Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 333

Trifluralin

CAS-No. 1582-09-8

Final version
Brussels, 15 January 2005

Disclaimer

This data sheet provides background information on the setting of the Environmental Quality Standard in accordance with Article 16 of the Water Framework Directive (2000/60/EC). The information was compiled, evaluated and used as outlined in the Manual [4] and has been discussed in a consultative process with the Expert Advisory Forum on Priority Substances and the Expert Group on Quality Standards. Furthermore, it has been peer-reviewed by the SCTEE [14]. The substance data sheet may, however, not necessarily represent the views of the European Commission.

New upcoming information was considered and included up to the date of finalisation of this data sheet. Information becoming available after finalisation of this document will be evaluated in the review process of priority substances according to Art. 16(4) of the Water Framework Directive. If necessary, the Environmental Quality Standard substance data sheets will then be revised in the light of technical and scientific progress.

1 Identity of substance

Priority Substance No: 33	Trifluralin
CAS-Number:	1582-09-8
Classification WFD Priority List *:	PSR

* PS: priority substance; PHS: priority hazardous substance; PSR: priority substance under review according to Decision 2455/2001.

2 Proposed quality standards

2.1 Overall quality standards

Ecosystem	Quality Standard	Quality Standard "rounded values"	Comment
AA-QS all surface waters covered by the WFD	0.03 µg/l	**0.03 µg/l**	see section 8.1 & 8.6
MAC-QS (ECO) *	0.88 µg/l	**0.9 µg/l**	see section 8.1

* The proposal by the Commission may include a MAC-QS value which is based on the calculation of 12 * AA-EQS. This derivation is based on the minimum annual frequency of monitoring of priority substances in accordance with the Water Framework Directive. The derivation of such a MAC-QS is based on monitoring, compliance and reporting considerations rather than derived from effect data as presented in this EQS datasheet.

2.2 Specific quality standards

Protection Objective #	Quality Standard	Comment
Pelagic community all types of surface waters covered by the WFD	0.03 µg/l corresponding conc. in SPM: freshwater - 25.2 µg/kg dry wt saltwater – 25.4 µg/kg dry wt	see section 8.1
Benthic community sediment of all types of waters covered by the WFD	3.14 mg/kg (dry wt) 0.683 µg/kg (wet wt) corresponding concentration in water: 3.7 µg/l	see section 8.2
Predators (secondary poisoning)	6.7 mg/kg prey (wet wt) corresponding concentration in water: 1.18 µg/l	see section 8.3
Food uptake by man	1.46 mg/kg fishery product (wet wt) corresponding concentration in water: 0.25 µg/l	see section 8.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A1-value for Σpesticides in CD 75/440/EEC; see section 8.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

\# If justified by substance properties or data available, QS for the different protection objectives are given independently for freshwater environments, transitional waters or coastal and territorial waters

3 Classification

R-Phrases and Labelling	Reference
Xi; R36 - R43 - N; R50-53	[15]
Xn, Xi, N; R40(Carc. Cat. 3)-43-50/53	[11]

4 Physical and chemical properties

Property	Value	Ref.
Vapour pressure	9.5×10^{-3} Pa at 25 °C (pure 100%)	[11]
Henry's law constant	10.2 Pa m^3 mol^{-1} at 20°C (pure 100%)	[11]
Solubility in water	At 20 °C (pure 100%): In distilled water: 0.194 mg/l pH 5: 0.184 mg/l pH 7: 0.221 mg/l pH 9: 0.189 mg/l	[11]
Dissociation constant	Not determinable since trifluralin does not contain ionizable functional groups	[11]

5 Environmental Fate and Partitioning

Property	Value	Ref.
Hydrolytic stability (DT_{50})	Less than 10% degradation at pH 4, 7 and 9 after 5 days at 50 °C, therefore the extrapolated half-life (at 25 °C) is estimated >1 year (technical 96.8%)	[11]
Photostability (DT_{50}) (aqueous, sunlight, state pH)	pH 7: DT_{50}= 7 hours (xenon lamp)	[11]
Readily biodegradable (yes/no)	No	[11]
Degradation in Water/sediment -DT_{50} water - DT_{50} whole system - DT_{50} sediment	 13 d (worst-case value) 4.9 - 5.9 d 16.6 d (by using the solver function) 18.5 d (Timme-Frehse program)	[11]
Mineralization		
Bound residue	26% of A.R. (day 60 - end of the study I) 52 % of A.R. (day 100 - end of the study II)	[11]
Distribution in water / sediment systems (active substance)	2 % in water phase, 90% in sediment at day 3	[11]
Residues relevant to the aquatic environment	The toxicity of the anaerobic metabolite TR-4 for the aquatic environment and for chronic toxicity to the midge *Chironomus riparius* in a 28-day exposure period is defined by the value of NOEC= 0.3324 mg as/l. Even in the absence of a "no-spray" zone, and assuming a maximum formation rate of 26.5%, the TERlt for Chironomus is far in excess of the Annex VI trigger of 10 (TER=124). Consequently, there is no chronic risk to sediment-dwelling organisms from the formation of the anaerobic degradation product TR-4.	[12]
Partition co-efficient (log P_{OW}) Koc	log K_{ow} = 5.27 at 20 °C (pure 100%) pH ranged 7.73-8.86 (pH of aqueous phase after partition) log Koc 3.93 (average experimental, 27 samples) log Koc 4.68 6400 – 13600 (in different soils)	[11] [7] [8] [5]
BCF (fish) Helisoma sp (snail)	5674 2360	[11] [1]

6 Effect data (aquatic environment)

The data presented in section 6 are either provided by Greece [10], the Rapporteur Member State (RMS) for the trifluralin risk assessment in the context of Council Directive 91/414/EEC, or are taken from the most recent "List of endpoints" (Jan 2004) [11] collated for the ongoing risk assessment. Only the information referring to possible endocrine effects of the substance is taken from reference [2].

The quality standards proposed in section 8 of the data sheet are based on the data evaluated and selected in the trifluralin risk assessment [10 – 13].

Supplementary aquatic toxicity data provided by Member States and stakeholders represented in the Expert Advisory Forum on Priority Substances are collated in Table A.1 of Annex 1.

Table 6.1: Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2) [11]

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish (*Oncorhynchis mykiss*)	Trifluralin	Acute 96h	Mortality LC_{50}	0.088
Fish (*Fathead minnow*)	Trifluralin	Chronic 35-day juvenile growth test	Abnormalities, NOEC	0.0003
Invertebrates *(D.magna)*	Trifluralin	Acute 48h	Immobilization, EC_{50}	0.245
Invertebrates *(D.magna)*	Trifluralin	Chronic 21 days	Reproduction, NOEC	0.0507
Algae(*Selenastrum capricornutum*)	Trifluralin	Chronic 96h	Growth rate, EC_{50}	0.0122
Aquatic plants (*Lemna gibba*)	Trifluralin	Chronic 14d	Inhibition of frond growth, EC_{50}	0.0435
Sediment organisms (*Chironomus riparius*)	Trifluralin	Chronic 21d	Survival or emergence, NOEC	810 mg /kg
Fish (*Oncorhynchis mykiss*)	Metabolite TR-6	Acute 96h	Mortality LC_{50}	1
Invertebrates (*Daphnia magna*)	Metabolite TR-6	Acute 48h	Immobilization, EC_{50}	3.52
Algae (*Selenastrum capricornutum*)	Metabolite TR-6	Chronic 72 hours	Biomass-Growth rate, E_bC_{50} E_rC_{50}	 8.19 >5.56
Fish (*Oncorhynchis mykiss*)	Metabolite TR-15	Acute 96h	Mortality LC_{50}	5.46
Invertebrates (*Daphnia magna*)	Metabolite TR-15	Acute 48h	Immobilization, EC_{50}	9.36
Algae (*Selenastrum capricornutum*)	Metabolite TR-15	Chronic 72 hours	Biomass-Growth rate, E_bC_{50} E_rC_{50}	 1.67 >9.15

Table 6.1 continued

Microcosm or mesocosm tests
The preliminary and the refined risk assessment based on the comparison between the toxicity end-points from laboratory studies and the estimated PEC values for the active substance and the metabolites, in water and sediment phase, whenever this was possible, allowed to conclude that, the risk from the use of trifluralin to aquatic organisms is considered acceptable with appropriate risk mitigation measures i.e. buffer zones, to protect the aquatic species under worst case conditions of use in orchards at early growth stage. For a refinement of the risk to aquatic organisms or for reducing the width of unsprayed buffer zones, the notifier may consider conducting new experimental tests to address specific concerns at MS level. This "tier 2" risk assessment, predicting no unacceptable effects on aquatic organisms, is substantiated by the findings of an extensive field monitoring study designed to investigate the ecological effects of trifluralin, primarily on fish (IIIA B.9.2.5/01). In this study, water samples were collected from a 2.1-acre farm pond that received run-off from a 39-acre watershed treated with trifluralin for three years. 20 run-off events occurred during the last eight months of the study. The sediment concentrations in field run-off ranged from 0.2-32.2 g/L but the annual run-off loss of trifluralin from the watershed did not exceed 0.3% of the amount applied (17.7 kg). Analyses of filtered and unfiltered pond water from the treated site indicated that trifluralin remained below the detection limit of 0.3 µg/L throughout the study. Trifluralin concentrations in the pond sediment generally were ≤ 0.004 mg/kg and the estimated half-life in sediment was 5-6 days. The maximum concentration observed in pond sediment was 0.039 mg/kg. Throughout the study, considerable variations in trifluralin residues were seen amongst spp and amongst individual fish of the same spps. Trifluralin residues were predictable, however, using a bioconcentration model developed in a separate laboratory study (IIA B.9.2.3/02). The model provided reliable estimates of trifluralin concentrations in fish resulting from a wide range of exposure conditions associated with agricultural run-off. During the 14-month monitoring period 88 out of the 1277 fish collected at the treated site (6.9%) were diagnosed as having compression and/or deviation of the vertebral column, compared to 23 out of 606 fish sampled at the control site (3.8%). None of the fish diagnosed as having vertebral column lesions showed any gross external deformities. During the last eight months of the study, when substantial amounts of field run-off entered the pond, the mean lesion frequency generally increased three-fold compared to periods of low run-off, but analysis of data from the control site showed the same trend. Characterization of the abnormal fish indicated that their trifluralin residues were comparable to those measured in normal fish and that the shapes of their bodies and spinal columns were within the ranges observed for normal fish. Overall, the vertebral lesion frequencies were significantly correlated to the suspended sediment concentrations in the pond but not to the trifluralin residues in the fish. In addition, there were no trends in the data that suggested that fish with vertebral lesions had higher trifluralin ressions had higher trifluralin resrmal fish. It is unlikely that trifluralin was the cause of the vertebral lesions because the aqueous concentration to which pond fish were exposed (<0.3 µg/L) was less than 2% of the no-effect concentration for acute vertebral injury in brown trout (IIA B.9.2.2/03). Furthermore, the trifluralin residues measured in pond fish diagnosed as abnormal were less than 7% of the mean tissue concentration observed in brown trout that showed no spinal column effects after acute trifluralin exposure. Another laboratory study (IIA B.9.2.3/02) indicated that vertebral lesions did not occur in bluegill, which had trifluralin residues that were more than five times greater than the highest concentration observed in the pond fish. Because vertebral column lesions seem to be a common response of fish to acute chemical/ physical stress, the increases in lesion frequency observed at the treated and control sites likely resulted from the generally stressful conditions in the catchment ponds caused not necessarily from a single factor but a combination of factors resulting from agricultural land run-off as well as the ecological pressures of a natural habitat.

Table 6.2: Mammal and bird oral toxicity data relevant for the assessment of non compartment specific effects relevant for the food chain (secondary poisoning). These data were provided by the RMS [10] and are as well listed in [11]

Species	Duration	Effect	Endpoint	Value	Reference (as given in [10])
Birds					
Mallard duck	14 day	Mortality	LD50	>2000 mg/kg bw	Redgrave 1993
Bobwhite quail	5 day	Mortality	LC50	2974 mg/kg diet	Fairley 1987
Mallard duck	19 week	Reproduction	NOEC	1000 mg/kg diet	Beavers et al. 1987a
Bobwhite quail	20 week	Reproduction	NOEC	1000 mg/kg diet	Beavers et al. 1987b
Mammals					
Rat	15 day	Mortality	LD50	>5000 *	Adams & Hawkins 1988
Rat	13 week	Renal function	NOAEC	200 mg/kg diet	Usher 1985
Rat	2 year	Tumour formation	NOAEC	200 mg/kg diet	Emmerson 1980

* unit not given in [10]

Summary on Endocrine Disrupting Potential

Comment	Reference
There is insufficient data on Trifluralin available (in the BKH-report)	[2]

7 Effect data (human health)

Table 7.1: Summary on ADI (Annex IIA, point 5.10) [11]

	Value	Study	Safety factor
ADI :	0.024 mg/kg b.w./day (0.03 mg/kg b.w./day)	1 year dog study (LOAEL rat carcinogenicity)	100 (1000)

The lowest relevant NOAEL from subchronic/chronic toxicity studies is derived from the one year oral toxicity study in dogs, and was equal to 2.4 mg/kg b.w/day, based on increased liver weight and some minor blood composition/ chemistry changes at 40 mg/kg b.w/day. The ADI proposed by the RMS is equal to 0.024 mg/kg b.w./day considering an assessment factor of 100.

This value is also in agreement with the ADI that could be derived from the chronic carcinogenicity study in Fischer 344 rats. The LOAEL derived from this study is equal to 30 mg/kg b.w./day, based on marginally increased incidence in kidney transitional cell carcinomas and testes interstitial cell tumours (unilateral, bilateral). Considering a margin of safety of 1000, the ADI would be equal to 0.03 mg/kg b.w./day.

The ADI proposed by the RMS is established based on the consideration that the mechanism of tumour formation observed in the Fischer 344 rat chronic toxicity/carcinogenicity study is expected to be hormonally regulated rather than to involve genotoxic effects. The issue of carcinogenicity will be reassessed when the data requested by the RMS in Volume 1, Level 4 of the Monograph (regarding the clarification of the mechanism of thyroid tumour formation in the Fischer 344 rat chronic toxicity/carcinogenicity study and the genotoxic potential of trifluralin) are provided for evaluation to the RMS. [12]

8 Calculation of quality standards

8.1 Quality standards for water

Freshwater

The lowest relevant aquatic toxicity data validated in the ongoing trifluralin risk assessment in the context of Council Directive 91/414/EEC are summarized in table 6.1.

Fish appear to be the species most sensitive to trifluralin. However, the differences in long-term toxicity between most sensitive fish, crustacean and algae species are only small. The lowest chronic endpoint is the 35 d NOEC of 0.3 µg/l for spinal cord deformation in the Fathead Minnow (*Pimephales promelas)*. Consequently this NOEC is divided by an assessment factor of 10 in order to derive the long term quality standard for freshwater.

$QS_{freshwater}$ = 0.3 µg/l / AF (10) = 0.03 µg Trifluralin /l

Koc values between 6400 to 47000 have been reported for trifluralin (see section 5 of this data sheet). Hence, the log Kp_{susp}[1] is 2.8 – 3.7 and the trigger criterion to calculate the corresponding concentration to the $QS_{freshwater}$ in SPM is met (see section 4.3.1 of the Manual [4]). It is proposed to use a Kp_{susp} of 850[2] for the calculation. The $QS_{SPM.freshwat}$ is derived as follows:

$$QS_{SPM.freshwat} = \frac{QS_{freshwater}\ [0.03\ \mu g/l]}{C_{SPM}\ [15\ mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [(850\ l/kg)^{-1}]} = \mathbf{25.2\ \mu g/kg\ SPM\ (dry\ wt)}$$

Transitional, coastal and territorial waters

Toxicity tests with marine fish, crustaceans, algae and mollusc species beside the data used in the risk assessment have been submitted by Member States and other stakeholders of the Expert Advisory Forum on Priority Substances (see table A.1). Only a limited number of tests with salt water species are reported, however, the sensitivity of marine species is comparable with the sensitivity of freshwater species of the same taxonomic group. Therefore, it is suggested to use the pooled data of freshwater and saltwater organisms for the derivation of the $QS_{saltwater}$.

Furthermore, there are additional data on marine molluscs and the most sensitive species appears to be fish for both freshwater and saltwater. Therefore, it may be reasonable to expect no significantly greater sensitivity of saltwater species belonging to other taxonomic groups than fish to trifluralin. Taking into account the recommendations for marine risk assessment of the revised TGD, the same quality standard for saltwater may be set as derived for freshwater.

$QS_{saltwater}$ = $QS_{freshwater}$ = 0.03 µg Trifluralin / l

1 Kp_{susp} is the partition coefficient solid-water in suspended matter = Koc * foc (with foc 0.1; see TGD section 2.3.5.3 [3]).

2 For the calculation of the Kp_{susp} (Koc * 0.1) it is suggested to use the average Koc calculated on the basis of measured data in [7] (8500 l/kg).

As the SPM concentration in marine waters is significantly lower than in freshwater (discussed in the context of the marine risk assessment: approx. 3 mg/l as standard concentration), the quality standard is also calculated for a SPM concentration of 3 mg/l:

$$QS_{SPM.saltwat} = \frac{QS_{freshwater}\ [0.03\ \mu g/l]}{C_{SPM}\ [3\ mg/l] * 10^{-6}\ [kg/mg] + Kp^{-1}\ [(850\ l/kg)^{-1}]} = \mathbf{25.4\ \mu g/kg\ SPM\ (dry\ wt)}$$

Quality standard accounting for transient concentration peaks (MAC-QS)

Following a comprehensive review of the available data submitted in the context of the trifluralin risk assessment, the critical endpoints listed in table 6.1 were identified. The lowest acute endpoint is the LC_{50} values of 88 µg as/l for cold Rainbow trout (Oncorhynchus mykiss). In order to provide protection from acute effects by an episodic exposure event, it is proposed to apply the assessment factor of 100 to the lowest LC50, in line with the provisions of the TGD and Council Directive 91/414/EEC (see section 4.3.6 of the Manual [4]).

MAC-QS = 88 µg/l / AF (100) = 0.88 µg trifluralin /l

8.2 Quality standard for sediment

Studies with sediment dwelling organisms were submitted by the notifier in the context of the PPP-RA [10]. The toxicity of trifluralin to sediment dwelling organisms has been assessed in two emergence studies with the midge *Chironomus riparius*, one with water spiking (Knoch 1996, unpublished) and one with sediment spiking (England and Leak 1994a, unpublished). The chronic NOEC was determined to be 250 µg/L, nominal, when the test substance was applied to the water phase of a sediment:water test system, and ≥810 mg/kg dry sediment when applied to the sediment phase. In addition, an NOEC of 157 mg/kg dry sediment (day 0 mean measured concentration) was also obtained from a separate study on the sediment-dwelling amphipod *Hyalella azteca*, with exposure to trifluralin-spiked sediment (England and Leak 1994b, unpublished).

For the purposes of determining a $QS_{sediment}$, the two studies conducted with trifluralin-spiked sediment are more relevant. The study on *Hyalella* provides the lowest NOEC and therefore this value of 157 mg/kg is selected as the critical endpoint. Application of an assessment factor of 50, in accordance with the provisions of the TGD [3], results in a $QS_{sediment}$ of 3.14 mg/kg (dry weight) and, using the dry weight – wet weight conversion from the TGD (4.6), 0.683 mg/kg (wet weight).

$\mathbf{QS_{sediment}}$ = 3.14 mg trifluralin /kg (dry wt) 0.683 mg trifluralin /kg (wet wt)

The water concentration corresponding to the $QS_{sediment}$ is calculated with the transformed equilibrium partitioning equation as follows:

$$QS_{sed.water} = \frac{QS_{sed.wet\_wt}\ (683\ \mu g/kg)}{1000} * \frac{bulk\ density_{SPM.wet}\ (1150\ kg/m^3)}{Kp_{SPM\text{-}water}\ (212.5\ m^3/m^3)} = 3.7\ \mu g\ Trifluralin\ /l$$

with:
$K_{SPM\text{-}water}$ = f_{solid} (0.1) * Kp_{susp} (850 l/kg) / 1000 * RHO_{solid} (2500 kg/m^3) = 212.5 m^3/m^3 (sect 2.3.5 of [3])
bulk $density_{SPM.wet}$ = 1150 kg/m^3
1000 = conversion factor m^3/kg to l/kg

The quality standard of 0.03 µg/l required for the protection of the pelagic community is by far lower than the water concentration corresponding to the $QS_{sediment}$. The QS_{water} is therefore protective for the benthic community as well.

8.3 Secondary poisoning of top predators

Trifluralin is bioaccumulating (BCF_{fish} 6000). Thus the trigger criterion to derive a quality standard referring to the protection of top predators from secondary poisoning is met (see table 1a of the Manual [4]).

As agreed at the Expert Workshop on Quality Standards (12-16 May 2003 in Brussels), Greece as RMS provided information on oral toxicity studies with birds and mammals (see table 6.2).

The RMS suggested to use the lowest dietary NOEC (i.e. 200 mg/kg diet from the mammalian studies) and divide it by an AF of 10 to determine the QS for residues in food:

$PNEC_{oral} \approx QS_{secpois.biota}$ = 20 mg Trifluralin / kg diet

However, the revised TGD foresees an assessment factor of 30 to derive the $PNEC_{oral}$ from chronic studies with mammals (section 3.8.3.5 of Part II of the TGD).

Hence, the $QS_{secpois.biota}$ (contaminant level in prey of top predators) is:

$QS_{secpois.biota}$ = 6.7 mg Trifluralin / kg (wet weight)

Trifluralin has been shown to bioconcentrate. The BCF_{fish} agreed is 5674 [10]. This BCF value is taken to calculate the concentration in water that corresponds to the $QS_{secpois.biota}$.

According to the guidance given in the TGD [3] regarding the assessment of secondary poisoning of top predators, biomagnification factors (BMF) should be taken into account for the calculation of the PEC_{oral} of top predators. The use of default BMFs as proposed in the TGD is recommended, if the bioconcentration factor of the substance concerned exceeds a level of 2000 and measured BMFs are not available (see section 4.3.2.5 of the Manual [4]).

As measured BMF values are not available for Trifluralin, the use of a default BMF needs to be considered. The recommendation of the TGD is to use for substances with a BCF >5000 default-BMFs of 10 for inland waters and 100 for marine waters. However, the RMS is the opinion that bioaccumulation is not likely to occur in the environment due to rapid dissipation and depuration of Trifluralin [10]. Nonetheless, some scenario calculations may highlight the potential of Trifluralin for secondary poisoning (table 8.1).

The $QS_{secpois.water}$ is calculated as follows:

$QS_{secpois.water} = QS_{secpois.biota}$ (6.7 [mg/kg prey]) / BCF * BMF

Table 8.1: Scenario calculations for "safe" water concentrations with respect to secondary poisoning

Scenario	BCF	BMF	$QS_{secpois.water}$
Marine waters	5674	100 (TGD default)	0.0118 µg/l
Inland waters	5674	10 (TGD default)	0.118 µg/l
No biomagnifcation	5674	1	1.18 µg/l

The risk of bioaccumulation of trifluralin occurring in the aquatic environment is considered to be low [13]. Data from an extensive field monitoring study confirmed that actual residue levels, although typically increasing after run-off events, are low under environmental conditions. The maximum whole body residue level measured in fish was approximately one order of magnitude lower than the residues found in fish continuously exposed to the chronic NOEC of 0.3 µg/L for 35 days. Even after severe run-off events, typical mean residue levels in fish were in the range 0.02 to 0.06 µg/g, i.e. *ca*. 40-130 times lower than residues in fish at the chronic NOEC exposure level.

Taking account of the bioaccumulation assessment conducted in the context of the risk assessment [13], it appears over-precautionary to expect biomagnification in the trophic net to a significant extent. Therefore, the quality standard of 0.03 µg/l required for the protection of the pelagic community is considered as protective against secondary poisoning of predators as well.

8.4 Quality standard referring to food uptake by humans

Trifluralin has a BCF_{fish} of 5674 (see section 5 of this data sheet) but is not classified with one of the R-phrases that serve as triggers for the derivation of the quality standard referring to the protection of humans from adverse effects on health due to the ingestion of food from aquatic environments. Therefore, it is not required to calculate this standard (see table 1b of the Manual [4]).

However, the SCTEE [14] recommended to derive a specific quality standard addressing protection from adverse effects on human health due to the uptake of fishery products. For this purpose, it is suggested to use the ADI of 24 µg/kg bw/d derived in the trifluralin risk assessment as starting point (see section 7).

In the Manual (section 4.3.2.6) [4] it is suggested that the relevant threshold level (i.e. ADI in this case) may not be exhausted for more than 10% by consumption of food originating from aquatic sources. For a person weighing 70 kg, this would mean that the daily uptake with fishery products should not exceed 24 (µg/kg bw/d) * (70 kg bw) * 0.1 = 168 µg d^{-1}.

The average fish consumption of an EU citizen is 115 g d-1 (TGD [3]). Thus, 115 g fish (or fishery products) must not contain more than 168 µg trifluralin.

$$QS_{hh.food} = \frac{168\ \mu g\ \text{trifluralin}}{115\ g\ \text{fishery product}} * 1000\ g = \mathbf{1460\ \mu g\ trifluralin\ /\ kg\ fishery\ product}$$

Using the BCF of 5674 l/kg identified in the risk assessment [11] as reasonable worst-case, a tissue concentration of 1460 µg trifluralin per kg fishery product results in a water concentration of:

$$QS_{hh.food.water} = \frac{1460\ \mu g/kg}{5674\ l/kg} * 1000 = \mathbf{0.25\ \mu g\ trifluralin\ /l}$$

The QS_{water} required to protect the freshwater and saltwater communities are lower than the concentration not to be exceeded in order to protect human health from adverse effects due to ingestion of food from aquatic sources.

8.5 Quality standard for drinking water abstraction

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (Council Directive 75/440/EEC). The drinking water standard (DWS) set in CD 98/83/EC is 0.1 µg/l for individual pesticides.

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) derived for the protection of the freshwater community (1 µg/l) may therefore not suffice to allow for compliance with the DWS if only simple purification techniques (category A1 of CD 75/440/EEC, i.e. filtration and disinfection) are used for the abstraction of drinking water from surface water bodies according to Art. 7 of the WFD.

An assessment by experts in drinking water technology with regard to the question which fraction of the amount of trfluralin present in raw water can be removed by usual simple treatment procedures might be helpful. If the respective fraction were known, this figure could be used together with the drinking water standard to set the maximum acceptable concentration in surface water bodies designated for the **a**bstraction of **w**ater **i**ntended for **h**uman **c**onsumption (AWIHC).

MAC-QS (AWIHC) = DWS (0.1 µg/l) / fraction not removable by simple treatment

8.6 Overall quality standard

The quality standard derived for the protection of the aquatic communities in both freshwater and saltwater is the lowest and may therefore be used as the overall annual average quality standard.

9 References

[1] UK response to request for information relating to quality standards for the Priority List. Submission of data on toxicity, persistence and bioaccumulation by DETR (e-mail of 23 May 2001 by Natasha Robinson)

[2] COM(2001)262 final: Communication from the Commission to the Council and the European Parliament on the implementation of the Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone system of humans and wildlife.

[3] Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, © European Communities 2003. Available at the internet-site of the European Chemicals Bureau: http://ecb.jrc.it/existing-chemicals/

[4] Manual of the Methodological Framework Used to Derive Environmental Quality Standards for Priority Substances of the Water Framework Directive. Peter Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, 15 November 2004. Available at the internet-site of the European Commission: http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm

[5] Frimmel, FH et al., 2001: Ableitung von Qualitätszielen für Kandidatenstoffe der prioritären Liste für die EU-Wasserrahmenrichtlinie. Projektbericht zum Forschungsvorhaben. Substance data sheet for Trifluralin

[6] Excel - database provided by RIVM. Personal communication (e-mail Dr. Dick Sijm, 14 February 2002)

[7] Crommentuijn, T, et al.; 1997: Maximum Permissible Concentrations and Negligible Concentrations for Pesticides. National Institute of Public Heath and the Environment, Bilthoven. RIVM report no. 601 501 002

[8] Les Etudes des Agences de l'Eau Nº 64: Systéme d'Évaluation de la Qualite de l'Eau des Cours d'Eau. SEQ-Eau (version 1) Annexe A – Grilles de seuils par altération avec justifications (Annexe 4: Classes d'Aptitude Pour Divers Micropollutants, Fonction "Potentialites Biologiques de l'Eau", Trifluraline - Fiche de Donnees). Agences de l'Eau, Janvier 1999. ISSN 1161-0425

[9] Kussatz, C et al., 2001: Quality Targets for Active Ingredients of Pesticides to Protect Inland Surface Waters. Substance data sheet for Trifluralin. Texte 08/01, ISBN 0722-186X. Federal Environmental Agency, Berlin

[10] RMS proposal for environmental quality standards (EQS) for Trifluralin, based on evaluation of the ecotoxicology data submitted by the notifier Dow Agro Sciences (Task Force) according to Directive 91/414/EEC and Regulation 451/2000. Letter of the Hellenic Republic Ministry of Agriculture, Directorate of Plant Protection – Department of Pesticides to European Commission DG ENV B.1 (M. Brättemark), 27.05.2003

[11] Trifluralin: List of end points (based on EPCO Manual D 4, rev. 0, 21.11.2003). File Pt 2.03 Trifluralin_end_points_(Jan2004).doc

[12] Trifluralin_addendum_1_residues_ecotox_(March2004).doc

[13] Trifluralin draft assessment report (June 2003), Volume 1, Level 2. Reasoned statement of the overall conclusions. File: Trifluralin_DAR_03_Vol1_Level2.doc

[14] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on "The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof", adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004, European Commission Health & Consumer Protection Directorate General, Brussels. http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf

[15] ESIS: European Chemicals Bureau – ESIS (European Substances Information System), January 2005. http://ecb.jrc.it/existing-chemicals/ ⇒ tick ESIS button, then enter CAS or EINECS number of substance.

ANNEX 1: Supplementary aquatic toxicity data for trifluralin

Table A.1: Trifluralin aquatic toxicity data for most sensitive species from different sources (master reference)

Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
Freshwater									
Pimephales promelas	Pisces	fw	35 d	Spinal cord deformation	NOEC	0.3	µg/l	[5]	PSM-Datenbank 1992
Oncorhynchus mykiss	Pisces	fw	21 d	Sub-lethal	NOEC	0.64	µg/l	[5]	PSM-Datenbank 1992
Oncorhynchus mykiss	Pisces	fw	48 d	Behaviour	NOEC	1.14	µg/l	[5]	PSM-Datenbank 1990
Pimephales promelas	Pisces	fw	427 d	Reproduction	NOEC	1.9	µg/l	[6]	RIVM Report No 601501002
Pimephales promelas	Pisces	fw	430 d	Reproduction / Growth	NOEC	2	µg/l	[8]	Mayer et Ellerseick (1986)
Daphnia magna	Crustacea	fw	64 d	Reproduction / Survival	NOEC	2.4	µg/l	[8]	Maceck et al (1976)
Selenastrum capricornutum	Algae	fw	96 h	Growth	NOEC	5.37	µg/l	[5]	PSM-Datenbank 1990
Scenedesmus subspicatus	Algae	fw	7 d	Growth	NOEC	18	µg/l	[5]	PSM-Datenbank
Daphnia magna	Crustacea	fw	21d	Reproduction / Immobilization	NOEC	26.2	µg/l	[9]	PSM-Database
Chironomus riparius	Insecta	fw	28 d	Development	NOEC	250	µg/l	[5]	PSM-Datenbank 1996
Selenastrum capricornutum	Algae	fw	30 d	Growth (biomass)	NOEC	1000	µg/l	[8]	Johnson (1986)
Oncorhynchus mykiss	Pisces	fw	96 h	Mortality	LC50	10	µg/l	[8]	Mayer et Ellerseick (1986)
Selenastrum capricornutum	Algae	fw	7 d	Growth	EC50	10.38	µg/l	[5]	PSM-Datenbank 1990
Bufo bufo japonicus	Amphibia	fw	48 h	Mortality	LC50	14	µg/l	[5]	PSM-Datenbank 1983
Navicula pelliculosa	Algae	fw	5d	Growth	EC50	15.3	µg/l	[10]	Hughes, J.S et al. (1993)
Oncorhynchus mykiss	Pisces	fw	96 h	Mortality	ELC50	22	µg/l	[6]	RIVM Report No 601501002
Lemna gibba	Cormophyta	fw	14 d	Growth	EC50	43.5	µg/l	[5]	Pest. Program 1995
Eucyclops sp.	Crustacea	fw ?	48 h	Mortality	LC50	50	µg/l	[9]	Naqvi et al. 1985
Bufo woodhousii fowleri	Amphibia	fw	96 h	Mortality	ELC50	110	µg/l	[6]	RIVM Report No 601501002
Pimephales promelas	Pisces	fw	96 h	Mortality	ELC50	130	µg/l	[6]	RIVM Report No 601501002
Daphnia magna	Crustacea	fw	48 h	Mortality	LC50	193	µg/l	[8]	Maceck et al (1976)
Cypridopsis vidua	Crustacea	fw	48 h	Mortality	ELC50	250	µg/l	[6]	RIVM Report No 601501002
Daphnia magna	Crustacea	fw	48 h	Immobilisation	ELC50	367	µg/l	[6]	RIVM Report No 601501002, geometric mean (n=2)
Ictalurus punctatus	Pisces	fw	96 h	Mortality	LC50	417	µg/l	[5]	Mc Corkle et al. 1977
Chironomus riparius	Insecta	fw	48 h	Mortality	EC50	1000	µg/l	[5]	Johnson 1986

Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
Pteronarcys californicus	Insecta	fw	96 h	Mortality	EC50	2800	µg/l	[5]	Johnson 1986
Saltwater									
Cyprinodon variegatus	Pisces	sw	166 d	Reproduction	MATC	1	µg/l	[9]	Parrish et al. 1978
Cyprinodon variegatus	Pisces	sw	166 d	Reproduction	LOEC	5	µg/l	[9]	Parrish et al. 1978
Cancer magister	Crustacea	sw	69 d	Reproduction	NOEC	15	µg/l]	[5]	Caldwell 1977
Skeletomena costatum	Algae	sw	5 d	Growth	EC50	28	µg/l	[5]	Pest. Program 1995
Cyprinodon variegatus	Pisces	sw	96 h	Mortality	LC50	160	µg/l	[6]	RIVM Report No 601501002
Palaemonetes pugio	Crustacea	sw		Mortality	LC50	638	µg/l	[10]	Adams, E.R et al. (1988)
Mytilus edulis	Mollusca	sw	96 h	Behaviour	EC50	350	µg/l	[5]	Liu et al. 1975
Mytilus edulis	Mollusca	sw	96 h	Mortality	ELC50	240000	µg/l	[6]	RIVM Report No 601501002

*: fw = freshwater, sw = saltwater