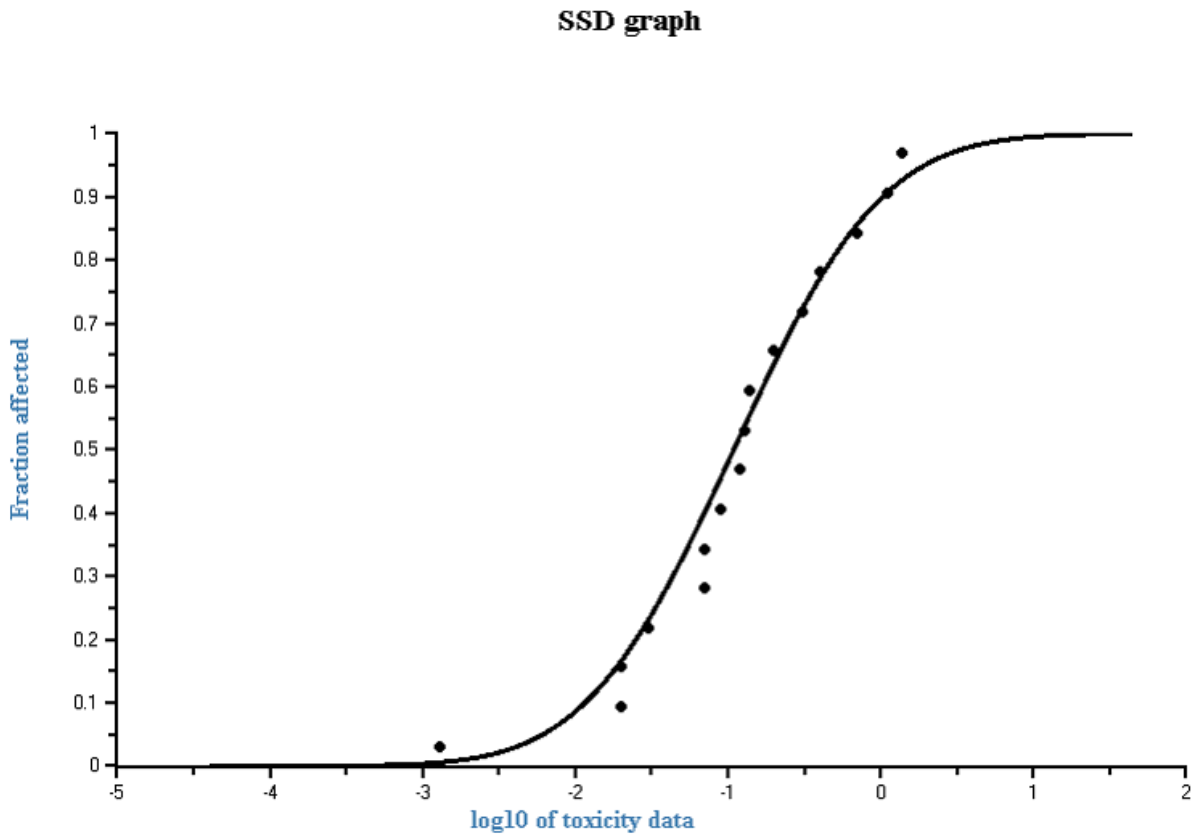


Figure 1. SSD for cypermethrin based on acute toxicity data for insects and crustaceans. The toxicity data are in µg/L.

The SSD for cypermethring shows a HC_5 of 5.8 ng/L, with an lower- and upper limit of 1.3 and 15.1 ng/L, respectively. However, since this SSD is based on $L(E)C_{50}$ values, an assessment factor of 10 is used in order to reach the no-effect level. Therefore, the MAC-$QS_{water\ SSD}$ becomes 0.58 ng/L.

7.4.2 Marine environment

For the marine environment, a factor of 10 higher assessment factor is applied on the HC_5 value, based on the need to account for the additional uncertainties associated with extrapolation for the marine ecosystem, especially the general under-representation in the experimental dataset of specific marine key taxa and possibly a greater species diversity, as explained in the Technical Guidance for Deriving EQS (EC 2011). Therefore, the MAC-$QS_{eco,\ marine}$ becomes 0.0058 µg/L / 100 =
0.058 ng/L.

7.5 DERIVATION OF THE AA-QS_{WATER}

The base set is complete and additional chronic data are available for *Daphnia* and fish and the marine crustacean *Acartia tonsa*. The effect concentrations found in the laboratory toxicity studies are within one order of magnitude of the (indicative) results of the cosm studies, showing that the effects in the mesocosm studies are comparable with the effects in the LC50 studies (i.e. substantial mortality) at similar concentrations. The lowest LC_{50}s are thus confirmed by the results from the mesocosm experiments. Based on the laboratory toxicity test for *Pseudokirchneriella subcapitata*, it can be assumed that algae are not among the most sensitive organisms to cypermethrin.

7.5.1 Freshwater environment

Based on the available data, the AA-$QS_{eco,\ water}$ is usually derived by using an assessment factor of 10 on the lowest NOEC value (0.0041 µg/L for the marine crustacean *Acartia tonsa*). However, an acute toxicity study with *Gammarus pulex* shows an LC_{50} value lower than this NOEC (0.0013 µg/L). Further, unassignable data are available showing lower LC_{50} values as well (0.0039 and 0.0026 µg/L for *Asellus aquaticus* and *Crangonyx pseudogracilis*). Besides these unassignable data, lower LC50 values are available which are assigned Ri 3 based on the fact that a static test without analysis of concentrations was performed. Since this means that the actual LC50 values are most likely even lower than the reported LC50 values, it was concluded that an AA-$QS_{eco,\ water}$ derived by using an assessment factor of 10 on the lowest NOEC value would be insufficiently protective for the most sensitive species. The AA-$QS_{eco,\ water}$ was derived by applying an assessment factor of 50 on the lowest NOEC value (0.0041 µg/L for Acartia tonsa), resulting in

0.000082 µg/L (0.082 ng/L).

7.5.2 Marine environment

The AA-$QS_{eco,\ marine}$ was derived by applying an additional assessment factor of 10 on the AA-$QS_{eco,\ water}$, since no reliable data for additional marine taxonomic groups were available, as explained in the TGD-EQS (2011), resulting in 0.0000082 µg/L (0.0082ng/L).

7.6 DERIVATION OF THE AA-$QS_{SEDIMENT}$

Since the log Kow of cypermethrin is > 3, the derivation of an AA-$QS_{sediment}$ is required in order to protect the benthic environment.

7.6.1 Freshwater environment

Toxicity data for cypermethrin in freshwater sediments are reported for the amphipod *Hyalella azteca* and the midge larva *Chironomus tentans*. The 10-day LC_{50} values for *Hyalella azteca* were 3.6, 18, and 23 µg/kg dry weight in sediments containing 1, 3 and 13 percent organic carbon (growth NOECs <1.8, 2.3 and 1.8 µg/kg dw). The corresponding LC_{50} values at similar organic carbon contents for *Chironomus tentans* were 13, 67 and 62 µg/kg dw (corresponding NOEC values for growth were < 3.8, 25 and 14 µg/kg dw).

In one study, the midge *Chironomus riparius* at different population densities (0.5, 1.2 and 4 cm^{-2}) and population parameters monitored for 67 days. Initial measured cypermethrin concentration in the test sediments (10 percent peat) were approximately 0.125, 0.175 and 0.21 mg/kg dw and had declined to 0.049, 0.073 and 0.086 mg/kg dw by the end of the study. All concentrations of cypermethrin led to effects on

population parameters such as juvenile survival to emergence, time to emergence and reproduction, and population growth rate. However, reduction in the initial larval densities resulted in an increase in the available resources for the survivors. Exposed populations therefore emerged sooner and started producing offspring earlier than the controls. Cypermethrin had no effect on estimated fecundity and adult body weight, but interacted with density to reduce the time to first emergence and first reproduction. As a result, population growth rate increased with cypermethrin concentration when populations were initiated at high densities. Since this effect is not based on direct toxicity, but on competition, the NOEC value from this study cannot be used for the derivation of the AA-$QS_{sediment}$.

Since two NOEC values are available for sediment toxicity, the AA-$QS_{sediment}$ is derived by using an assessment factor of 50 on the lowest NOEC value standardised to an organic carbon content of 5%. The most sensitive organism is *Hyalella azteca* with NOEC values of 2.3 and 1.8 µg/kg dw (organic carbon 3 and 13%). Recalculating these values to standardised sediment and using the geometric mean results in a NOEC of 1.63 µg/kg dw. Applying an assessment factor of 50, the AA-$QS_{freshwater\ sediment}$ becomes 0.033 µg/kg sediment.

7.6.2 Marine environment

For the marine environment, an assessment factor of 500 is used on the lowest NOEC of 1.63 µg/kg for the reasons explained above. This results in an AA-$QS_{marine\ sediment}$ of 0.0033 µg/kg sediment.

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
MAC-$QS_{freshwater,\ eco}$	SSD	10	0.00058 µg.l^{-1}
MAC-$QS_{marine\ water,\ eco}$	HC_5 : 0.0058 µg.l^{-1}	100	0.000058 µg.l^{-1}
AA-$QS_{freshwater,\ eco}$	*Acartia tonsa* / 96 h	50	0.000082 µg.l^{-1}
AA-$QS_{marine\ water,\ eco}$	NOEC : 0.0041 µg.l^{-1}	500	0.0000082 µg.l^{-1}
AA-$QS_{freshwater,\ sed.}$	*Hyalella azteca* / 10 d NOEC : 1.63 µg.kg^{-1}	50	0.033 µg.kg^{-1}_{dw}
AA-$QS_{marine\ water,\ sed.}$	*Hyalella azteca* / 10 d NOEC : 1.63 µg.kg^{-1}	500	0.0033 µg.kg^{-1}_{dw}

7.7 SECONDARY POISONING

Secondary poisoning of top predators		Master reference
Mammalian oral toxicity	Mouse / Oral/ 2 years / Body weight gain NOAEL : 66 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 400 mg.kg$^{-1}_{feed}$ (AF=30)	(EC, 2006): Lindsay *et al.*, 1982
	Rat / Oral / 35 days / Body weight gain, food uptake NOAEL : 37.5 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 750 mg.kg$^{-1}_{feed}$ (AF=300)	(EC, 2006): Coombs *et al.*, 1976
	Rat / Oral / 35 days / Reproduction NOAEL : 10 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 100 mg.kg$^{-1}_{feed}$ (AF=300)	(EC, 2006): Hend *et al.*, 1978
	Rat / Oral / 90 days / Liver weight NOAEL : 20 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 400 mg.kg$^{-1}_{feed}$ (AF=90)	(EC, 2006): Pickering and Hendy, 1981
	Rat / Oral / 91 days / Kidney weight NOAEL : 5 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 100 mg.kg$^{-1}_{feed}$ (AF=90)	(EC, 2006): Hend and Butterworth, 1976
	Rat / Oral / 90 days / Immunotoxicity NOAEL : 10 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 100 mg.kg$^{-1}_{feed}$* (AF=90)	(EC, 2006): Varshneya *et al.*, 1992
	Rat / Oral / 2 years / Organ weight **NOAEL : 5 mg.kg$^{-1}_{bw}$.d^{-1}** **NOEC : 100 mg.kg$^{-1}_{feed}$ (AF=30)**	**(EC, 2006):** **Mc Ausland *et al.*, 1978**
	Dog / Oral / 35 days / Body weight gain, food intake NOAEL : 3.75 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 150 mg.kg$^{-1}_{feed}$ (AF=300)	(EC, 2006): Coombs *et al.*, 1976
	Dog / Oral / 90 days / Subacute toxicity NOAEL : 12.5 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 500 mg.kg$^{-1}_{feed}$ (AF=90)	(EC, 2006): Buckwell and Butterworth, 1977
	Dog / Oral / 2 years / Neurotoxicity NOAEL : 7.5 mg.kg$^{-1}_{bw}$.d^{-1} NOEC : 300 mg.kg$^{-1}_{feed}$ (AF=30)	(EC, 2006): Buckwell and Dix, 1981
Avian oral toxicity	*Coturnix coturnix japonica* / Oral / 20 weeks / Reproduction NOEC : 130 mg.kg$^{-1}_{feed}$	(EC, 2006): Dighe, 1994

* NOEC value (mg.kg$^{-1}_{feed}$) extrapolated from NOAEL value (mg.kg$^{-1}_{bw}$.d^{-1}).

Tentative QS_{biota}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
Biota	NOEC : 100 $mg.kg^{-1}_{feed}$	30	3.33 $mg.kg^{-1}_{biota}$ corresponding to 2.77 $\mu g.L^{-1}$ (freshwater) 2.77 $\mu g.L^{-1}$ (marine waters)

7.8 HUMAN HEALTH

Human health via consumption of fishery products		**Master reference**
Mammalian oral toxicity	**Cypermethrin** **Rat / Oral / 2 years / Organ weight** **NOAEL : 5 $mg.kg^{-1}_{bw}.d^{-1}$** **NOEC : 100 $mg.kg^{-1}_{feed}$ (AF=30)** **ADI : 0.05 $mg.kg^{-1}_{bw}.d^{-1}$**	(EC, 2006): Mc Ausland *et al.*, 1978
	Alpha-cypermethrin **Dog / Oral / 1 year / Skin reaction** **NOAEL : 1.5 $mg.kg^{-1}_{bw}.d^{-1}$** **NOEC : 0.05 $mg.kg^{-1}_{feed}$ (AF=30)** **ADI : 0.015 $mg.kg^{-1}_{bw}.d^{-1}$**	(EC, 2003): Dean and Jackson, 1995
	Zeta-cypermethrin **Dog / Oral / 90 days / Neurotoxicity** **NOAEL : 6 $mg.kg^{-1}_{bw}.d^{-1}$** **NOEC : 0.067 $mg.kg^{-1}_{feed}$ (AF=90)** **ADI : 0.03 $mg.kg^{-1}_{bw}.d^{-1}$**	(EC, 1999): Daly, 1994
CMR	No	

Tentative $QS_{biota, hh}$	**Relevant study for derivation of $QS_{biota, hh}$**	**Assessment Factor**	**Tentative $QS_{biota, hh}$**

Human health	Cypermethrin ADI: 0.05 $mg.kg^{-1}_{bw}.d^{-1}$ bw 70 kg; DFI 115 g/d BCF 1204 L/kg		3.04 $mg.kg^{-1}_{biota\ ww}$ (2.53 $\mu g.L^{-1}$)
	Alpha-cypermethrin ADI: 0.015 $mg.kg^{-1}_{bw}.d^{-1}$ bw 70 kg; DFI 115 g/d BCF 1204 L/kg		0.91 $mg.kg^{-1}_{biota\ ww}$ (0.76 $\mu g.L^{-1}$)
	Zeta-cypermethrin ADI: 0.03 $mg.kg^{-1}_{bw}.d^{-1}$ bw 70 kg; DFI 115 g/d BCF 397 L/kg (geometric mean of 356 and 443 L/kg)		1.83 $mg.kg^{-1}_{biota\ ww}$ (4.6 $\mu g.L^{-1}$)

Human health via consumption of drinking water		**Master reference**
Existing drinking water standard(s)	0.1 $\mu g.L^{-1}$ (preferred regulatory standard)	Directive 98/83/EC
Any guideline		

Annex Description of mesocosm studies

Annex 3 Description of mesocosm studies

Annex 3.1 Summaries of mesocosm studies in the DAR

Several mesocosm and field studies were performed to assess the behaviour and the effects of both alpha-cypermethrin and cypermethrin in the aquatic environment under more realistic conditions than the laboratory conditions.

STUDY ID. An outdoor tank experiment to study the fate of 'FASTAC' in the aquatic environment **(Dutton *et al*., 1987, Cyanamid)**

Guidelines :

Not specified

GLP :

Study is GLP

Material and Methods :

Test substance :

Emulsifiable concentrate containing 100 a.s. g/l radio-labelled Alpha-cypermethrin

Benzyl-labelled : specific radioactivity : 10.65 µCi/mg, radiochemical purity = 99 %

Cyclopropyl-labelled : specific radioactivity : 20.0 µCi/mg, radiochemical purity = 97 %

Test conditions :

An experiment was carried out in an outdoor enclosure, using radiolabelled material, to study the fate and behaviour of the a.s. and, in less extent, the effects of the formulation in an aquatic system. Three tanks, dimensions (70 cm x 70 cm x 80 cm deep) were set up, each containing 340 litres of pond water and 10 cm of coarse-filtered pond sediment. Two tanks were treated with [^{14}C] alpha-cypermethrin, at a rate equivalent to near 15 g a.s./ha (i.e. 1.5 mg/m² of surface area), one with alpha-cypermethrin labelled in the benzyl ring, the other with alpha-cypermethrin labelled in the cyclopropyl ring. The remaining tank was untreated serving as a control.

The fate of alpha-cypermethrin was monitored by radiochemical and chromatographic analysis of water and sediment samples taken up to 202 days after application. *In situ* bioassays of the water and sediment/water interface were carried out using *Gammarus*; an animal known to be very susceptible to pyrethroids (3 x 10 *Gammarus*).

Findings :

Table B.8.2.12-1 : Mesocosm experiment - Evolution of the alpha-cypermethrin concentrations in water and sediment; *Gammarus* bioassay

	Days after application										
	-6	0	1	2	4	8	16	27	62	105	202
Application of benzyl-labelled alpha-cypermethrin at the rate of 1.8 µg a.s/l											
Water											
(µg a.s./l water)		1.8	1.17	0.83	0.54	0.17	0.02	-	ND	ND	ND
(% of the applied conc.)		100	66	47	31	10	1	-	-	-	-
Sediment 0-1 cm layer											
(% of the applied conc.)			8	20	28	39	42	16	38	14	6
Bioassay with *Gammarus*											
Mean % mortality after 96h - in water	3	ND	100	100	100	100	97	20	0	3	7
Mean % mortality after 96h - on sediment	43	ND	100	100	100	100	100	40	13	33	93
Application of cyclopropyl-labelled alpha-cypermethrin at the rate of 2.4 µg a.s/l											
Water											
(µg a.s./l water)		2.4	2.46	1.24	0.90	0.30	0.04	-	ND	ND	ND
(% of the applied conc.)		100	100	52	38	13	2	-	-	-	-
Sediment 0-1 cm layer											
(% of the applied conc.)			8	11	10	23	42	29	26	15	4
Bioassay with *Gammarus*											
Mean % mortality after 96h - in water	17	ND	100	100	100	100	100	3	7	10	10

	Days after application										
	-6	0	1	2	4	8	16	27	62	105	202
Mean % mortality after 96h - on sediment	50	ND	100	100	100	100	100	53	63	90	100
Control											
Bioassay with *Gammarus*											
Mean % mortality after 96h - in water	10	ND	3	20	7	0	0	20	3	7	20
Mean % mortality after 96h - on sediment	3	ND	37	40	13	7	23	3	7	13	70

(*) : sediment concentrations at > 1 cm depth are negligible. ND : Not determined

Conclusion :

The maximum concentrations of total [^{14}C] and alpha-cypermethrin in water were found in samples taken 1 day after treatment. The apparent half-life of alpha-cypermethrin in water was 2 to 4 days, a considerable proportion of the a.s. being absorbed onto the sediment. The only metabolites characterised in the water phase were :

- 3-Phenoxybenzoic acid (WL44607) - The concentration of this acid increased to 52 % of the recovered [^{14}C] activity in the sample at day 16, after which the concentration began to decrease. More polar, unidentified metabolites increased to 58% at day 27. There were no further samples taken for characterisation purposes after this time.

- 2,2-dimethyl-3-(2,2-dichlorovinyl) cyclopropane carboxylic acid (WL44776) - The concentration increased to 70 % of the recovered [^{14}C] in the sample at day 16 and remained at a similar level at day 27. More polar unidentified metabolites increased to 31 % at day 27. No further samples for characterisation purposes were taken after this time.

- Practically all of the residues found in the sediment were in the top 1 cm layer, and were mainly alpha-cypermethrin particularly at the earlier sampling times. After 16 days approximately 40 % of the total radioactivity applied was present in the sediment as the parent material.

- The water in both treated tanks remained acutely toxic to *Gammarus* for at least 16 days after the application of the emulsifiable concentrate, but was not so 27 days after application. However, *Gammarus* exposed at the sediment/water interface at 105 days after application indicated the persistence of toxic effects.

STUDY ID. The fate of FASTAC in experimental ponds **(Pearson M., 1990, Cyanamid)**

Guidelines :

Not specified

GLP :

Study is GLP

Material and Methods :

Test substance : Emulsifiable concentrate containing 100 g/l alpha-cypermethrin

Test conditions :

The experiment was carried out using three experimental ponds situated at Grigg Farm, Headcorn, Kent. The ponds had dimensions 10 m x 5 m with a water depth of approximately 0.8 m. Each pond had approximately 10 cm of sediment lying over a clay base.

In mid June, 1987 two ponds were treated with emulsifiable concentrate at a rate equivalent to 15 g a.s./ha of pond surface and an volume rate of 400 l/ ha using a modified boom and nozzle sprayer. One pond was oversprayed onto the surface of the water from about 10-15 cm. In the other pond the emulsifiable concentrate was incorporated into the sub-surface water by using the sprayer with its nozzles just below the surface. A third pond was not treated and served as a control.

- The surface film was sampled by placing a 10 cm diameter disc of fine stainless steel mesh onto the water surface.The sampler collected water to a depth of 0.2 mm.

- Samples of water were taken from each pond at weekly intervals throughout the experiment and taken to the laboratory for determination of pH, alkalinity, total hardness, suspended solid concentration and particle size distribution. Measurements of maximum and minimum water temperature and dissolved oxygen concentration were made in-situ in the ponds at mid-depth.

- Samples of sediment were collected from day 16 to the end of the study. The 1 cm top of the sediment core was analyzed. Analytical determinations by gas chromatography.

- On one occasion before treatment and at intervals up to 54 days after the application of the emulsifiable concentrate, *in-situ* bioassays were carried out using *Gammarus pulex* . Animals were housed in mesh cages placed on the sediment and in mid-water.

- Sampling of zooplankton and macroinvertebrates was carried out once before, and at intervals up to 65 days after the application of the emulsifiable concentrate.

Findings :

Table B.8.2.12-2 : Mesocosm study - Evolution of the alpha-cypermethrin concentrations in water and sediment; *Gammarus* bioassay

	Days after application									
	-1	1	2	4	8	16	25	33	47	54
Pond treated by overspraying (15 g a.s./ha)										
Water - surface film (µg a.s./l water)	2	340	121	27	9	ND	ND	ND	ND	ND
Water - sub-surface (µg a.s./l water)	ND	0.36	0.28	0.38	0.03	0.02	ND	ND	ND	ND
Sediment 0-1 cm layer (µg/core.)	ND	ND	ND	ND	ND	0.06	0.05	0.03	0.02	0.03

Bioassay with *Gammarus*										
Mean % mortality after 24 h - in water		100	100	100	57	80		0	10	10
Mean % mortality after 24 h - in cages on sediment		100	100	100	87	87		0	0	17
Pond treated by incorporation										
Water - sub-surface (µg a.s./l water)	ND	0.28	0.72	0.64	0.04	0.05	ND	ND	ND	ND
Sediment 0-1 cm layer (µg/core.)	ND	ND	ND	ND	ND	0.06	0.05	0.03	0.02	0.04
Bioassay with *Gammarus*										
Mean % mortality after 24 h - in water		100	100	100	90	97		13	7	7
Mean % mortality after 24 h - in cages on sediment		100	100	100	97	100		7	0	0
Control										
Bioassay with *Gammarus*										
Mean % mortality after 96 h - in water		0	7	17	0	3		0	7	3
[2]Mean % mortality after 96 h - in cages on sediment		0	3	13	3	20		0	33	0

Taxonomic inventory of sweepnet and zooplankton samples was performed.

The phantom midge *Chaoborus* which is well represented in the control 269-507 insects (from start to day 47) , is totally absent of the samplings made at day 8 and 26 in the spray and incorporation treatments. Only partial recovery is observed at day 47 in the pond treated by spray. No recovery occurred in the pond treated by incorporation.

Notonecta, Chloeon are strongly affected by both spray and incorporation treatments.

Lymnea are not affected by both spray and incorporation treatments

The examination of other insect taxa found at very low population levels showed that both spray and incorporation treatments affect them .

Nauplii and Cyclops copepods species are strongly affected by both spray and incorporation treatments : disappearance of the populations at day 8. Both stages recovered and their populations were similar to the control at day 26 for the spray treatment. Recovery occurred after 45 days for the incorporation treatment.

Effects of the incorporation treatment on other zooplankton species lead to important population reduction without any recovery at day 65. The effects of spray treatment on the other zooplankton species were milder (but nevertheless clearly present for *Diaptomus*).

Molluscs (Bivalvia, Planorbidae), Oligocheta were absent in control and treatments groups. No assessment can be made for these organisms. Fish were not present in the mesocosm.

Conclusions :

This mesocosm study realized at an application rate of 15 g a.s./ha revealed that this level of alpha-cypermethrin caused long-term effects on several arthropod taxa.

STUDY ID. A Pond Enclosure Study of the Effects of FASTAC Formulations on Aquatic Invertebrates **(Inglesfield, 1985a)**

Material and methods :

Test substance :

Emulsifiable concentrate containing 400 g/l cypermethrin

Experimental design :

- The trial was carried out at Grigg Farm,UK using two small experimental ponds. About two months before the experiment began a mature, rectangular pond 20 m long, 5 m wide and 0.7 m deep was divided into two similar ponds, each 10 m long, by constructing a concrete wall across it.

- One of the ponds was treated with cypermethrin on 1st June, 1977 by spraying over its surface with a hand-held, 2 m boom fed from a knapsack sprayer. The formulation was applied at a volume application rate of 333 l/ha equivalent to 100 g/ha cypermethrin . The other pond remained untreated.

- Physico-chemical parameters of water, a.s. residues in sediment and water, zooplankton ,macroinvertebrates and introduced fish were monitored during 16 weeks.

Findings :

Table B.8.2.12-3 : Mesocosm study - a.s. concentrations and effects of cypermethrin

	Control	Treatment
application rate above the water body (g a.s./ha)	0	100
surface film concentration (µg a.s./l)	<1-5 µg/l	0h : 23000 µg/l 2d: 1240 µg/l 7d : 35 µg/l 14d : 20 µg/l
sub-surface water concentration (µg a.s./l)	0h : <0.01µg/l 2d : 0.06 µg/l	0h : 1.4 µg/l 2d : 0.69 µg/l 7d : 0.21µg/l 14d : 0.06 µg/l wk 3 to 16 : <0.01 -0.02 µg/l
sediment concentration (µg a.s./kg)	0-16wk :	0-16 wk : <1 - 6.9 µg/kg

	<1 - 2.3 µg/kg	
Effects		
Fish		no mortality of the introduced rudds (*Scardinius erythrophthalmus*) shoals of fish were observed 50µg a.s./kg wet weight, in fish at day 1 to day 14 3-8 µg a.s./ kg wet weight, in fish, after 16 weeks. These figures reveal the high BCF with very slow depuration
Aquatic vegetation		No effect on macrophytes filamentous algae bloom
Zooplankton		Complete disappearance of daphnids and copepods from wk 1 to 7 recovery after wk 12
Macroinvertebrates (dip net)		Shannon diversity index : recovery after wk 8 Number of species : recovery after wk 15 Number of animals : sharp decrease to wk 7, then incomplete recovery Crustacean *Asellus* did not recover Mayfly *Cloeon dipterium* did not recover Surface dwelling insects (*Dytiscus marginalis, Colymbetes fuscus, Notonecta glauca, Corixa spp*) found dead within 24 h after treatment

Conclusion :

No mortality of the fish is observed at a water concentration of 1.4 µg/l cypermethrin. However bioaccaumulation is important. The depuration is very low. Long-term impact on the invertebrates is observed.

STUDY ID. Spray drift from Ripcord applications to vineyards in France : Fate and effects in adjacent streams **(Bennett *et al.*, 1981)**

Material and methods :

Test substance :

EC formulation containing 100 g/l cypermethrin

Experimental design :

A diluted EC formulation of RIPCORD was applied to vines for the control of tortrix moth caterpillars at three locations in the South of France. The insecticide was applied at dosages of 30 and 45 g a.s./ha by mistblowers delivering volumes of about 400 l/ha. 2 applications were made during the season. As a result of drought conditions two of the three sites dried-up shortly before the second application (5.7.79) and in consequence the fate and effects of RIPCORD were monitored at only one site.

- Site 1, Cazouls-les-Beziers : 1.3 ha vineyard adjacent to a clear, stony stream with alternating short riffles and longer pools. In many places the stream was partially screened from the vineyard by a 2 m high bank, bushes and small trees. The maximum flow rate in May was 0.5 m sec^{-1} and the volumetric discharge was estimated to be 3 m^3 min^{-1}. In July the flow rate in riffle sections was much less than in May.

- Site 2, Fontalinières : Vineyard of 3.0 ha with a small stony stream flowing along its southern boundary. The width of the stream varied from 0.25 - 1.5 m and its depth from 5 - 20 cm. The maximum flow rate was 0.5 m sec^{-1} and the volumetric discharge was estimated to be 0.4 m^3 min^{-1}. Much of the 270 m long stretch of stream adjacent to the vineyard was screened by a canopy of small trees.

- Site 3, Marseillan : A vineyard of 1.0 ha with a drainage ditch flowing along its western and northern boundaries. The width of the ditch varied from 0.2 - 2.0 m, its depth from 2 - 10 cm and its flow rate, in the deeper parts, from 0.01 - 0.03 m/s (50 - 100 m/h). It was heavily overgrown with grasses, flag iris and water crowfoot.

Findings :

Table B.8.2.12-4 : Effects of cypermethrin spray drift in small streams situated near vineyards

Location	Cazouls-les-Beziers (20.5.79)	Cazouls-les-Beziers (5.7.79)	Marseillan (18.5.79)	Fontalinières (22.5.98)
Nominal application rate (g a.s./ha)	30	30	45	30
field deposit (g a.s./ha)	65	10	29	21
drift part reaching the water body (g a.s./ha)	6.9 (23%)	3.7 (12%)	2.1 (5%)	4.5 (15%)
surface film concentration (µg a.s./l)	0h : 450 µg/l 0.5 h : 40 µg/l	0-1h : 1010 µg/l 3h : 10 µg/l	-	0.5h : 140 µg/l 2h : 20 µg/l

sub-surface water concentration (µg a.s./l)	0h : 1.7 µg a.s./l 0.5h : 0.09 µg a.s./l	0h : 0.52 µg/l 3h : 0.05 µg/l	0h : <0.01 µg/l 1h : 0.17µg/l	0.5h : 0.40 µg/l 1h : 0.22 µg/l 4h : 0.08µg/l
Effects (*)	no effect on tadpoles 2h : effects on gammarids, waterbeetles, mayfly larvae, no effect on dipterous larvae (stream drift samples) no effect on benthic invertebrates	0-6h : abnormal behaviour of *Caenis* and *Cloeon* nymphs *Notonecta, Corixa, Gerris* no effect on free swimming macroinvertebates, Zooplankton : no effect on ostracods, daphnids, chironomids	no evidence of hyperactivity among the various kinds of insects no effect on macroinvertebrates	hyperactivity of the aquatic invertebrates (Dyticid larvae and adult hydrophilids) effect on tadpoles (swimming downstream) 1-2h : effects on arthropods (stream drift samples)
Toxicity test using mayfly larvae (*Cloeon spp*)	not performed	one sampling position out of 3 with high mortality just after appl.	not performed	not performed

(*) : The samplings were not made according to a defined program for the 3 locations. Its is therefore very difficult to analyze the impact of the a.s. in the 3 locations taking into account the type of streams, the a.s. concentrations, the effects on the different water organisms.

Conclusions :

Spraying of vineyards situated along small water streams leads to drift percentages in accordance with the Ganzelmeyer model (5-23%). The a.s. concentrations decrease rapidly after application due to the water flow. The a.s. is not uniformally dispersed in the whole water body : A surface film with very high a.s. concentration is observed. The impact of the a.s. contamination on the streams leads to temporary effects on the invertebrate fauna.

STUDY ID. Spray drift form Ripcord applications to arable crops in Suffolk, UK : Fate and affects in adjacent ponds **(Shires *et al*., 1981)**

Material and methods :

Test substance :

EC formulation containing 100 g/l cypermethrin

Experimental design :

The formulation RIPCORD was applied on two occasions at each site at the nominal application rate of 70 g a.s./ha at a volume rate of 300l/ha by local farm staff using tractor-mounted, boom and nozzle equipment.

The first site situated at Badwell Ash, UK consisted of a large field (19 ha) divided into approximately equal areas of sugar beet and potatoes and contained two small farm ponds each of which was at least partly bordered by the field. - Pond A : A distance of 0.5 m to 2 m separated the outermost row of sugar beet from the water's edge. The surface area of the pond was about 950 m^2 and the maximum water depth at the start of the study was 1.2 m.

- Pond B: the pond was entirely surrounded by the sugar beet and potato crops. A large proportion of the pond was screened by bushes. In most places the distance between the edge of the pond and the crops was less than 2 m. The surface area of the pond was about 350 m² and the maximum water depth was 1 m.

- Park Farm : This site was situated at Mendlesham Manor, UK. The trial area consisted of a large field of sugar beet (20 ha) with a small triangular-shaped pond located on its north-west boundary. The banks of the pond adjacent to the sugar beet where steeply sloping and varied from 1 m to 3 m in width. The surface area of the pond was about 200 m² and the maximum water depth was 1.2 m.

Findings :

Table B.8.2.12-5 : Effects of cypermethrin spray drift in ponds situated near sugarbeet and potato fields

Location	Dairy farm, pond A		Dairy farm, pond B		Park farm pond	
Application date	19-6-79	17-7-79	19-6-79	17-7-79	21-6-79	19-7-79
Nominal application rate (g a.s./ha)	70	70	70	70	70	70
field deposit (g a.s./ha)	63	58	58	66	42	-
drift part reaching the water body (**mg** a.s./ha)	1.0 - 1.4	0.1 -280	2.3-5.4	1.6 - 18	0.9 - 1.7	0.4 -1.0
surface film concentration (µg a.s./l)	<5 - 23	<5 - 26	<5 - 15	<5 - 6	<5 - 11	<5 - 12
sub-surface water concentration (µg a.s./l	<0.01 - 0.03	<0.01 -0.07	<0.01 - 0.05	<0.01 -0.03	< 0.01- 0.02	< 0.01- 0.02
Effects						
Zooplankton (Cyclopoida, Calanoida, Ostracoda, Chydoroidae)	no significant decrease	no significant decrease	decrease of adult cyclopoids and	decrease of copepod nauplii	decrease of copepod nauplii	no significant decrease

			copepod nauplii			

The active substance concentrations determined in fish collected at several time intervals in the 3 ponds were <0.005 mg/kg on a wet weight basis. No bioaccumulation is possible as the chemical analysis is not enough accurate.

The mortality of organisms known to be susceptible to cypermethrin (*Daphnia, Asellus, Cloeon*) was assessed in an outdoor bioassay (4-42 replicates of 10 animals for treated and control groups). The organisms were maintained for 48 h in beakers containing water samples collected from the surface layers of the ponds. The mortality level in the control and treated groups was very low.

Other macroinvertebrates were collected using sweep-nets at days -1, 4 hours after appl., day 1 and day 7. No dramatic changes in populations levels were observed. However, due to very limited drift, the water contamination is very low. In absence of an untreated control, the significance of the observed effects cannot be easily assessed.

Conclusions :

Effects on zooplankton were observed at concentration of 0.01-0.05 µg a.s./l

STUDY ID. Spray drift from an aerial application of Ripcord to winter wheat in Kent, UK : Fate and effects in adjacent drainage ditches (**Shires, 1982)**

Material and methods :

Test substance :

EC containing 100 g/l cypermethrin

Experimental design :

A diluted EC formulation of RIPCORD was applied at 25 g a.s./ha by fixed-wing aircraft to a large field of winter wheat surrounded on 3 sides by drainage ditches

The stations 1, 2, 3 were established along a large drainage ditch 6-8 m wide and with a water depth of 1-1.5 m

The stations 4 and 5 were established along another ditch 3-4 m wide with a water depth of 0.5m. No measurable flow rate could be detected in both ditches.

Water quality parameters, a.s. water concentrations, caged fish samples, zooplankton, macroinvertebrates in sweep-net were monitored during 65 days after application. Spray deposit in/around the field (up to 175 m of field edge) was also measured.

Findings :

Table B.8.2.12-5 : Effects of cypermethrin drift in small ditches situated near a cereals field sprayed by an aircraft

Location	station 1 200 m of the field, downwind	station 2 along the field, downwind	station 3 200 m of the field, upwind	station 4 along the field, upwind	station 5 250 m of the field, upwind
Nominal application rate (g a.s./ha)	25				

field deposit (g a.s./ha)	16				
drift part reaching the water body (g a.s./ha)	nd	1.4	nd	0.68	nd
surface film concentration (µg a.s./l)	1h : 25	1h : 45	1h : 35	1h : 60	1h : 25
sub-surface water concentration (µg a.s./l	<0.01 - 0.03	<0.01 - 0.02	<0.01 - 0.02	< 0.01 - 0.01	< 0.01

Effects					
% mortality of *Gammarus pulex* in a 24h bioassay					
1h	0	48	2.2	1.1	3.3
4h	1.1	37	1.1	3.3	2.
1d	42	82	0	0	2.2
2d	17	11	0	4.4	0
4d	1.1	0	1.1	0	1.1
6d	0	1.1	0	0	0

Conclusions :

The study protocol is acceptable (sampling design). A throrough examination of the zooplankton (Cyclopoida, Calanoida, Ostracoda, Chydoroidae) sweep-net samples (Chironominae, Corixidae, Coleoptera, Hydracarina, Gastropoda, Naididae, Gammaridae) and emergence traps (Chironomidae) showed minor short-term effects on a few sensitive forms of invertebrates. *Gammarus* tests showed however that contamination of the ditches was effective at least in locations 1 and 2. It is therefore proposed to consider the sub-surface water concentration of 0.03 µg a.s./l as a level witout unacceptable risk.

STUDY ID. A comparison of the toxicities of WL 85871 and Ripcord to freshwater invertebrates in small field enclosures **(Garforth, 1982b)**

Test substance :

EC containing 100 g/l cypermethrin,

EC containing 100 g/l alpha-cypermethrin,

Experimental design :

An artificial pond 10 mX 5 m in area was subdivided in 22 enclosures with stainless boxes 1 m square pushed down into the sediment.

The pond contained an abundant invertebrate population. The depth of the pond was 1 m. The bottom of the pond was covered by naturally accumulated sediment and organic matter.

There were 2 replicates per treatment group and control allocated in a two blocks experiment.

EC formulations were sprayed above the water surface of each enclosure

a.s. concentrations in water in sediment and on plant surface, water quality parameters (temperature, oxygen concentration , pH) , zooplankton, macroinvertebrates , macrophytes cover, chlorophyll and suspended solids were monitored from day -2 to day +7. A bioassay with Gammarus was also performed. The main results are presented below.

Table B.8.2.12-5 : Effects of cypermethrin in field enclosures sprayed at several application rates

Nominal application rate (g a.s./ha)	0	1	3	10	30	100
Nominal water concentration (µg a.s./l)	0	0.1	0.3	1	3	10
Mean number of organisms at day 6 in both replicates (*)						
Daphnia	22-48	0-1	0-0	0-0	0-0	0-0
Chydoridae	1-1	1-1	0-1	0-0	0-0	0-0

Ostracoda	0-1	0-1	1-1	1-3	0-0	0-1
Calanoids	2-3	0-0	0-0	0-0	0-0	0-0
Cyclopoids	51-61	36-58	4-5	2-16	1-7	1-2
Copepod nauplii	87-116	59-73	0-0	0-0	0-0	0-0
Number of families in both replicates (**)						
Mollusca	2-2	2-3	2-3	1-2	2-3	1-2
Insecta	8-10	4-6	1-2	0-2	0-0	0-0
Crustacea (Asellidae)	1	0	0	0	0	0

(*) : data obtained at days 1 and 3, not included in the monograph, reflect the same effects

(**) : The effects of the a.s. are also well reflected by the number of organisms per family, not included in the monograph.

Table B.8.2.12-6 : Effects of alpha-cypermethrin in field enclosures sprayed at several application rates

Nominal application rate (g a.s./ha)	0	1	3	10	30	100
water concentration (µg a.s./l)	0	0.1	0.3	1	3	10
Mean number of organisms at day 6 in both replicates (*)						
Daphnia	22-48	0-0	0-0	0-0	0-0	0-0
Chydoridae	1-1	1-1	0-0	0-0	0-0	0-1

Ostracoda	0-1	1-1	1-3	0-1	0-1	0-0
Calanoids	2-3	0-0	0-0	0-0	0-0	0-0
Cyclopoids	51-61	9-40	4-16	1-2	4-8	1-12
Copepod nauplii	87-116	11-28	0-1	0-0	0-0	0-0
Number of families in both replicates (**)						
Mollusca	2-2	2-3	1-2	2-2	2-3	2-2
Insecta	8-10	3-3	1-2	0-0	0-0	0-0
Crustacea (Asellidae)	1	0	0	0	0	0

(*) : data obtained at days 1 and 3, not included in the monograph, reflect same effects

(**) : The effects of the a.s. are also well reflected by the number of organisms per family, not included in the monograph.

LC_{50} (24 h, Gammarus) were determined in this outdoor study at day 1, 3 and 6 :

Cypermethrin : LC_{50} = 0.08-0.11 µg a.s./l

Alpha-cypermethrin : LC_{50} <0.05-0.06 µg a.s./l

Conclusions :

The concentration of each a.s. in the water was around 50% of the nominal 24 h after application , and 10-20% of the nominal 7 days after applications.

Both compounds were toxic to several invertebrate taxa when applied at the lowest rate of 1 g a.s./ha. Arthropods were eliminated at 10 g a.s./ha. Molluscs were not affected at the highest rate of 100 g a.s./ha

STUDY ID. Catastrophic macroinvertebrate drift and sublethal effects on brown trout, *Salmo trutta*, caused by cypermethrin spraying on a Tasmanian stream **(Davies, 1991, data from the literature provided by Mitchell Cotts)**

Summary of the article:

Cypermethrin, a pyrethroid insecticide, was aerially sprayed on a *Eucalyptus nitens* plantation in northern Tasmania, Australia. Several tributary streams of the Meander River draining the plantation received direct spray drift contamination of the order of 0.5 g/ha above the streams (max. water conc of 0.1 - 0.5 µg/l). Increases in invertebrate drift of over 200-times were observed on the day of spraying in Sales Rivulet. Drift was significantly elevated for 8 days after spraying, recovering both in density and relative abundance after early winter floods. Plecoptera and ephemeroptera comprised 89-92 % of the drift immediately after spraying, compared with 6-21 % prespraying and at an uncontaminated site. Benthic abundances of plecoptera and ephemeropta decreased after spraying in all small streams draining the plantation. Early winter floods were observed to facilitate recolonisation at affected sites. Resident *Salmo trutta* were collected from the streams before and during 6 months after spraying. Plasma chloride, glucose and protein concentrations were not affected by the spraying event. Significant transient changes in muscle RNA/DNA levels as well as brain and muscle acetylcholinesterase levels and hepatic mixed function oxygenase activity were related to the spraying event. These changes conmmenced around day 7 and persisted until day 26. Changes in fish diet were also observed, related to the sequence of abundant and depauperate invertebrate drift after spraying. Pathological symptoms in fish were apparently related to dietary intake of cypermethrin from dead and dying invertebrate drift.

Conclusions :

This study showed that cypermethrin at a level of 0.1-0.5 µg a.s./l in water streams just after a spray application presents acute risk (destruction of the insects, transient changes in cholinesterase and oxygenase enzymes) and long-term risk for the aquatic fauna (insect recolonization after several months, sublethal effects on fish, algal bloom) .

STUDY ID. Determining the toxicity and hazard to fish of a rice insecticide **(Stephenson et al., 1984, data from the literature submitted by Mitchell Cotts)**

Material and methods :

Korea study : The experiment site was a paddy field at the College of Agriculture, Seoul.

Five treatment regimes were used for the experiment :

1. Control - no insecticide
2. Cypermethrin - low rate - 15 g a.s./ha (equivalent to 10 µg a.s./l in field water)
3. Cypermethrin - high rate - 40 g a.s./ha (equivalent to 27 µg a.s./l in field water)
4. Chlorfenvinphos - 1200 g a.s./ha (as 3 % granule)
5. Carbofuran - 1200 g a.s./ha (as 3 % granule)

with three replicate plots of each treatment allocated within a rendomized block design. The 15 plots required were constructed in the paddy using earth bunds and rigid plastic sheeting. Each plot was 6 m x 9 m and contained a 30 cm deep, 50 cm wide trench along one short edge. The plots flooded to a depth of approximately 15 cm (45 cm in the trenches) one week before the application of the insecticides.

The *C. carpio* used were obtained from a local commercial supplier. At the time of the experiment a sample of 40 fish has a mean weight of 4.6 g (SD 1.3).

The fish were introduced into the plots 2 days before application of the insecticides, 50 into each plot. They were divided into five groups on ten and placed in cages previously positioned in the plot. After their introduction the fish were checked daily for deaths and any dead found before application of the insecticides, were replaced.

Spain study : The experiment was carried out near Valencia during the week 26 July to 2 August 1982. A large plot of rice was treated with cypermethrin 1.25 % (an Ultra Low Volume formulation) at 25 g a.s./ha, using aerial application by fixed-wing aircraft. In total about 250 ha of rice were sprayed at 2 l/ha. The rice crop was about 50 cm high at the time of application and gave a dense cover. The water in the paddies was generally 5-10 cm deep with a slow and intermittent flow (equivalent to 25-50 µg a.s./l considering no water flow, no crop interception)

Cyprinus carpio for the experiment were obtained from a local hatchery. On the day before the application of the insecticide two open-topped cages, each containing 50 fish (5-10 cm long) were placed in the paddy to be treated. One cage was placed at the edge of the paddy, clear of the crop, in water 15-20 cm deep. The other was placed in a ditch draining part of the paddy where the water was somewhat deeper, 25-50 cm.

From the time of their introduction until 3 days after the application of the insecticide the cages were checked daily for dead fish; at the same time the water temperature and concentration of dissolved oxygen were recorded.

Findings :

Korea study : Mortality of the fish in the plots treated with cypermethrin at the low rate was 13 % and this was not significantly different ($P > 0.05$) from that in the control plots, 6.6 %. The mortality of fish in the plots treated with cypermethrin at the higher rate was 15 % and this significantly greater ($P < 0.05$) than that in the control plots, but not significantly different ($P > 0.05$) from that in the plots treated with cypermethrin at the low rate. Fish mortalities in the plots treated with chlorfenvinphos and carbofuran were 97 % and 67 % respectively and both were significantly higher than those in the control plots and the plots treated with cypermethrin at the higher rate ($P < 0.001$).

Spain study : There was no mortality of fish in either of the cages during the three days following the application of the cypermethrin.

Conclusions :

This study showed that fish would be less sensitive than invertebrates to cypermethrin. Fish mortality was observed at level of 10-27 µg a.s./l.

A pond enclosure study of the effects of FASTAC formulations on aquatic invertebrates **(Thorpe E., 1985)**

Summary of the study :

FASTAC EC, FASTAC SC and FASTAC SC + anti-evaporant were applied at a range of doses to the water surface within metal enclosures sited in an outdoor experimental pond.

Effects of the treatments on aquatic invertebrates were assessed by bioassaying water samples with *Gammarus pulex* and by sampling macroinvertebrate and zooplankton populations within each enclosure.

Results for macroinvertebrates and zooplankton were inconclusive (large variability in the control, no replicates for the treated groups).

However, the bioassay results indicated that FASTAC SC, with or without anti-evaporant, was less toxic to *Gammarus* than the EC formulation during the first 24 h after treatment. However the EC lost its toxicity more rapidly than the SC.

Conclusions :

The results of this study cannot be taken into account in the final evaluation.

STUDY ID. Evaluation of direct and indirect effects of Cyperkill 10 on aquatic organisms in outdoor enclosures (multi-site study) **(Schnöder F, Kroos M., 2003)**

Summary and conclusions of the study:

Two applications of cyperkill 10, EC, 100 g/l cypermethrin. Dose 0, 0.0016, 0.005, 0.016, 0.05, 0.2 and 1.0 µg a.s./L. Observations until 98 days after exposure. DT 50 < 1 day. Measurements 2 h after exposure ranged from 98%-129% of nominal. Although the summary in the DAR is not giving all details, needed for a sound evaluation, it can be concluded that significant effects on Chaoboridae are found in the lowest dose. It is however also indicated that large variations in abundance existed in abundance of invertebrate taxa between control cosms, and that also decreases were found between the two treatments. This renders the test less reliable. Therefore the result NOEC < 0.0016 µg/L (initial nominal concentration) can be used for MAC derivation for comparison only. Since further concentrations are not reported in the summary, a TWA can only be calculated using the DT50 of < 1 d.

STUDY ID. Aquatic toxicology of cypermethrin. II. Fate and biological effects in pond experiments **(Crossland, 1982)**

Summary of the study :

Two pond studies are performed to investigate dispersion, persistence and biological effects of cypermethrin in natural waters.

Pond experiment 1:

An emulsifiable concentrate, containing 400 g/L cypermethrin 10% emulsifiers and 50% mixed pertroleum xylenes was sprayed over an unlined pond (20 m long, 5 m wide and 0.8 m deep) at 100 g a.i./ha in June, 1976. Water and sediment samples were taken from the pond.

Pond experiment 2:

A mature, unlined pond (20 m long) was divided by constructing a concrete wall across it to produce two similar ponds (9-10 m long, 5 m wide, 0.7 m deep). The vegetation around their margins was dominated by rushes, *Juncus effuses*. The submerged vegetation consisted of a mixed community of vascular plants and filamentous algae. The pond was oversprayed with cypermethrin in June 1977 (similar to the experiment 1). The adjacent pond was left untreated. Water and sediment samples were taken. Twelve days before treatment each pond was stocked with 75 small rudd. Behaviour of fish was observed and samples for residue analysis were obtained. Zooplankton was sampled.

Findings

Pond experiment 1

Four hours after treatment, the concentration of cypermethrin in the surface water of the pond was 100 µg/L and after 48 h 4.8 µg/L. The concentration of cypermethrin in water samples taken from beneath the surface increased form 0.8 to 2.3 µg/L during the period 1 to 4 h after treatment, remained at about this level until 48 h after treatment, and then gradually decreased to 0.9 µg/L about 2 weeks after treatment.

No effects were observed on wild populations of fish and amphibia. There was a considerable overall effect on the community of invertebrates and this was reflected in a marked reduction in species richness, arising from mortality of aquatic insects and crustacea. There was considerable variation in the rate at which different species of insects and crustaceans were affected by the treatment. Aquatic invertebrates that frequently come to the surface for air were affected most rapidly. Late instar nymphs of waterboatmen *Notonecta* sp., were soon affected and showed typical signs of pyrethroid poisoning, i.e. hyperactivity and disorientation.Water beetles were affected within 1 h after treatment and died at the surface of the pond within a few hours. Dipterous larvae such as chironomids,*Tanypys, Forcipomyia and Corynoneura* were not noticeably affected until 24 h after treatment. Two weeks after application of cypermethrin, there was a greater quantity of filamentous algae present than before treatment.

Pond experiment 2

Soon after treatment, concentrations of cypermethrin associated with surface water and emergent leaves were two to four orders of magnitude greater than those associated with subsurface water and sediment. The highest concentrations in both surface and subsurface water were found in samples taken 1 h after treatment (0.13-1.3 µg/L). Three weeks after treatment the concentrations in both kinds of water samples approached the LOD. Concentrations in leaves of *P. natans* collected from the surface were relatively high at first but had decreased by two to three orders of magnitude 4 wk after treatment. Concentrations in sediment were always very low. The mean concentration of cypermethrin in six fish recovered in the period 1-14 day after treatment was 50 µg/kg. After 2 wks the residue in fish gradually decreased to ≤ 5µg/kg at 16 w. Fifteen weeks after treatment, there was no difference in the numbers of invertebrate species found in the treated compared with the untreated pond. However, populations of the mayfly *C. dipterum* and the crustacean *Asellus* sp. had not recovered from the effects of the treatment.

Conclusion

Due to the rapid decline, the study is not relevant for derivation of the AA-QS. Measured concentrations are variable, most likely because overspray was used without mixing. Since the NOEC is lower than the tested concentrations, the result cannot be used for derivation of the MAC-QS.

STUDY ID. A comparison of the fate and effects of two pyrethroid insectides (lambda-cyhalothrin and cypermethrin) in pond mesocosms **(Farmer *et al.*, 1994)**

Summary of the study :

Cypermethrin was applied to four mesocoms four times each with two week intervals at a rate of 0.7 g a.i./ha, equivalent to a drift rate of 2% from field crops and corresponding to 70 ng/L nominal. The mesocosms (25 x 25 m, 1 m deep water) consisted of steel-reinforced concrete tanks and organisms collected from nearby natural ponds were added to establish the biota. Effects of the treatments were assessed by physicochemical monitoring and sampling. Algal biomass was determined from cell biovolume measurements. Macrophyte and filamentous algal distributions were mapped as percentage surface cover and the major species present were identified. Zooplankton were sampled and macroinvertebrate populations were assessed.

Findings

Results showed a rapid decline in cypermethrin residue in water samples. Results are only reported for the 3rd application (31-35 ng/L after 1 h; 13% of nominal after 24 h; 9% of nominal after 2 d and <LOD of 2 ng/L after 6 d). Thirteen weeks after the final application, residues in hydrosoil samples were at or below the LOD in the 0 – 2.5 cm depth fractions and absent from lower depths.

There were no adverse effects of applications on algal chlorophyll content, productivity or community metabolism. There was an indication of a treatment-related enhancement in phytoplankton gross primary productivity. There was no apparent effect on phytoplankton community structure. There were no effects of treatment on macrophyte communities. There was no statistically significant effect on any individual group of zooplankton. Populations of Gammaridae were eliminated, there was no indication of recovery before the end of the study. Hemipterans and coleopterans were significantly reduced in numbers. Reductions in the abundance of Asellidae were observed after the second application. Some recovery was observed.

Conclusions :

This study showed that cypermethrin applied four times at a level of 0.7 g a.i./ha, with an application interval of two weeks presents acute risk (destruction of the Gammaridae) and long-term risk for the aquatic fauna (insect recolonization only after several months). Due to the rapid decline, the study is not relevant for derivation of the AA-QS. Since the NOEC is lower than the tested concentrations and concentrations in the water phase are not adequately reported, the result cannot be used for derivation of the MAC-QS.

STUDY ID. Effects of the pyrethroid insecticide, cypermethrin, on a freshwater community studied under field conditions. I. Direct and indirect effects on abundance measures of organisms at different trophic levels. **(Friberg-Jensen *et al.*, 2002)**

Summary of the study :

The effects of the pyrethroid insecticide cypermethrin on a natural freshwater community were studied in small in situ enclosures over an 11-day period. The experiment was conducted in a eutrophic lake using a regression design that included three untreated controls and a gradient of six unreplicated cypermethrin concentrations, ranging from 0.01 to 6.1 µg/l. This paper is the first in a series of two, and describes the fate of cypermethrin and its effects on the abundance of crustaceans, rotifers, protozoans (cilliates and heterotrophic nanoflagellates (HNF)) and bacteria and the biomass of periphytic and planktonic algae.

Systems were polyethylene enclosures (44 cm width, 150 cm deep, 200 L water), cypermethrin (96%) in acetone was added to the water below the surface, initial nominal concentrations 0.01, 0.04, 0.13, 0.47, 1.7 and 6.1 µg a.i./L. Estimated actual initial concentrations were calculated by linear regression of measured concentrations after 3 h, and 1, 4, and 11 days. Zooplankton was sampled after 4-12 h, and on days 1, 2, 4, 7 and 11.

Findings

The concentration of cypermethrin decreased quickly during the experiment, with a half-life of 48 h for the total and 25 h for the dissolved fractions of cypermethrin, respectively. Estimated actual initial concentrations were 0.006, 0.024, 0.078, 0.281, 1.015 and 3.643 µg/L, expressed as the sum of particle bound and dissolved fractions. Cypermethrin proved to be acutely toxic to crustaceans in enclosures receiving nominal cypermethrin concentrations of ≥ 0.13 µg/l (0.078 µg/L estimated initial). No Effect Concentration (NEC) for sampling points 4h-4 days were 0.02-0.07 µg/L for total crustaceans, 0.02-0.07 µg/L for cladocerans and 0.06-0.03 µg/L for copepods. EC50 values were 0.04-0.17 µg/L for total crustaceans, 0.03-0.17 µg/L for cladocerans and 0.05-0.11 µg/L for copepods (all based on estimated initial concentrations). The abundance of rotifers, protozoans and bacteria and the chlorophyll-a concentration of planktonic and periphytic algae was significantly related to the concentration of cypermethrin. All groups proliferated within 2 - 7 days after the cypermethrin application in those enclosures where the abundance of crustaceans was seriously affected by cypermethrin (i.e. ≥ 0.13 µg/l nominal). We hypothesise that the proliferation of rotifers, protozoans, bacteria and algae was due to a reduced grazer control from crustaceans and thereby mediated indirectly by cypermethrin.

Conclusions

Lowest NEC for the crustacean community, cladocerans and copepods is 0.02 µg/L. This value refers to the estimated initial concentrations, expressed as the sum of particle bound and dissolved fractions, and relates to nominal exposure level 0.04 µg/L. Measured dissolved concentrations after 3 h were <LOD, except for the three highest doses (0.47-6.1 µg/L). Only one replicate per concentration was used. Due to the raspid decline, the study is not relevant for derivation of the AA-QS. Since at the level of the NEC no adequate analysis is available, the study cannot be used for the MAC-QS either.

Probabilistic risk assessment of cotton pyrethroids: II. Aquatic mesocosm and field studies **(Giddings *et al*., 2000)**

Summary of the study :

Results of four mesocosm and field studies with cypermethrin and esfenvalerate were analysed and interpreted to support an ecological risk assessment of cotton pyrethroids in aquatic ecosystems. The studies revealed a trend in sensitivity from amphipods, isopods, midges, mayflies, copepods, and cladocerans (most sensitive) to fish, snails, oligochaetes, and rotifers (least sensitive).

Conclusion

This article does not provide detailed new information from which endpoints for EQS derivation can be distracted.

Community level analysis of ecotoxicological field studies: I. Biological monitoring **(Kedwards *et al.*, 1998)**

Summary of the study:

A number of multivariate techniques were used to analyze data from a farm pond study in which cypermethrin was aerially applied adjacent to the water body.

Cypermethrin was sprayed aerially onto a cotton crop planted in the 16-ha drainage basin of a 3,4-ha pond. Applications were made on 10 occasions at 1-week intervals at the recommended field rate of 112 g as/ha. Only data concerning the abundance of macroinvertebrates and the concentration of cypermethrin in both the hydrosoil and overlying water column were considered. The macroinvertebrate communities of the pond were studied using artificial substrates (at two depths) and emergence traps. Insect emergence was assessed using emergence traps. Water was sampled following application at 3-weeks intervals for 12 weeks.

Findings

Increases in the concentration in hydrosoil were related to declines of deseasonilised Diptera abundance. The lowest NOEC was found using canonical discriminant analysis resulted in a NOEC for emergence of Diptera of 1.6 µg/kg dry weight.

Non-metric clustering and nonmetric multidimensional scaling clearly identified a cypermethrin concentration-related decrease in the abundance of Diptera in the artificial substrate samples. The NMC technique resulted in a NOEC of 2.5 µg/kg dw.

Conclusion.

From the results as presented in the paper it is impossible to derive a reliable endpoint, The substance was applied 10 times. From the paper onset and duration of effects cannot be derived. Details about soil composition are not provided. The NOEC's as presented therefore can only be used as a rough indication and for comparison with other results for the order of magnitute of the effects of cypermethrin on insects in the hydrosoil.

The influence of simulated immigration and chemical persistence on recovery of marcroinvertebrates from cypermethrin and 3,4-dichloroaniline exposure in aquatic microcosms **(Maund *et al*., 2009)**

Summary of the study:

The study site was at Syngenta Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. The microcosms were constructed from cylindrical, fibre-glass tanks of 1.25m diameter and 1.25m height, each with an integral base. To regulate microcosm temperatures, the tanks were maintained in 5 × 5 × 1.2m outdoor concrete ponds filled with water to a depth of 1 m. The microcosms were established with sediment from a mature pond on site (added sediment depth 10 cm), and microcosms were filled to a depth of 1 m using a combination of pond water and potable mains water. Aquatic macrophytes were added to each microcosm, which were either collected from nearby ponds or grew from propogules present in the added sediment. The dominant floating-leaved plant species was *Potamogeton natans* L. The most abundant submerged species were *Ceratophyllum demersum* L. and *Myriophyllum spicatum* L.

Application rate was 70 ng cypermethrin/L. Two blocks of five microcosms were used, and two replicateswere assigned to each treatment. Treatments were assigned at random within these blocks to treatments of control (no chemical or organism addition), 70 ng cypermethrin/L with immigration, 70 ng cypermethrin/L without immigration. The application solutions (including 100 mL methanol) were poured over the surface of the microcosm on 25 June 1996, and the microcosm was gently stirred to mix in the chemical. An equal volume of the solvent was added to each of the control microcosms. After treatment, each microcosm was covered with a removable net hood (0.45×0.78 mm mesh), which allowed water and 90% light penetration (as indicated by the manufacturer) but prevented entry of macroinvertebrates. Apart from the very short time in which samples were collected (ca 2 min per sample), the microcosms remained covered for the remainder of the experiment. To determine exposure concentrations of cypermethrin and 3,4-DCA in the microcosms, depth-integrated water column samples were taken for analysis using a water column sampler.

Findings

Analysis of water samples taken immediately after chemical application showed that cypermethrin concentrations in the microcosms on day 0 ranged from 41 to 58 ng/L (58–83% of nominal). Cypermethrin water concentrations in the microcosms on day 2 were close to the limit of determination of 10 ng/L, indicating a median dissipation time (DT50) from water of approximately 1 day or less.

Microcosms exposed to 3,4-dichloroaniline treatment suffered substantial loss of taxon richness and by 10 months after treatment had only recovered where invertebrates had been added. Those treated with cypermethrin underwent an initial decline in certain crustacean (*Asellus aquaticus*) and insect populations (Chaoboridae and *Crangonyx pseudogracilis*), and a clear effect on the macroinvertebrate community. The populations showed some signs of recovery over a period of 5 months through internal processes alone. However, rate of recovery was further enhanced where immigration was simulated, and in this case recovery had occurred around 100 days after treatment.

Conclusion

A single treatment of cypermethrin at 70 ng/L (nominal concentration) resulted in a decline in certain crustacean and insect species. Since in other studies NOEC's below this value are found, this study underpins the results from these other studies. The value of 70 ng/L therefore will not attribute to the value of an EQS.

Field evaluation of *Simulium* larvicides: Effects on target and non-target insects **(Mohsen, Z.H, Mulla, S., 1982)**

Summary of the study:

A 10% EC formulation of cypermethrin was applied at a concentration of 0.01 mg/L in a manmade streamlet or creek at Thousand Palms Canyon, 100 km east of Riverside. Five sampling sites were established in the creek, four of which were located downstream from the treatment point. The population density of aquatic insects pre- and posttreatment was studied using strip and surber sampling methods.

Findings

The number of *Thienemaniella* larvae in the drift was lower than the larvae of other chironomid midge species, indicating these to be less susceptible, or occurring in lower density, than the other chironomids. The population trends of Chironomidae did not decline markedly except at the 50-m site 1 and 7 days posttreatment. There was a substantial reduction in the larval and pupal populations of *Simulium* 1 day after treatment, particularly at the farther distances of 250, 750 and 1300 m.

Conclusion

A single application was performed, no measurements of cypermethrin residues took place. Therefore the results of this study are not suitable for MPC derivation.

The use of small enclosures to assess the toxic effects of cypermethrin on fish under field conditions (**Shires, 1983)**

Summary of the study:

An emulsifiable concentrate formulation of cypermethrin was applied at seven different dose rates (between 5 and 500 g as/ha) to the water surface of enclosures (1 m^2, 1,2 m high), located in a small outdoor pond. Small rainbow trout and common carp were introduced to the enclosures. At daily intervals, the concentration of cypermethrin was determined in water samples, collected form the enclosure treated with 5, 50 and 500 g as/ha. Two further water samples were collected from these enclosures, and their toxicity was assessed by bioassay, using *Gammarus pulex* as the test organism. The experiment was terminated 96 h after application, when all the fish were removed and examined for mortality or adverse toxic effects.

Findings

Cypermethrin residues in the enclosures treated with 5 and 50 g as/ha, attained peak concentration of 0.55 and 2.40 µg/L 24 h after application and thereafter declined to about 50% of this level, 96 ha post treatment. Bioassays with *Gammarus pulex* expressed as the delution of water samples, result in recalculated EC50 values of 0.01-0.08 µg/L. Maximum cypermethrin concentrations were not attained until about 72 h after application in the enclosure treated with 500 g as/ha. Highly consistent responses, closely correlated with the applied dose rates, were obtained with *G. pulex* and both species of fish. Rainbow trout appeared to be about three times more susceptible to cypermethrin than common carp, with calculated LD_{50} values of 92 and 300 g as/ha, respectively. The author concludes that fish mortality due to the application of cypermethrin in normal agricultural use is very unlikely.

Conclusion

The author conludes that fish mortality in the enclosures is very well comparable with the results found in laboratory studies. Therefore it does not yield new endpoints for EQS-derivation. The result of the bioassay with *Gammarus pulex (*EC50 values of 0.01-0.08 µg/L), can be used for comparison with the results of laboratory studies.

Impact of selected synthetic pyrethroids and organophosphorous pesticides on the tadpole shrimp *Triops longicaudatus* (Le Conte)(Notostraca: Triopsidae) **(Walton *et al.*, 1990)**

Summary of the study:

Field tests were conducted in 30-36 m^2 ponds at the university of California-Riverside. The ponds were filled with well water. Cypermethrin was applied at rates of 0.0001, 0.0003, 0.0006, 0.001, 0.003, 0.012 and 0.056 kg as/ha at 4 d after flooding. All pesticide treatments were triplicated. All posttreatment samples were taken 3 d after pesticide application. Actual concentrations were not measured. Tadpole shrimp were sampled along the perimeter of each pond. To determine the impact of the pesticide against Triops the Mann-Whitney U statistic was used to compare the tadpole shrimp counts in each pairwise treatment combination.

The toxicity of cypermethrin was also determined in the laboratory. Field-collected tadpole shrimp (4-5 d old) were used.

Findings

Cypermethrin provided complete control at 0.0006 kg as/ha. Shrimp abundance differed significantly in treated (≥ 0.0003 kg as/ha) and untreated ponds. Small-sized tadpole shrimps were never observed. The author reports a LC_{50} in the laboratory of 0.084 µg/L for *Triops longicaudatus* at 28 ± 2 °C.

Conclusion

Since actual concentrations were not measured and the $LogK_{ow}$ of cypermethrin is 6.6, it is not possible to derive a reliable exposure concentration in the water, and therefore no reliable endpoint for EQS derivation can be obtained from the study.

Effects of the pyrethroid insecticide cypermethrin on a freshwater community studied under field conditions. II.Direct and indirect effects on the species composition **(Wendt-Rasch et al., 2003)**

Summary of the study:

The effects of cypermethrin, a commonly used pyrethroid insecticide, were studied in small in situ enclosures (diameter: 44 cm, depth 150 cm) situated in an eutrophic lake over an 11-day period. The experimental design used a regression principle that included three untreated controls and a gradient of six unreplicated cypermethrin concentrations: 0.01, 0.04, 0.13, 0.47, 1.7 and 6 µg/l. This paper is the second in a series of two and describes the effects on the species composition of the crustacean, rotifer, periphyton and phytoplankton communities.

Findings

Multivariate ordination technique (redundancy analysis (RDA) combined with Monte Carlo permutation tests) showed that exposure to cypermethrin caused significant changes in the species composition of the communities. Changes in the structure of the communities were observed following exposure to a nominal concentration of 0.13 µg cypermethrin per litre above. The direct acute effect of exposure to cypermethrin was a rapid decrease of many species of crustacean zooplankton. The alterations in crustacean species composition were probably due to variations in susceptibility to the direct toxic effects of cypermethrin. No effects concentration (NOEC) for individual zooplankton species were calculated using inverse regression based on actual concentrations and revealed that copepod nauplii were the most sensitive (NOEC = 0.01 µg/l) of the crustacean groups examined. The observed alterations of the species composition of the autotrophic communities as well as of the rotifers were most likely caused indirectly by cypermethrin, mediated through the direct negative effects of the insecticide on the crustacean grazers.

Conclusions

The NEC for community effects is 0.04 µg/L. The NOEC for the most sensitive species *nauplii* was 0.01 µg cypermethrin/L, based on actual concentration 4 h post treatment..

From Zeta-cypermethrin addendum to DAR (direct copy):

Zeta-Cypermethrin 100 g as/L EW (Zeta-Cypermethrin 10 EW) : Assessment of the ecological effects on aquatic communities using outdoor aquatic mesocosms after a single treatment. **(Schanné C., February 2007a).**

Guidelines :

SETAC, 1991; SETAC/RESOLVE, 1991; EWOFFT, 1992; World Wildlife Fund/RESOLVE, 1992; Hill *et al*., 1994

OECD Draft Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms), July 1994

SANCO Guidance Document 3268/2001, rev. 4 (final), 17 October 2002

GLP :

Yes

Material and Methods :

Test substance :

- zeta-cypermethrin 100 g a.s./L EW formulation, containing 9.5 % zeta-cypermethrin, batch n° : PL05-0111

- analytical standard : zeta-cypermethrin, chemical purity : 85.3 (S), 95.1 % total cypermethrin, cis/trans ratio 51/49, batch n° : E6788:122B
- radiolabeled : [cyclopropyl-^{14}C]-zeta-cypermethrin, specific radiopurity : 62.3 mCi/mmol, certified radio-purity : 98.4 %, batch n° : 244

Type of test : 98 days outdoor mesocosm test, single treatment

Test system :

The in-life phase of this study was conducted in 26 outdoor mesocosms located in Horne, Switzerland. Each mesocosm consisted of a stainless steel enclosure (0.95 m³, 1 m water layer and 20 cm sediment layer) contained within an equilibrated test basis of 9 x 9 m. The test system was established in December 2004 by the addition of sediment and water to the test basin. Both the water and the sediment were sourced from the Bay of Fussach, Lake Constance, Austria.

Stocking of the test basin with zooplankton and macroinvertebrates began on 4 May 2005. Care was taken as far as possible, to include organisms potentially sensitive to the test item, e.g., *Asellus aquaticus* (Isopoda) and *Gammarus* spp. (Amphipoda), caddis fly (Trichoptera), mayfly (Ephemeroptera), *Chaoborus* spp. and dragonfly (Odonata) larvae. The selection of these species was based on ecotoxicity data.

On 26 May 2005 (day –33 of the study), pre-treatment monitoring of the test basin was initiated. On 24 June 2005, the stainless steel enclosures ("mesocosms") were placed in the test basin. The first treatment was made on 28 June 2005 (day 0). Post-treatment monitoring of the aquatic organisms within the mesocosms continued until 4 October 2005 (day 98).

Test design :

untreated control (6 replicates), single treatment at 0.001, 0.005, 0.012, 0.018 and 0.024 µg a.s./L (3 replicates), analytical concentration-verification (1 replicate with ^{14}C-zeta-cypermethrin); 26 enclosures in total

The test item was applied once on June 28, 2005 into the water by means of glass pipettes, followed by a careful and thorough mixing of the water to achieve a fast and homogeneous distribution of the test item in the water column.

Analytical, biological and physical sampling :

Post-treatment sampling was conducted on day 0 (0.5, 2 and 5 hours after treatment) and on days 1, 2, 3, 7, 14, 21, 28, 41, 55, 84 and 98 following treatment.

The test concentrations applied were verified analytically. Depth-integrated water samples were collected up to day 98 and analysed by HPLC with UV detection. The samples were analysed until the concentration of zeta-cypermethrin was <LOQ, i.e., up to day 3 for concentrations of 0.001, 0.005, 0.012 and 0.018 µg a.s./L and up to day 7 for the 0.024 µg a.s./L test concentration. The LOQ (total radioactivity residue, TRR) for water samples was 0.001 µg a.s./L or 100 % of the lowest test level. The LOQ (^{14}C-zeta-cypermethrin) for water samples was 0.0005 µg a.s./L or 50 % of the lowest test level 0.001 µg a.s./L. Sediment cores were sampled and analysed by LSC and radio-TLC. The LOQ (TRR) was 0.015 µg a.s./kg sediment (dry weight).

Measurements of water quality, temperature, dissolved oxygen, pH, conductivity, alkalinity, hardness, TOC and N/P were conducted. To assess the effects on the biology of the mesocosms the following parameters were recorded; chlorophyll-a and phaeophytin concentrations, macrophyte volume, density and composition of phytoplankton, abundance of open-water invertebrates, invertebrates associated with macrophytes and pebbles, invertebrates associated with sediment and the water-sediment interface overlaying the sediment and the number of hatched insects. The systems were sampled by taking depth-integrated water samples to analyse for algae, zooplankton and macroinvertebrates. Macrophytes and pebble substrate samplers were collected for macrophyte associated zooplankton, macroinvertebrates and benthic organisms. Analysis of organisms > 100 µm was conducted *in vivo*. Analysis of organisms < 100 µm was conducted after preservation. Sediment cores were analysed for sediment dwelling organisms and zooplankton associated with the water-sediment interface. Emerging insects were collected in emergence traps.

NOEC values for population and community effects were determined using univariate (TOXSTAT 3.5 and SPSS, Bonferroni and Williams and Games-Howell's tests) and multivariate (CANOCO 4.5) statistical methods. Through consideration of the NOEC values and the potential for recovery, a NOEAEC could also be determined.

Findings :

Analytical concentration verification :

Application of target concentrations was confirmed by an application validation experiment using the radioactive test item, formulated as 100 EW. The results verified that the treatment emulsions were quantitatively transferred into the water of the mesocosms, with a recovery that was ≥ 97% for all treatment groups. Hence, the application method was suitable to transfer all prepared test item into the water of the mesocosm test systems.

Measurement of the stock treatment emulsions demonstrated that appropriate amounts of the test item were prepared, per concentration and replicate. While taking the following parameters into account, the water volume per enclosure, the results of the application validation experiment, the measurements of the stock solutions and the measurements of the rinses of the application glassware, it could be shown that the mesocosms received 89.2 % up to 96.0 % of the following nominal concentrations : 0.001, 0.005, 0.012, 0.018 and 0.024 µg a.s./L. The results of the study are therefore based on nominal concentrations.

Immediately following application and mixing, water samples were collected and analyzed. The results ranged from 51.4 to 62.0 % of nominal concentration for the 0.005, 0.012, 0.018 and 0.024 µg a.s./L treatment groups. The results for the 0.001 µg a.s./L test group were all below the limit of quantification. The DT_{50} of zeta-cypermethrin in surface waters as determined at the highest test concentration was 2 hours. The corresponding DT_{90} value was 30 hours, demonstrating that zeta-cypermethrin rapidly dissipated from the water phase.

Sediment samples of the 0.024 µg a.s./L test group (highest test concentration) were analyzed as being representative for the study. Generally, the residues in sediment were all below the LOQ (0.015 µg a.s./kg dry weight) with the exception of one sample on day 55. This sample resulted in a residue of 0.025 µg a.s./kg dry weight but was considered an outlier since at the next sampling interval (day 84), the residue was below the limit of detection. Since the results of the highest test concentration were below or near the LOQ, the sediment samples of the other test concentrations and other sampling days were not analyzed. This indicates that zeta-cypermethrin does not accumulate in the sediment following a single application up to nominal water concentraions of 0.024 µg a.s./L.

Water quality :

The water quality for the treated mesocosms during the pre-and post-treatment assessment periods was similar to the control mesocosms. Water quality was typical of an oligo- to mesotrophic, shallow water system that was rich in aquatic invertebrates.

Biological results :

The biological results were assessed based on the SANCO Guidance 2002[†] criteria (Table B.9.2.12-1) with the appropriate NOEC values are indicated by an X in Tables B.9.2.12-2 to B.9.2.12-6.

Table B.9.2.12-1 : Assessments criteria used based on SANCO Guidance 2002

[†] Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final). 17 October 2002.

1	No effects demonstrated	If one of the following criteria is satisfied, no effect is assumed: • No consistent adverse effects were observed as a result of the treatment, i.e. statistically significant values were found at isolated and sporadic sampling points only • Observed differences between treated test systems and counts did not demonstrate a clear causality , i.e. no clear concentration-response • The findings made during the in-life assessment phase did not indicate a biological significance, i.e. no relationship between counts of predators and their prey
2	Slight effects	• Isolated statistically significant values occurred and there was a trend that populations increased or decreased on the sampling occasions before and/or after the significant finding(s) • Subsequent statistically significant effects were found on two consecutive sampling occasions only • Effects observed for maximum two weeks after effect onset • Recovery observed within short time with respect to the life cycle of the affected species
3	Clear short-term effects with a duration of < eight weeks	• Effects observed on at least two subsequent sampling occasions • Recovery occurred within eight weeks after the last treatment • Statistically significant increase or decrease in sensitive endpoints, e.g. a systematic increase or decrease in abundance of individuals associated with a clear concentration response • Transient, recoverable effects reported on all sensitive and less sensitive endpoints
4	Pronounced effect in short-term study	• Recovery of these endpoints not demonstrated before termination of the in-life assessment phase
5	Pronounced long-term effects	• Convincing reductions in sensitive endpoints • Recovery of these endpoints not observed before termination of the in-life assessment phase (98 - 112 days after treatment)

The effects on **phytoplankton** are summarised in Table B.9.2.12-2.

Table B.9.2.12-2 : Effects on phytoplankton

Effect characterisation	**Test concentration (µg a.s./L)**				
	0.001	**0.005**	**0.012**	**0.018**	**0.024**
1. Phytoplankton community (abundance):					
	1	1	1	1	1
2. Phytoplankton taxonomic groups:					
Chrysophyceae	1	1	1	1	1
Bacillariophyceae	1	1	1	1	1
Chlorophyceae	1	1	1	1	1
Cryptophyceae	1	1	1	1	1
Cyanophyceae	1	1	1	1	1
Flagellates	1	1	1	1	1
µ-algae	1	1	1	1	1
3. Phytoplankton biomass:					
Chlorophyll-a concentration [µg/L]	1	1	1	1	1
Phaeophytin concentration [µg/L]	1	1	1	1	1
Chlorophyll/Phaeophytin ratio (C/P ratio)	1	1	1	1	1
NOECpop based on univariate statistical analysis					**X**

X = NOEAEC concentration

The effects on **zooplankton** and **macroinvertebrates** are summarised in Tables B.9.2.12-3 and B.9.2.12-4, respectively.

Table B.9.2.12-3 : Effects on zooplankton

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.012**	**0.018**	**0.024**
1a. Zooplankton community (open water):					
	1	1	1	1	1
1b. Zooplankton community (substrates):					
	1	1	1	1	2^{+}
2, Zooplankton taxonomic groups:					
Rotatoria (open-water)	1	1	1	1	1
Rotatoria (substrates)	1	1	1	1	1
Keratella quadrata (open-water)	1	1	1	1	1
Keratella quadrata (substrates)	1	1	1	1	1
Rotatoria div. sp. (open-water)	1	1	1	1	1
Rotatoria div. sp. (substrates)	1	1	1	1	1
Crustacea (open-water)	1	1	1	1	1
Crustacea (substrates)	1	1	1	1	1
Copepoda (Crustacea):					
Copepoda (open-water)	1	1	1	1	1
Copepoda (substrates)	1	1	1	1	1
Cyclopoida (open-water)	1	1	1	1	1
Cyclopoida (substrates)	1	1	1	1	1
Calanoida (open-water)	1	1	1	1	1
Calanoida (substrates)	1	1	1	1	1
Nauplii (open-water)	1	1	1	1	1
Nauplii (substrates)	1	1	1	1	1

Effect characterisation	**Test concentration (µg a.s./L)**				
	0.001	**0.005**	**0.012**	**0.018**	**0.024**
Cladocera (Crustacea):					
Cladocera (open-water)	1	1	1	1	1
Cladocera (substrates)	1	1	1	1	1
Simocephalus vetulus (substrates)	1	1	1	1	1
Daphnia spp. (open-water)	1	1	1	1	1
Daphnia spp. (substrates)	1	1	1	1	1
Large cladocera (open-water)	1	1	1	1	1
Large cladocera (substrates)	1	1	1	1	1
Chydoridae (Cladocera):					
Chydoridae (substrates)	1	1	1	1	1
Chydorus spp. (substrates)	1	1	1	1	1
Alona sp./ Alonella spp. (substrates)	1	1	1	1	1
Acroperus harpae (substrates)	1	1	1	1	1
Graptoleberis testudinaria	1	1	1	1	1
Pleuroxus spp.	1	1	1	1	1
Ostracoda (substrates)	1	1	1	1	1
NOECpop based on univariate statistical analysis					**X**
NOECcom based on univariate statistical analysis				**X**	

± Increase/decreased counts were found

X = NOEAEC concentration

Table B.9.2.12-4 : Effects on macroinvertebrates

Effect characterisation	**Test concentration (µg a.s./L)**				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
1a. Macroinvertebrate community (open water):					
	1	1	1	1	1
1b. Macroinvertebrate community (substrates):					
	1	1	1	1	1
1c. Macroinvertebrate insecta (substrates):					
	1	1	1	1	1
1d. Macroinvertebrate community (sediment dwelling):					
	1	1	1	1	1
1e. Macroinvertebrate community (emerging insects):					
	1	1	1	1	1
2. Macroinvertebrate groups in each community:					
Nematoda (sediment)	1	1	1	1	1
Gastropoda (Prosobranchia):					
Bithynia tentaculata (substrates)	1	1	1	1	1
Gastropoda (Pulmonata):					
Lymnaeidae (substrates)	1	1	1	1	1
Planorbidae div. sp. (substrates)	1	1	1	1	1
Physidae (substrates)	1	1	1	1	1
Gastropoda div. sp. (substrates)	1	1	1	1	1
All Gastropoda (substrates)	1	1	1	1	1

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
Gastropoda clutches (substrates)	1	1	1	1	1
Oligochaeta:					
Oligochaeta (sediment)	1	1	1	1	1
Stylaria lacustris (substrates)	1	1	1	1	1
Oligochaeta div. sp. (substrates)	1	1	1	1	1
Oligochaeta all (substrates)	1	1	1	1	1
Hirudinea:					
Helobdella stagnalis (substrates)	1	1	1	1	1
Hirudinea all (substrates)	1	1	1	1	1
Hirudinea clutches (substrates)	1	1	1	1	1
Asellus aquaticus (Isopoda) (substrates)	1	1	1	1	1
Trichoptera larvae (substrates)	1	1	1	1	1
Ephemeroptera (Insecta):					
Baetidae larvae (substrates)	1	1	1	1	1
Cloeon dipterum (emerging)	1	1	1	1	1
Odonata:					
Zygoptera larvae (substrates)	1	1	1	1	1
Chaoboridae (Diptera, Insecta):					
Chaoboridae (open-water)	1	1	1	1	1
Chaoboridae (emerging insects)	1	1	1	1	1
Chironomidae (Diptera, Insecta):					

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
Chironominae (substrates)	1	1	1	1	1
Orthocladiinae:					
Corynoneura sp. (larvae)	1	1	1	1	1
Corynoneura spp. (emerging)	1	1	1	1	1
Tanypodinae (larvae in substrates):	1	1	1	1	1
Tanypodinae (larvae in sediment):	1	1	1	1	1
Chironomidae (substrates)	1	1	1	1	1
Chironomidae (sediment)	1	1	1	1	1
Chironomidae (emerging)	1	1	1	1	1
NOECpop based on univariate statistical analysis					**X**

X = NOEAEC concentration

The effect of the treatments on the **taxonomic richness** of the communities is summarised in Table B.9.2.12-5. In addition Table B.9.2.12-6 summaries the statistical significance of the **PRC** (principle response curve) and **PCA** (principle component analysis) **analyses** conducted.

Table B.9.2.12-5 : Effects on taxonomic richness

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
Community of phytoplankton (PHY)	1	1	1	1	2
Community of open-water	1	1	1	1	1

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
invertebrates (DIWO)					
Community of invertebrates associated with substrates (macrophytes and pebbles) (SA)	1	1	1	1	1
Community of sediment-dwellers including organisms of the water-sediment interface, overlaying the sediment (SED)	1	1	1	1	1
Community of emerging insects (EI)	1	1	1	1	1
NOECcomm based on univariate statistical analysis				**X**	

X = NOEAEC concentration

Table B.9.2.12-6 : Summary of the PRC and PCA analysis conducted

Effect characterisation	Test concentration (µg a.s./L)				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
PRC (Principle Response Curves):					
Aquatic community of phytoplankton (PHY)	P > 0.05				
Aquatic community of open-water invertebrates (DIWO)	P > 0.005				

Effect characterisation	**Test concentration (µg a.s./L)**				
	0.001	**0.005**	**0.015**	**0.018**	**0.024**
Aquatic community of invertebrates associated with substrates (macrophytes and pebbles) (SA)	P > 0.005				
Aquatic community of sediment-dwellers including organisms of the water-sediment interface, overlaying the sediment (SED)	**P = 0.0357**				
Community of emerging insects (EI)	**P = 0.0006**				
Bold: P ≤0.05: A significant difference between the test groups was found (Monte-Carlo simulation)					
PCA (Principle Component Analysis):					
Community of phytoplankton (PHY)	1	1	1	1	1
Community of open-water invertebrates (DIWO)	1	1	1	1	1
Community of invertebrates associated with substrates (macrophytes and pebbles) (SA)	1	1	1	1	1
Community of sediment-dwellers including organisms of the water-sediment interface, overlaying the sediment (SED)	1	1	1	1	1
Community of emerging insects (EI)	1	1	1	1	1
NOECcomm based on multivariate statistical analysis					**X**

X = NOEAEC concentration

Conclusions in the DAR:

A “state-of-the-art” outdoor pond mesocosm study was conducted, according to modern acceptable guidance, to determine the possible effects of zeta-cypermethrin (as 100 g as/L EW formulation) on algae, zooplankton and macroinvertebrates under realistic exposure conditions.

The biological results were assessed using the Sanco Guidance criteria (2002). Mesocosm endpoints were determined according to the Sanco guidance criteria, biological results, effect characteristics and recovery potential. For this mesocosm study, a NOEAEC was determined, since the focus of this study was on population-level and community-level effects.

Based on the biological results and the nominal water concentrations (0.001, 0.005, 0.012, 0.018 and 0.024 µg a.s./L) following a single application with a formulated product containing zeta-cypermethrin, the following mesocosm endpoints were determined:

$NOEC_{population}$: 0.024 µg a.s./L

$NOEC_{community}$: 0.018 µg a.s./L

$NOEAEC_{community}$: 0.024 µg a.s./L

Conclusion for the use of the results for EQS-derivation

Given the very low DT50 the results of the study cannot be use for AA-EQS derivation. From the results of the study as presented it is unclear which taxa caused the slight and transient effects at the community level. Furthermore only in the highest concentration some effects at population level were found. Therefore a dose-effect correlation is lacking. This renders it impossible to assess whether the study as presented is able to show effects of cypermethrin on the aquatic community. Therefore it is recommended not to use the results for EQS-derivation.

From Zeta-cypermethrin addendum to DAR (direct copy):

Zeta-Cypermethrin 100 g as/L EW (Zeta-Cypermethrin 10 EW) : Assessment of the ecological effects on aquatic communities using outdoor aquatic mesocosms after duplicate treatment at 14-day interval. (Schanné C., February 2007 b).

Guidelines :

SETAC, 1991 ; SETAC/RESOLVE, 1991; EWOFFT, 1992 ; World Wildlife Fund/RESOLVE, 1992; Hill *et al*., 1994

OECD Draft Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms), July 1994

SANCO Guidance Document 3268/2001, rev. 4 (final), 17 October 2002

GLP :

Yes

Material and Methods :

Test substance :

- zeta-cypermethrin 100 g a.s./L EW formulation, containing 9.5 % zeta-cypermethrin, batch n° : PL05-0111
- analytical standard : zeta-cypermethrin, chemical purity : 85.3 (S), 95.1 % total cypermethrin, cis/trans ratio 51/49, batch n° : E6788:122B
- radiolabeled : [cyclopropyl-^{14}C]-zeta-cypermethrin, specific radiopurity : 62.3 mCi/mmol, certified radio-purity : 98.4 %, batch n° : 244

Type of test : 112 days outdoor mesocosm test, duplicate treatment with 14-day interval

Test system :

The in-life phase of this study was conducted in 10 outdoor mesocosms located in Horne, Switzerland. Each mesocosm consisted of a stainless steel enclosure (0.95 m³, 1 m water layer and 20 cm sediment layer) contained within an equilibrated test basis of 9 x 9 m. The test system was established in December 2004 by the addition of sediment and water to the test basin. Both the water and the sediment were sourced from the Bay of Fussach, Lake Constance, Austria.

Stocking of the test basin with zooplankton and macroinvertebrates began on 4 May 2005. Care was taken as far as possible, to include organisms potentially sensitive to the test item, e.g., *Asellus aquaticus* (Isopoda) and *Gammarus* spp. (Amphipoda), mayfly (Ephemeroptera), *Chaoborus obsuripes* and dragonfly (Odonata) larvae. The selection of these species was based on ecotoxicity data.

On 26 May 2005 (day –33 of the study), pre-treatment monitoring of the test basin was initiated. On 24 June 2005, the stainless steel enclosures (“mesocosms”) were placed in the test basin. The first treatment was made on 28 June 2005 (day 0) followed by a second treatment on 12 July 2005 (day 14). Post-treatment monitoring of the aquatic organisms within the mesocosms continued until 12 October 2005 (day 112).

Test design :

untreated control (6 replicates), duplicate treatment at 0.024 µg a.s./L (3 replicates), analytical concentration-verification (1 replicate with ^{14}C-zeta-cypermethrin); 10 enclosures in total

The test item was applied first on June 28 2005 (day 0) followed by a second treatment on 12 July 2005 (day 14). On each treatment occasion, the test item was applied directly to the water column within each mesocosm and carefully mixed to ensure homogeneous distribution of the test item within the water column.

Analytical, biological and physical sampling :

Post-treatment sampling was conducted on day 0 (0.5, 2 and 5 hours after treatment), day 14 (0, 0.5, 2 and 5 hours post second treatment) and on days 1, 2, 3, 7, 13, 16, 17, 21, 28, 35, 41, 55, 79, 84, 98 and 112 after the first treatment.

The test concentration applied was verified analytically. Depth-integrated water samples were taken up to day 112 and analysed by HPLC. The samples were analysed until the concentration of zeta-cypermethrin was <LOQ, until day 7 after the first application and up to day 17 (3 days after the second application) for the 0.024 µg a.s./L test concentration. The LOQ (total radioactivity residue, TRR) for water samples was 0.001 µg a.s./L. The LOQ (^{14}C-zeta-cypermethrin) for water samples was 0.0005 µg a.s./L. Sediment cores were sampled and analysed by LSC and radio-TLC. The LOQ (TRR) was 0.015 µg a.s./kg sediment (dry weight).

To assess water quality, temperature, dissolved oxygen, pH, conductivity, alkalinity, hardness, TOC and N/P were measured. To assess the effects on the biology of the mesocosms the following parameters were recorded; chlorophyll-a and phaeophytin concentrations, macrophyte volume, density and composition of phytoplankton, abundance of open-water invertebrates, invertebrates associated with macrophytes and pebbles, invertebrates associated with sediment and the water-sediment interface overlaying the sediment and the number of hatched insects.

The systems were sampled by taking depth-integrated water samples to analyse for algae, zooplankton and macroinvertebrates. Macrophytes and pebble substrate samplers were collected for macrophyte associated zooplankton, macroinvertebrates and benthic organisms. Analysis of organisms >100 μm was conducted *in vivo*. Analysis of organisms <100 μm was conducted after preservation. Sediment cores were analysed for sediment dwelling organisms and zooplankton associated with the water-sediment interface. Emerging insects were collected in emergence traps.

NOEC values for population and community effects were determined using univariate (TOXSTAT 3.5 and SPSS, Bonferroni and Williams and Games-Howell's tests) and multivariate (CANOCO 4.5) statistical methods. Through consideration of the NOEC values and the potential for recovery a NOEAEC was also determined.

Findings :

Analytical concentration verification :

Application of target concentrations was confirmed by an application validation experiment using the radioactive test item, formulated as 100 EW. The results verified that the treatment emulsions were quantitatively transferred into the water of the mesocosms, with a recovery ≥ of 97 % of nominal. Hence, the application method was suitable to transfer all prepared test item into the waters of the mesocosm test systems.

Measurement of the stock treatment emulsions demonstrated that appropriate amounts of the test item were prepared, per concentration and replicate. While taking the following parameters into account, the water volume per enclosure, the results of the application validation experiment, the measurements of the stock solutions and the measurements of the rinses of the application glassware, it was demonstrated that the 0.024 µg a.s./L mesocosms received 96.8 % and 98.8 % after the first and second application, respectively. The results of the study are therefore based on the single nominal concentration.

The results from the water sample analysis collected within 0.5 hours after the first and second applications, determined zeta-cypermethrin recoveries were between 52.0 % and 59.1 % of nominal, respectively. The DT_{50} value for zeta-cypermethrin in surface water was determined to be 2 hours with a DT_{90} value at 30 hours. Following the second application the DT_{50} value was 0.24 hours, whereas the DT_{90} value was 35 hours. This demonstrated that zeta-cypermethrin rapidly dissipated from the water phase following application.

The residues of total radioactivity in the sediment samples collected on days 7, 21, 41, 55 and 84 were 0.021, 0.015, 0.019, 0.019 and 0.021 µg a.s./kg, respectively. These values are at or just above the LOQ of 0.015 µg a.s./kg dry weight. This indicates that zeta-cypermethrin does not accumulate in the sediment following a duplicate application using a 14 day interval.

Water quality :

The water quality during the pre-and post-treatment assessment periods was similar between the control and treated mesocosms. Water quality was typical of an oligo- to mesotrophic, shallow water system that was rich in invertebrates.

Biological results :

The biological results were assessed based on the SANCO Guidance 2002[‡] criteria (see Table B.9.2.12-1).

[‡] Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final). 17 October 2002.

The effects on **phytoplankton** are summarised in Table B.9.2.12-7.

Table B.9.2.12-7 : Effects on phytoplankton

Effect characterisation	**Test concentration (µg a.s./L)**
	0.024
1. Phytoplankton community (abundance):	
	1
2. Phytoplankton taxonomic groups:	
Chrysophyceae	1
Bacillariophyceae	1
Chlorophyceae	1
Cryptophyceae	1
Cyanophyceae	1
Flagellates	1
µ-algae	1
3. Phytoplankton biomass:	
Chlorophyll-a concentration [µg/L]	1
Phaeophytin concentration [µg/L]	1
Chlorophyll/Phaeophytin ratio (C/P ratio)	1
NOECpop based on univariate statistical analysis	**X**

X = NOEAEC concentration

The effects on **zooplankton** and **macroinvertebrates** are summarised in Tables B.9.2.12-8 and B.9.2.12-9 respectively.

Table B.9.2.12-8 : Effects on zooplankton

Effect characterisation	Test concentration (μg a.s./L)
	0.024
1a. Zooplankton community (open water):	
	1
1b. Zooplankton community (substrates):	
	1
2, Zooplankton taxonomic groups:	
Rotatoria (open-water)	1
Rotatoria (substrates)	1
Keratella quadrata (open-water)	1
Keratella quadrata (substrates)	1
Rotatoria div. sp. (open-water)	1
Rotatoria div. sp. (substrates)	1
Crustacea (open-water)	1
Crustacea (substrates)	1
Copepoda (Crustacea):	
Copepoda (open-water)	1
Copepoda (substrates)	1
Cyclopoida (open-water)	1
Cyclopoida (substrates)	1
Calanoida (open-water)	1
Calanoida (substrates)	1
Nauplia (open-water)	1
Nauplia (substrates)	1
Cladocera (Crustacea):	

Effect characterisation	**Test concentration (µg a.s./L)**
	0.024
Cladocera (open-water)	2[+]
Cladocera (substrates)	1
Simocephalus vetulus (substrates)	2
Simocephalus vetulus (open water)	1
Daphnia spp. (open-water)	2[+]
Daphnia spp. (substrates)	2[+]
Large cladocera (open-water)	2[+]
Large cladocera (substrates)	2
Chydoridae (Cladocera):	
Chydoridae (open-water)	1
Chydoridae (substrates)	1
Chydorus spp. (substrates)	1
Alona/Alonella spp. (substrates)	1
Acroperus harpae (substrates)	2[+]
Graptoleberis testudinaria	1
Pleuroxus spp.	1
Ostracoda (substrates)	1
NOECpop based on univariate statistical analysis	**< 0.024 µg/L**
NOECcom based on univariate statistical analysis	**X**

[+] Increased counts were noted

X = NOEAEC concentration

Table B.9.2.12-9 : Effects on macroinvertebrates

Effect characterisation	**Test concentration (μg a.s./L)**
	0.024
1a. Macroinvertebrate community (open water):	
	1
1b. Macroinvertebrate community (substrates):	
	1
1c. Macroinvertebrate insecta (open water):	
	1
1d. Macroinvertebrate insecta (substrates):	
	1
1e. Macroinvertebrate community (sediment dwelling):	
	1
1f. Macroinvertebrate community (emerging insects):	
	1
2. Macroinvertebrate groups in each community:	
Nematoda (sediment)	1
Gastropoda (Prosobranchia):	
Bithynia tentaculata (substrates)	1
Gastropoda (Pulmonata):	
Lymnaeidae (substrates)	1
Planorbidae div. Sp. (substrates)	1
Physidae (substrates)	1
Gastropoda div. sp. (substrates)	1
All Gastropoda (substrates)	1
Gastropoda clutches (substrates)	1

Effect characterisation	Test concentration (µg a.s./L)
	0.024
Oligochaeta:	
Oligochaeta (sediment)	1
Stylaria lacustris (substrates)	1
Oligochaeta div. sp. (substrates)	1
Oligochaeta all (substrates)	1
Hirudinea:	
Helobdella stagnalis (substrates)	2^{+}
Hirudinea all (substrates)	2^{+}
Hirudinea clutches (substrates)	1
Asellus aquaticus (Isopoda) (substrates)*	3
Trichoptera larvae (substrates)	1
Ephemeroptera (Insecta):	
Baetidae larvae (substrates)	1
Cloeon dipterum (emerging)	1
Odonata:	
Zygoptera larvae (substrates)	1
Chaoboridae (Diptera, Insecta):	
Chaoborus spp. (open-water)	1
Chaoborus spp.(emerging insects)	2
Chironomidae (Diptera, Insecta):	
Chironominae (substrates)	1
Chironominae (emerging)	1
Orthocladiinae:	
Orthocladiinae (substrates)	1

Effect characterisation	Test concentration (µg a.s./L)
	0.024
Orthocladiinae (emerging)	1
Corynoneura spp. (larvae in substrates)	2
Corynoneura spp. (emerging)	1
Tanypodinae (larvae in substrates):	2
Tanypodinae (larvae in sediment):	1
Tanypodinae (emerging):	1
Chironomidae (substrates)	2
Chironomidae (sediment)	1
Chironomidae (emerging)	1
NOECpop based on univariate statistical analysis	**< 0.024 µg/L**
NOECcomm based on univariate statistical analysis	**X**

* A note concerning the amphipod *Gammarus* spp.: In a supplementary acute toxicity laboratory experiment with mesocosm water removed immediately after the treatments, a statistically significant reduction in live amphipods was observed seven days after the 1st treatment when compared to the control. Three days after the 2nd application (day 14 after treatment) 100 % mortality was observed in the treatment group. In order to validate these results relative to the zeta-cypermethrin mesocosms (since they contained *Asellus aquaticus* not *Gammarus* spp.), the results of an *A. aquaticus* laboratory study (specifically a non-GLP 96-hour toxicity test) were generaed to directly compare the sensitivity of *Gammarus fossarum* and *Asellus aquaticus*. The results provided evidence that *G. fossarum* is less sensitive than *A. aquaticus* by a factor of four (4x). Hence, it is likely that if exposed *G. fossarum* will be impacted less and recover more rapidly under field conditions than *A. aquaticus*, following a duplicate treatment of 0.024 µg zeta-cypermethrin/L.

X = NOEAEC concentration

The effect of the treatments on the **taxonomic richness** of the communities is summarised in Table B.9.2.12-10.

Table B.9.2.12-10 : Effects on taxonomic richness

Effect characterisation	Test concentration (µg a.s./L)

	0.024
Community of phytoplankton (PHY)	1
Community of open-water invertebrates (DIWO)	1
Community of invertebrates associated with substrates (macrophytes and pebbles) (SA)	1
Community of sediment-dwellers including organisms of the water-sediment interface, overlaying the sediment (SED)	1
Community of emerging insects (EI)	1
NOECcommunity based on univariate statistical analysis	**X**

X = NOEAEC concentration

Conclusions of the authors:

A "state-of-the-art" outdoor pond mesocosm study was conducted, according to modern acceptable guidance, to determine the possible effects of zeta-cypermethrin (as 100 g as/L EW formulation) on algae, zooplankton and macroinvertebrates under realistic exposure conditions. The biological results were assessed using the Sanco Guidance criteria (2002). Mesocosm endpoints were determined according to the Sanco guidance criteria, biological results, effect characteristics and recovery potential. For this mesocosm study, a NOEAEC was determined, since the focus of this study was on population-level and community-level effects.

Based on the biological results and the nominal water concentration (0.024 µg a.s./L) of the duplicate (14-day interval) application mesocosm study with a formulated product containing zeta-cypermethrin, the following endpoints were determined :

Two applications with a 14-day application interval

$NOEC_{population}$: < 0.024 µg a.s./L

$NOEC_{community}$: 0.024 µg a.s./L

$NOEAEC_{community}$: 0.024 µg a.s./L

Conclusions for use of the endpoints for EQS derivation.

Because of the very low DT50 value, the results cannot be used for AA-EQS derivation. For MAC derivation, for the most sensitive endpoint effects were found at the only concentration tested, 0.024 µg/L nominal concentration, thus the value of < 0.024 µg/L can be used for comparison with the EQS from other studies.

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Responses to the detailed comments from the Scientific Committee on Health and Environmental Risks (SCHER)

The SCHER concluded that the document "appears to be quite imprecise, with many major and minor mistakes and inaccuracies, in particular to the reporting of the toxicity data". Eight "major points" are listed in the appendix, but this number is small compared with a total of around 500 data points.

Below, the comments of the SCHER are copied with the response of the Sub-Group rapporteur added in italics. Factual omissions or imprecisions have been corrected in this new version of the dossier and the Excel data table. Most issues are minor. Although the corrections in the normalisation of sediment toxicity influence the values in the Excel data table, the sediment EQS is not affected and remains 0.033 ug/kg dry weight. The EQS for water is also not affected by the SCHER's comments. The findings should provide reassurance in response to the SCHER's comment that "the reliability of the data used is highly doubtful and that derivation of all EQS's is uncertain".

SCHER comments, responses in *italics*

- Many data are quoted from EC 2006 (EFSA DAR on zeta-cypermethrin). The following imprecision have been noted:
    - The 96h EC50 on *Gammarus pulex* is reported as a geometric mean of four different values. It is not true, it is the result of a single test.
      In the factsheet, the 96h EC50 value should have been reported with the footnote:
      [c] Endpoint immobility; test duration 96 hours. The second footnote c was erroneously copied and will be deleted.
    - Toxicity data on *Ciprinus carpio* and *Scardinius erithrophtalmus* and *Pimephales promelas* are reported in the table but these species are not mentioned in the DAR. The references quoted in the complete data tables are useless.
      As outlined in the TGD EQS data from sources other than the DAR should be included in the derivation of the EQSs. The following references of the studies additional to the DAR can be found in the factsheet.
      Sources:
        - *Cyprinus carpio: Stephenson RR (1982) Aquatic toxicology of cypermethrin. I. Acute toxicity to some freshwater fish and invertebrates in laboratory tests. Aquatic Toxicology 2, 175-185*
        - *Scardinius erithrophthalmus: Stephenson RR 1982. Aquatic toxicology of cypermethrin. I. Acute toxicity to some freshwater fish and invertebrates in laboratory tests. Aquatic Toxicology 2, 175-185*
        - *The reference for Pimephales promelas will be corrected: Montforts MHMM, van der Pol JJC, Smit CE. 1998. Evaluatie alfa-cypermethrin. National Institute for Public Health and the Environment (RIVM): Bilthoven, The Netherlands.*
    - The 96h EC50 on *Oncorhynchus mikiss* is reported as a geometric mean of 10 different values. In the DAR only 4 vales are reported, also considering the results of two tests on the formulations (10% cypermethrin).
      DARs are composed for cypermethrin as well as alpha-cypermethrin as well as zeta-cypermethrin, so there is not a single DAR but three DARs. Not all values are reported in all DARs. References to the DARs and studies by Stephenson and Davies can be found in the factsheet.
    - If data on the formulations are used, the DAR reports long term NOEC for *Oncorhynchus mikiss* (21d), *Daphnia magna* (21d) and *Chironomus riparius* (28d). These data are not used while, in other cases, data on formulations are reported.
      The data mentioned above are not used for derivation of the EQS because of lack of information on the studies, or significant shortcomings of the studies, not because the test was performed with a formulation.

- A 21d toxicity on *Daphnia magna* is reported (quoted as EC 2006) but it is not the same reported in the DAR. In the complete data tables is quoted as Linders;60 (reference unavailable).
  The following reference has been added: v.d. Plassche E and Linders L. 1991. Cypermethrin (definitieve versie; M-88). Adviesrapport 88/678801/060. 53 pp. In Dutch. National Institute for Public Health and the Environment (RIVM): Bilthoven, The Netherlands.
  Reference 60 of this report is: Cypermethrin: 21 day Daphnia magna life cycle study. Unpublished report of ICI provided by ICI, report no. RJ 0177 B, 01-01-1981.

- The 21d NOEC on Pimephales *promelas*, (quoted in the table as EC,2006) is quoted in the complete data tables as Thorpe, 1983 (reference unavailable).
  The NOEC for Pimephales promelas reported in the factsheet is a 34-d NOEC reported in the DAR for cypermethin. The reference for the DAR can be found in the factsheet.

- The value of 0.129 mg/L as 96hEC50 for *Acartia tonsa* refers to eggs. The original paper (Barata et al., 2002) reports a value of 0.108 for adults and 0.005 for nauplii.
  The LC50 value of 0.1288 ug/L indeed refers to eggs. In the table, it is explained that the values for adults and nauplii cannot be used for EQS derivation since the animals were fed during the acute toxicity test, which is not in accordance with the guideline for acute toxicity to daphnids.

- Acute toxicity data for sediment dwelling organisms *Ampelisca abdita* and *Eohaustorius estuaries* do not correspond to those reported in the original paper (Anderson et al., 2008) that are more 10 times lower. Even applying the normalisation for the standard sediment, as proposed by the TGD, the results are different. Moreover the data are indicated as also reported by Willis & Ling (2004) and this is not true.
  The data presented in the factsheet from the study by Anderson et al., 2008 will be normalised to 5% o.c. This results in LC50 values of 3006 and 70.5 ug/kg dry weight for A. abdita and E. estuaries, respectively. The reference to Willis and Ling in the factsheet will be removed.

- Toxicity for *Acartia tonsa* is quoted from Willis & Ling (2004). However these authors also report data for other three copepods much more sensitive. Some of these data (e.g. *Temora longicornis*:48h EC50 0.12 mg/L) are quoted as Wilson &LeBlanc (1980), but the reference is not reported.
  The results for Acartia clausi, Pseudocalanus elongatus, Temora longicornis and Oithona similis are all from the study by Willis and Ling instead of Wilson and LeBlanc. The references were corrected.

- Data on 10d NOEC on *Chironomus tentans* (Maund et al, 2002) do not refer to marine water but to freshwater sediments.
  This was corrected.

- The 10d NOEC for *Hyalella atzeca* reported in the same paper (Maund et al, 2002) is not those reported in the table (3.25 mg/kg) or in the footnote. The paper reports a NOEC range between <1.8 and 2.3 mg/kg. In this case too, data do not correspond even applying the normalisation for the standard sediment.
  The data from the study by Maund et al., 2002 presented in the excel file with tables accompanying the factsheet are now correctly normalised to 5% o.c. This results in NOEC values of 3.83 and 0.69 ug/kg dry weight for 3 and 13% o.c. respectively.

- A 24h NOEC for survival of *Chironomus tentans* cannot be assumed as a chronic effect. Moreover, in the paper of Muir et al. (1985) there is no mention on a 0.99 mg/L NOEC. The paper reports survival in sediments at 5 ng/g.
  The values have been placed under acute effects. The study reports no effect on mobility at initial concentrations of 17 ng/g cis-cypermethrin and 64 ng/g trans-cypermethrin, at higher concentrations most larvae were immobilised. Based on the reported aqueous concentrations of the substance in the study, two NOECs for freshwater were calculated based on TWA. The geometric mean of these NOECs is 0.99 ug/L.

- The origin of the 96h NOEC of 0.0041 mg/L for *Acartia tonsa* is unclear. The figure is not reported in the original paper (Barata et al., 2002). Moreover, in the complete data tables, a value of 0.0041 mg/L is reported as 32d LC50.
  This NOEC is no 96h but a 32d NOEC based on the data of Barata et al. (see text and table on page 376, figure on page 377). Both the factsheet and the table were corrected.

Some additional minor comments are listed below.

- Section 5.2 Abiotic and biotic degradation (page 4). Data on hydrolysis are reported at different pHs (3, 7, 11). However, some relevant European documents from which all these data are probably derived (e.g. EC, 2005) report also data at pH 8 (5-21 d, depending on isomer ratio), much more relevant for fresh and marine water than pH 3 or 11. It would be relevant reporting also this value.
  Data on hydrolysis in river water and sea water (both at pH 8) were added to the factsheet.

- 6.1 Measured concentrations (page 7). The table of data is unclear. The footnote mentions that "*Most measurements show concentrations below the LOQ*". However, it is unclear if the reported means represent the average of data above the LOQ. If this is the case it would be useful reporting the percentage of positive records.
  This point is not important to the EQS derivation but can be added.

- Figure 1, page 11. The units on the x axis are not reported. Reasonably, they should be µg/L.
  The units were added.

- References in section 5.1. It would be better quoting the reference Anonymous (2002) as Tomlin (2002) as in the June version. So the origin of the data would be more clear. The Anonymous (2002) is not mentioned in the reference list.
  References were adjusted.