

Trifluralin



**OSPAR Commission
2005 Update**

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the “OSPAR Convention”) was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.

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Executive summary

Trifluralin (α, α, α -trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine) is a dinitroaniline herbicide used to control a wide spectrum of annual grasses and broadleaf weeds in agriculture, horticulture, viticulture, amenity and home garden. The major crops it is used on are oilseed rape and sunflowers and, to a lesser extent, cotton and cereals. Trifluralin was added to the OSPAR List of Chemicals for Priority action in 2002.

Trifluralin is manufactured at one facility in the European Union in Northern Italy. Technical grade trifluralin is shipped by road from here to a main formulation plant for the European, Middle Eastern and African market in North-East France and also to a number of third party formulators in France and UK. No discharges to water courses are permitted from the main formulation plant, which is 500 km upstream of the River Rhine's outflow into the North Sea. Approximately 3200 tonnes of active substance trifluralin annually are used in the EU (including accession countries). Trifluralin is presently authorised for use in Belgium, Finland, France, Germany, Ireland, Portugal, Spain and the United Kingdom.

Trifluralin has been detected on few occasions in river waters and sediments and in low concentrations in marine water in the OSPAR area. Data from marine sediments are not available. Trifluralin is considered to be a PBT substance. Significant amounts may evaporate into the air from the agricultural use (estimated 64 t/y for total Europe), but photochemical oxidative degradation will rapidly decrease this load before it can be transported far beyond the coasts. Inputs to the marine environment through adsorption to sediment, although a theoretical risk, are not considered relevant. A general quest for a reduction of use of trifluralin does not seem appropriate based on the current risks for the marine environment. Therefore measures and actions by OSPAR should be directed, in general, to avoid a potential future entry of trifluralin into the marine environment.

Trifluralin was listed as a priority hazardous substance by the 3rd North Sea Conference with the target of a 50% reduction in inputs via rivers and estuaries and this has resulted in bans and restrictions in a number of North Sea Contracting Parties. The target has not been achieved in three Contracting Parties. Trifluralin has been designated as "priority substance" under the Water Framework Directive and is currently under review for identification as a "priority hazardous substance". It is also currently under review for inclusion Annex I of the EU Directive 91/414/EEC concerning the placing on the market of plant protection products.

The actions recommended in this background document are: to monitor the possible occurrence of trifluralin in surface water and coastal waters, as well as in sediments, in order to identify areas of intensive emission; to apply trifluralin under 'good agricultural practice', and to consider integrated crop management and ecological farming when ever possible; to reduce the levels of use of synthetic pesticides and substitute for them non-chemical pest and weed management methods; to check that the operation of plants manufacturing or formulating trifluralin is regulated according to the principles of BAT (Best Available Technology) and that any releases are eliminated, or minimised to the greatest possible extent; to seek appropriate restrictions on trifluralin use within the framework of the 91/414/EEC Directive and within the framework of the EC Water Framework Directive; to communicate this background document to the European Commission and to other appropriate international organisations which deal with hazardous substances.

A monitoring strategy for trifluralin is attached to this background document.

Récapitulatif

La trifluraline (α, α, α -trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine) est un herbicide dinitro-aniline employé afin de détruire un large spectre de graminées annuelles et de mauvaises herbes à feuilles larges dans l'agriculture, l'horticulture, la viticulture, les jardins d'agrément et les jardins individuels. Les grandes cultures sur lesquelles elle est utilisée sont le colza et le tournesol, et, à un moindre degré, le coton et les céréales. La trifluraline a été inscrite en 2002 sur la liste OSPAR des produits chimiques devant faire l'objet de mesures prioritaires.

Dans l'Union européenne, la trifluraline est fabriquée à une seule installation, située dans le Nord de l'Italie. De là, la trifluraline de grade technique est envoyée par la route jusqu'à une installation principale de formulation desservant les marchés européens, moyen-orientaux et africains, située dans le nord-est de la France, de même qu'à plusieurs autres laboratoires implantés en France et au Royaume-Uni. Il est interdit au laboratoire principal d'effectuer des rejets dans les cours d'eau ; ce laboratoire est situé à 500 km en amont de l'embouchure du Rhin en mer du Nord. Dans l'Union européenne, (y compris les pays accédants), la consommation annuelle est de l'ordre de 3200 tonnes de trifluraline active. Son utilisation est à l'heure actuelle autorisée en Belgique, en Finlande, en France, en Allemagne, en Irlande, au Portugal, en Espagne et au Royaume-Uni.

De la trifluraline a été détectée en quelques occasions dans les eaux fluviales et dans les sédiments, et l'on a observé de faibles teneurs dans les eaux marines de la zone OSPAR. L'on ne dispose d'aucune donnée concernant les sédiments marins. La trifluraline est considérée comme une substance PBT. Des quantités significatives peuvent s'en évaporer dans l'air, du fait de son application dans l'agriculture (estimée à 64 t/an pour l'ensemble de l'Europe), quoique la dégradation oxydative photochimique diminue rapidement cette charge avant qu'elle ne puisse être transportée loin au-delà des côtes. Les apports au milieu marin, par adsorption sur les sédiments, quoiqu'il s'agisse d'un risque théorique, ne sont pas considérés comme pertinents. Une recherche générale de la réduction de la consommation de la trifluraline ne paraît pas appropriée compte tenu des risques actuels pour le milieu marin. Par conséquent, il conviendrait que les mesures et les actions d'OSPAR soient orientées, d'une manière générale, sur l'objectif qui consiste à éviter une pénétration potentielle future de la trifluraline dans le milieu marin.

La trifluraline a été classée dans les substances dangereuses prioritaires par la troisième Conférence sur la mer du Nord, avec l'objectif d'une réduction de 50% des apports par les cours d'eau et les estuaires, ce qui a abouti à des interdictions chez plusieurs des Parties contractantes aux Conférences sur la mer du Nord. Trois des Parties contractantes n'ont pas atteint cet objectif. La trifluraline a été classée dans les « substances prioritaires » dans le contexte de la Directive cadre relative à l'eau, et fait à l'heure actuelle l'objet d'une étude afin de savoir s'il s'agit d'une « substance dangereuse prioritaire ». L'on étudie par ailleurs son inscription à l'Annexe I de la Directive 91/414/CEE de l'Union européenne, qui concerne la mise sur le marché des produits phytosanitaires.

Les actions recommandées dans le présent document de fond sont les suivantes : surveiller la présence éventuelle de trifluraline dans les eaux de surface et dans les eaux côtières, ainsi que dans les sédiments, de manière à déterminer les zones d'émissions intensives; répandre la trifluraline en respectant les « bonnes pratiques agricoles », et envisager une gestion intégrée des cultures ainsi qu'une exploitation agricole écologique lorsque possible; réduire l'ampleur de la consommation des pesticides de synthèse et les remplacer par des méthodes non chimiques de destruction des parasites et des mauvaises herbes; s'assurer que l'exploitation des installations qui fabriquent ou formulent de la trifluraline est bien conforme aux principes de la BAT (meilleure technologie disponible) et que toutes les émissions sont éliminées ou minimisées dans toute la mesure du possible; chercher à obtenir des restrictions appropriées à la consommation de trifluraline dans le cadre de la Directive 91/414/CEE ainsi que dans celui de la Directive communautaire cadre relative à l'eau; communiquer le présent document de fond à la Commission européenne ainsi qu'à d'autres organisations internationales compétentes chargées des substances dangereuses.

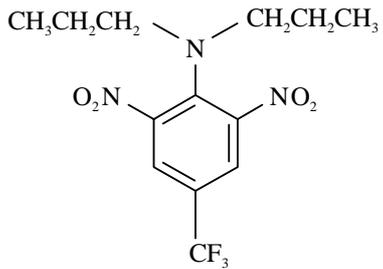
Une stratégie de surveillance sur la trifluraline est jointe à ce document de fond.

Introduction

Trifluralin, a selective, pre-sowing or pre-emergence dinitroaniline herbicide, is used to control a wide spectrum of annual grasses and broadleaf weeds in agriculture, horticulture, viticulture, amenity and home garden. It prevents weed growth by inhibiting root development through the interruption of mitosis. Trifluralin is applied as a soil-incorporated pesticide, though there are also some applications to the soil surface (PAN 2001).

The chemical identity of trifluralin is presented in Table 1; further information on the physico-chemical properties and metabolic pathways is given in Appendix 1.

Table 1. Chemical identity of trifluralin

CAS-No. 1582-09-8 EINECS-N o. 216-428-8	 <chem>CCCN(CCC)c1cc(C(F)(F)F)cc([N+](=O)[O-])c1[N+](=O)[O-]</chem>	Trifluralin <u>Synonyms:</u> α,α,α -trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine (IUPAC) 2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)-benzenamine
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Most of the information in this background document is taken from the documents provided by European Union Trifluralin Task Force (EUTTF) for the summary dossiers for trifluralin in accordance with Article 6 of Commission Regulation (EC) No 451/2000. The EUTTF was formed in March 2001 by agreement between Agan Chemical Manufacturers Ltd. of Ashdod, Israel and Dintec Agroquímica Produtos Químicos Lda. of Madeira, Portugal. Dintec is an incorporated company formed in 1994 between Dow AgroSciences, B.V., established at Rotterdam, The Netherlands, and I.Pi.Ci. S.p.A. Industria Prodotti Chimici (I.Pi.Ci.), established at Novate, Milanese, Italy. The producer applies for the inclusion of trifluralin into Annex I of the EU-Directive 91/414/EEC ("placing of plant protection products on the market"). The Draft Assessment Report (DAR) was finalised in July 2003 and submitted by the Rapporteur Member State (RMS) Greece to the European Commission and the European Food Safety Agency (EFSA). The Member States commented on the DAR and the first EFSA Evaluation Meeting was held in January 2004. A few points were passed for a recommendation to Expert Groups which met in April and May 2004. A second EFSA Evaluation Meeting will be held later in 2004 but no date has been published.

1 Identification of sources of trifluralin and its pathways to the marine environment

1.1 Production of trifluralin

The active ingredient, trifluralin, is manufactured in only one plant in the European Union, which is at Manerbio in the centre of Northern Italy. Production volume is fairly constant at around 6000 tonnes per year (information provided by EUTTF). The IUCLID dataset states a production volume of 10 000 – 50 000 tonnes per year in Europe, which appears to be high in the light of 24 000 tonnes worldwide production as reported by PAN (2001; from Farm Chemicals International, 1999).

The Manerbio plant is situated approximately 1,5 km from the River Mella which is a tributary of the River Po and is approximately 200 km upstream of the River Po's outflow into the Adriatic Sea. Therefore, any discharges will not affect the OSPAR Convention area but rather reach the Mediterranean Sea.

The Manerbio facility obtained ISO 9002 quality certification in 1994, ISO 14001 environmental management system certification in 1998, and safety management system UNI 10617 in 2003. The management system is integrated and supported by manuals and procedures.

Under Italian law (Decreto Legge 152/99), the Manerbio site is permitted to discharge wastewater containing trifluralin up to 50 $\mu\text{g/l}$ into the River Mella or wastewater containing halogenated pesticides up to 50 $\mu\text{g/l}$ into the sewage system. Normally, the wastewater goes to the sewage system; in case of e.g. a mechanical failure of the pumps at the treatment works, wastewater may be discharged directly to the river. The wastewater is monitored internally to ensure that concentrations are maintained well below the permitted level. At intervals of twice a year, the local Environmental Protection Agency samples the wastewater and over the last five years levels have never exceeded 10 $\mu\text{g/l}$. The results of these independent analyses are

provided in Table 2. Sampling related to 2000 is more frequent because an accident occurred to Finchimica production plants on February 19, 2000.

Table 2. Wastewater analysis from the Finchimica plant in Manerbio conducted by the local Italian Environmental Protection Agency

Date	Trifluralin Content (µg/l)						
19/10/94	50	06/10/99	n.d.	09/05/00	n.d.	03/09/01	3
26/10/95	1	18/02/00	n.d.	09/06/00	n.d.	28/03/02	n.d.
30/09/96	n.d.	19/02/00	n.d.	15/06/00	n.d.	19/07/02	n.d.
30/09/96	5	19/02/00	n.d.	16/06/00	n.d.	20/05/03	n.d.
18/09/97	7	21/02/00	n.d.	19/09/00	n.d.		
01/10/98	10	21/02/00	n.d.	04/10/00	6		
14/04/99	n.d.	21/02/00	n.d.	23/04/01	4		

n.d.: not detected.

A record is kept of the total annual amount of halogenated pesticides, which are discharged in the wastewater at the Manerbio facility. These values are given in Table 3. The total chlorinated pesticide amount dischargeable by Finchimica, permitted by Italian law, is 70 kg/year. In practice, Finchimica discharges 2,9 kg of trifluralin per year.

Table 3. Total halogenated pesticides in wastewater discharged to the sewage treatment plant by the Manerbio facility

Year	1994	1995	1996	1997	1998	1999	2000	2001	2002
Total halogenated pesticides [kg/year]	39	14	20	7	8	7	14	12	13
Average discharge per day [kg/day]	0,107	0,038	0,055	0,019	0,022	0,019	0,038	0,033	0,036

Any trifluralin in the local wastewater will become strongly adsorbed to solid organic waste at the sewage treatment plant and therefore levels entering the River Mella from that source will be reduced. The Manerbio plant is situated approximately 1,5 km from the River Mella and adsorption losses will occur from wastewater discharged directly from the site during its journey to the river. When water enters the river from the sewage treatment plant or directly from the facility it will be diluted and trifluralin will be adsorbed to sediment and organic matter in the river to some extent. Further massive dilution will occur in the River Po and loss from the water due to adsorption and photolysis will further reduce the amount of trifluralin reaching the Adriatic Sea 200 km downstream of the plant.

Actual measurements in the Adriatic Sea or the Mediterranean Sea are presently not available.

Any other liquid or solid waste is stored for burning or disposal by licensed waste treatment companies according to Italian laws DPR 915/82 and DL 22/97.

Formulation of products containing trifluralin intended for supply to the European Union, Central and Eastern Europe, the Baltic, the Middle East, the Near East and Africa by the main producer, Dow AgroSciences, takes place at a plant at Drusenheim in the North-East of France, close to the border to Germany. This site is ISO 14001 certified.

The annual volume of technical trifluralin shipped to Drusenheim is in the range of 1500 to 1700 tonnes and this is transported by road in bulk ISO containers of 20 tonnes each. Supply to third party formulators (see below) is in 250 kg drums also transported by road. All of this transport is outsourced to a logistic provider who is certified ISO 9000 version 2000 and SQAS road (Safety Quality Assessment System).

The plant at Drusenheim is situated close to the River Moder, which is a tributary of the River Rhine and is approximately 500 km upstream of the River Rhine's outflow into the North Sea.

No discharges are permitted into any nearby watercourses from the Drusenheim facility. All the manufacturing equipment is housed on retained areas from which all liquid is collected and incinerated in a dedicated special facility on site. Release of rainwater is also controlled in case of contamination. This rainwater and the well water are regularly monitored by Dow AgroSciences and the local authorities. Under normal operating conditions, there is no risk of contamination of the marine environment as a result of discharges from the Drusenheim formulation facility.

Another producer, IPIci, formulates in Italy. Some of the technical material is sold to third party formulators, which are mainly based in France and the UK. Makhteshim Agan manufactures and formulates in Israel. No details on quality assurance concerning the transport of IPIci or Makhteshim Agan end-use product or that of the third party formulators are known.

1.2 Main uses of trifluralin

Trifluralin is a herbicide for pre-sowing or pre-emergence treatment of grasses and dicotyledonous weeds at a rate of 1200 g active substance per ha (using 150 – 500 l/ha). Major crops are oilseed rape and sunflowers and, to a lesser extent, cotton and cereals. There are other minor uses in a wide range of agricultural and horticultural crops. Non-agricultural uses of trifluralin are not known.

Approximately 3200 tonnes active substance trifluralin annually are used in the EU including the accession countries Poland, Czech Republic, and Hungary. This figure was provided by industry in 1999 for chemicals prioritisation in connection with the Water Framework Directive. According to industry sales of active substance remain at a constant level of about 3200 tonnes/year in Europe. These figures, in addition to those from IUCLID dataset, are also mentioned in BÖHM ET AL. (2002).

Within the EU, Trifluralin is presently authorised in Austria, Belgium, Finland, France, Germany, Greece, Italy, Ireland, Portugal, Spain and the United Kingdom. An indication of uses may be derived from the 5th North Sea Conference Report (cf. Chapter 4.1) stating figures from 1999/2000: Belgium (15,1 t/a), France (1600 t/a), Germany (< 102 t/a), Switzerland (0,5 t/a) and the UK (657 t/a). Denmark reported minor uses for seed production (2002, 19 kg) as a derogation to the ban of trifluralin in this country. In Finland, uses oscillate around 16 t/a with a minimum in 1997 (6 t) and a maximum in 2002 (20 t).

2 Monitoring data, quantification of sources and assessment of the extent of problems

2.1 Monitoring data

2.1.1 European rivers (surface water)

Within the Water Framework Directive 2000/60/EC, the European Commission has set up a legal framework and a clear methodological basis for the prioritisation of substances potentially hazardous for the aquatic environment. A combined monitoring-based and modelling-based priority setting (COMMPS) was applied in the selection process of the proposed priority substances. In this context, monitoring data from many European rivers were collected, weighted and aggregated (see Chapter 3.3 of the COMMPS-Report; available under http://europa.eu.int/comm/environment/water/water-dangersub/commmps_report.pdf).

In the 1990s, trifluralin has been found in samples of surface water from Austria, Belgium, France, Germany, Great Britain and Italy. All together, 12 800 measurements were done at 752 sampling stations. 819 of the 128 000 measurements were above the determination limit (positive finding). These monitoring data in COMMPS passed a check for representativeness, i.e. monitoring stations with less than 10% positive findings were discarded.

For the remaining sampling stations, arithmetic means were calculated and the EU-level 90-percentile was derived from its sampling station mean levels. The data collated from Belgium, UK and Spain were treated within this procedure and a 90th percentile concentration of 0,0306 µg/l was determined (see Table 4). Although many measurements resulted in findings below the determination limit (which is in the range of 0,005 to 0,2 µg/l), findings stated in Table 4 represent the situation, where trifluralin is to be expected due to regular uses.

Table 4. Results of the aggregation of monitoring data for trifluralin in the freshwater aquatic phase from the COMMPS procedure (EC 1999; from table A9; DL: determination limit).

CAS No.	Compound	90-perctle.	Median [µg/l]	Arithm. Mean	Standard Deviation	Sampling Station	Entries used	Entries > DL
Water phase		[µg/l]	[µg/l]	[µg/l]	[µg/l]	[-]	[-]	[-]
1582-09-8	trifluralin	0,0306	0,0061	0,0269	0,1214	61	874	538

Means for trifluralin are in the range of the German quality standard for trifluralin in surface waters with respect to aquatic biocoenoses (0,03 µg/l; cf. Chapter 4.1). The 90-percentile value of 0,0306 µg/l is lower than the drinking water threshold concentration for individual plant protection products (0,1 µg/l).

A survey of monitoring programmes and occurrence data of trifluralin across Europe (15 EU Member States, as well as Norway and Switzerland) was undertaken by the producer (Table 5). The survey focused on data for surface waters and ground water, although some drinking water data were also included. The information was obtained from professional contacts by the producer across Europe (government departments and research organisations), in-house data and published studies.

A considerable amount of data for trifluralin monitoring in European waters was found, although it cannot be considered complete. The information was critically assessed in terms of reliability (analytical method, quality assurance) and collated in the survey report. An attempt was made by the producer to classify the data in terms of their reliability (Categories I to III, where III is the most reliable¹), although a low category assignment does not necessarily mean the data are unreliable. For example, there may have been inadequate information given to assign a higher category.

Trifluralin was detected in surface waters, particularly in Belgium, France, Greece and the UK (Table 5). The maximum concentrations reported from these countries were in the range 0,2-0,7 µg/l. One value of 8,3 mg/l was reported from the UK – presumably due to an isolated pollution incident. A large number of negative findings have also been reported from Germany (one positive finding from over 1000 samples), Switzerland (no positive findings in 150 samples), and the International Rhine Commission (one positive result at very low concentration). In addition, trifluralin was not detected in the small number of samples reported from Austria and Italy.

2.1.2 Drinking water

One case of non-compliance with the drinking water standard of 0,1 µg/l has been reported (UK in 1994; Table 5 lower part), requiring remedial measures, i.e. additional water treatment to remove trifluralin. In addition, one case was reported from Germany, where remedial measures were implemented at one site for the abstraction of drinking water from surface water, although the trifluralin concentration (0,05 µg/l) was below the drinking water limit at this site. These findings relate to a large amount of data from Germany, Ireland and the UK, and a small number of samples from the Netherlands.

Altogether, trifluralin was detected in 1,5% of over 30 000 samples from over 4500 sites (Table 5). Of these, concentrations above 0,1 µg/l were found in 9 samples (0,03%). Overall, the data are considered reasonably reliable in the survey report by the producer; in some cases a low reliability category has been assigned, mainly because insufficient information was available and, in particular, where large amounts of data were collated from a wide variety of sources. The limits of detection were mostly at or below 0,1 µg/l.

¹) The monitoring report describes the categories as follows:
 Category III: Reliable data (i.e. analytical method with specific detection and including analytical quality control).
 Category II: Moderately reliable data (e.g. adequate analytical methods but no information on analytical quality control, or insufficient information to assign to Category III).
 Category I: Reliability uncertain (e.g. screening only with semi-quantitative method, such as immunoassay based techniques) or inadequate information to determine reliability of data, or data compiled from various sources with little information concerning the reliability of the data.

Table 5. Summary of trifluralin monitoring data in surface water, drinking water and others (unpublished survey report by producer Dow AgroSciences)

Country	Date	No. sites	No. samples	Detected (samples)		Samples >0,1 µg/l		Max. µg/l	LoD (LoDtm) µg/l	Cat.
				No.	%	No.	%			
Surface water										
Austria ©	1998	2	6	0	-	0	-	-	0,045	I
Belgium	96-99	n.d.	1281	87	7	1	0,08	0,7	n.d.	I
Belgium ©	1997	33	177	12 sites	>6,8	0	-	0,09	n.d.	I
France	1996	n.d.	128	21	16,4	n.d.	-	n.d.	n.d.	I
	1997	38	304	1	0,3	n.d.	-	n.d.	(0,02)	III
France ©	1996	37	165	5 sites	>3	>1	>0,6	0,22	n.d.	I
Germany	1992	n.d.	n.d.	0	-	0	-	-	0,03-0,05	I
	91-93	5	147	0	-	0	-	-	<0,1n.d.	II
	93-94	44	936	1	0,1	0	-	0,05	0,01-0,1 (0,005-0,2)	I
Germany ©	1996	9	122	1	0,8	0	-	0,05	n.d.	I
Greece	92-93	7	63	6	9,5	2	3,2	0,36	0,005	I
Italy ©	1997	2	2	0	-	0	-	-	0,05	I
Switzerland	95-97	12	150	0	-	0	-	-	0,05-0,1	III
UK	91-92	3	56	4	7,1	0	-	0,036	0,01	III
	92-94	n.d.	n.d.	n.d.	-	n.d.	0,07-0,3	n.d.	n.d.	II
	1995	n.d.	3264	98	3	1	0,03	0,002**	n.d.	II
	1999	729	4888	214	4,4	2	0,04	0,27***	0,005-0,01	II
River Rhine (CH D NL)	92-95	7	>19	0	-	0	-	-	0,005-1,0	I
	1996	5	72	1	1,4	0	-	0,005	0,005-0,08	I
	1997	5	68	0	-	0	-	-	0,005-0,2	I
	1998	7	104	0	-	0	-	-	0,005-0,05	I
Total*	91-99	870	11651	437	3,8	7	0,06	0,005-0,7	0,005-0,2 (0,005-0,2)	I-III
EU-COMMPS (A B D F I)	96-98	83	472	18 sites	>3,8 (22% sites)	1-5 sites	0,2-1 (1-6% sites)	0,22	n.d.	I
Drinking water										
Germany	93-94	166	1092	0	-	0	-	-	0,01-0,1 (0,01-0,1)	I
Ireland	95-96	50	50	0	-	0	-	-	0,02	I
Netherlands	1992	7	7	0	-	0	-	-	0,002	II
UK	94-96	59	5228	1	0,02	1	0,02	>0,1	0,01	III
Total*	92-96	282	6377	1	0,02	1	0,02	>0,1	0,002-0,01 (0,01-0,1)	I-III
Unspecified waters										
Greece	95-97	42	255	3	1,3	0	-	0,01	0,0005	II
All water types										
Total*	90-99	4682	30575	449	1,5	9	0,03	0,7***	0,0005-0,2 (0,005-0,2)	I-III

Notes to Table 5:

LoD = limit of detection (LoDtm = limit of determination)

© Data ex COMMPS database.

* Where there was a risk of multiple reference (e.g. COMMPS and national data), sites or samples have not been added in the total count, i.e. the total sample number represents the minimum number.

** 95th percentile.

*** One value at 8,3 mg/l (must be due to isolated pollution incident).

n.d. No data available.

2.1.3 Ground water

Occurrence of trifluralin in ground water is rare (Table 6). Of a considerable number of sites (almost 3500) and samples analysed (over 12 000), a small number of positive findings were reported from Austria (1 of 7000 samples, 1992-1997), France (1 of 336 samples, 1997) and the UK (6 of 517 samples, 1999). The highest concentration reported was 0,1 µg/l (one report from Austria).

Table 6. Summary of trifluralin monitoring data in ground water (unpublished survey report by producer Dow AgroSciences)

Country	Date	No. sites	No. samples	Detected (samples)		Samples >0,1 µg/l		Max. µg/l	LoD (LoDtm) µg/l	Cat.
				No.	%	No.	%			
Ground water										
Austria	92-97	170-580	7000	1	0,01	1	0,01	>0,1	0,1	II
France	1997	56	336	1	0,3	?	-	>0,02	(0,02)	III
Germany	90-93	20	100	0	-	0	-	-	0,1 *	II
	93-94	344	2114	0	-	0	-	-	0,01-0,1 (0,01-0,1)	I
	1997	2 146	2146	0	-	0	-	-	<0,1 *	II
Switzerland	1996	>1	72	0	-	0	-	-	0,01	I
Netherlands	1992	7	7	0	-	0	-	-	0,002	I
UK	1999	334	517	6	1.2	0	-	0,1	0,005-0,01	II
Total**	90-99	3 488	>12292	8	<0,06	1	<0,008	>0,1	0,002-0,1 (0,01-0,1)	I-III

LoD = limit of detection (LoDtm = limit of determination)

* Determination of the limit of detection is uncertain.

** Where there was a risk of multiple reference (e.g. COMMPS and national data), sites or samples have not been added in the total count, i.e. the total sample number represents the minimum number.

2.1.4 European rivers (sediment)

Trifluralin has also been found in sediments in France and Great Britain (COMMPS reports 21 sampling stations, 36 measurements, 5 of which were above the determination limit). However, trifluralin was excluded from the monitoring-based ranking of substances (COMMPS) because it was reported from only 2 EU Member States but not in a transboundary river basin in both of the Member States.

France reported 2450 individual measurements of trifluralin in sediment. However, all but four of these measurements were below the determination limit, which was given between 5 µg/kg and 100 µg/kg. In three cases the limit of quantification was given to 1000 µg/kg. Four measurements were quantified with 66, 95, 156 and 220 µg/kg. There is no indication whether these values refer to dry weight or wet weight of the sediment.

2.1.5 Marine waters

Due to the high K_{oc} of trifluralin (6400-13 400 l/kg), the substance has the tendency to dissipate rapidly from the water phase and to bind to organic matter (suspended matter and sediment). The theoretical probability that trifluralin is transported to the estuaries with suspended matter and sediment may be considered as low (cf. Chapter 2.2.2).

The German Marine Environmental Database (Meeres-Umweltdatenbank, MUDAB) reports a few findings of trifluralin in sea water from 1997 to 1999 in the range of 0,002-0,02 ng/l for the North Sea and 0,0-0,06 ng/l for the Baltic Sea. Details on the sampling locations (e.g. near to the coast) or the analytical methods are presently not available. The reported values are below the limit of detection reported for findings in freshwater (cf. Tables 5 and 6). The quality of the data could be assigned "Category I" (cf. Footnote 1). Data from marine sediment is not available.

In an investigation of the occurrence of several pesticides in the Bering and Chukchi Seas (North Pacific) in the summer of 1993 by CHERNYAK ET AL. (1996), trifluralin was found in the water surface microlayer at concentrations of about 1150 pg/l (detection limit 10 pg/l). It is suggested by the authors that at these locations, which are near to the shore, passages of fog may have left behind trifluralin. Trifluralin was found in the marine arctic fog, but quantification remains uncertain (detection limit for fog 100 pg/l). Concentrations of trifluralin in samples of subsurface water and ice were below the detection limit (0,5 and 2 pg/l, respectively). No trifluralin was detected in air samples. Analysis of trifluralin was reported to be made with a HPLC and GC/MS method. Trifluralin was determined using electron capture negative chemical ionisation

(NCI) detection methods, together with other chlorinated compounds. The reported minimum detection limits for the different compartments (0,5-100 pg/l) are far lower than those presented in Table 5 (2-100 ng/l).

In general, CHERNYAK ET AL. (1996) suggested that occurrence of pesticides in the Arctic Sea is most probably due to long-range atmospheric transport, although the authors admit that trifluralin is very photodegradable and not likely to persist for long periods of time in water.

2.2 Quantification of sources

2.2.1 Emissions to the atmosphere and atmospheric deposition to surface water

If trifluralin is applied to the soil surface without incorporation, a large amount (approx. 60% in 24 h; see Chapter 2.3.2, Removal from soil and degradation in air) will volatilise into the atmosphere due to the vapour pressure of $9,5 \cdot 10^{-3}$ Pa (see Appendix 1). However, when trifluralin is incorporated into the soil (as in most uses), this loss is reduced to < 2% in 24 hours. Evaporation may also take place from water bodies, as has been demonstrated in the water/sediment test (see Chapter 2.3.2, Aerobic biodegradation in water and sediment).

Considering an annual use of 3200 tonnes of trifluralin in whole Europe and an evaporation of 2% from agricultural use (cf. Chapters 1.2 and 2.3.2. (Removal from soil and degradation in air)) assuming the main use in oilseed rape and sunflower with incorporation into the soil), a load to air of about 64 tonnes/year can be estimated. In air, trifluralin is subject to rapid photodegradation. Regardless of the photodegradation known to occur, CHERNYAK ET AL. (1996) attribute low findings of trifluralin in the Bering Sea to atmospheric transport, probably from the USA and Canada (cf. Chapter 2.1.5).

The calculation of transport distance with the computer model ELPOS resulted in 95 km. Dutch calculations of the mean atmospheric deposition to surface water result in 0,21 g/ha/year (for 2000) and 0,30 g/ha/year (for 2001) (calculations provided by the Umweltbundesamt, Berlin).

2.2.2 Drainage, run-off an riverine inputs to the North Sea

A review of the available data for estimating potential damage to aquatic ecosystems caused by the use of trifluralin (KORDEL 1992) comes to the conclusion that, in view of the high K_{oc} value of trifluralin (6400-13 400 l/kg), the non-volatile remaining amount of trifluralin will be bound to the soil. Drainage is unlikely to lead to appreciable contamination of aquatic ecosystems following the agricultural use of trifluralin due to the low water solubility and high adsorption coefficients of the compound. According to model calculations (e.g. PELMO), a leaching to ground water is not to be expected.

Considering run-off events, trifluralin will be transported predominantly as particle-bound solids (borne in mind that erosive rain events occur sporadically), remaining on the solid surface for a certain period of time before run-off events start. Trifluralin is unstable on the soil surface due to high volatility (62% within 24 hours) and susceptible to rapid photodegradation. This is particularly relevant when it is applied directly to uncultivated soil without incorporation (only in cereals). During the autumn application, evaporation rather than photodegradation is mainly responsible for the loss from the soil surface without incorporation. When trifluralin is incorporated, which is the usual agricultural practice, the processes mentioned above are also responsible for the rapid fall in concentration on the soil surface, which is the relevant layer during a run-off event (10-25% reduction in surface concentration due to incorporation). If the test results available for trifluralin are average, the loss due to run-off is 0,22% of the quantity applied.

BÖHM ET AL. (2002) quote a study from Germany, which estimates a total input of trifluralin to rivers by run-off of 1 kg/year (1999) in Germany. If trifluralin enters the water phase of rivers by run-off or spill, it will dissipate to the sediment rapidly. Calculations with ELPOS resulted in a persistence of 18 days and a transport distance of approx. 30 km (calculations provided by the Umweltbundesamt, Berlin). This renders a riverine transport of trifluralin to the North Sea unlikely, if treated areas are not very close to the coast.

The UK reported input of trifluralin in rivers and estuaries to the 5th North Sea Conference (cf. Chapter 4.1) based on use data between 1991 and 1999. Estimates for the upper input level were around 0,25 tonnes per year until 1997 and increased to 0,56 t/a in 1999 in total. Estimates of the lower input level did not exceed 100 kg/a for the total of the UK. In terms of concentrations, these loads are generally considered to be below the level of detection (LOD).

2.2.3 Discharges, losses and emissions

As pointed out in Chapter 1.1, discharges, losses and emissions from the formulation of trifluralin are limited to the lowest technically possible limit for the facility in Drusenheim (relevant for North-West Europe), provided that no mechanical failures occur.

Discharges and losses on the level of farms may occur by cleaning of spraying equipment on the farm yard. This has been identified as the major source of surface water contamination with pesticides in general (see BÖHM ET AL. 2002). This seems to be the only pathway for trifluralin to sewage treatment plants. However, trifluralin has not been reported in sewage treatment plants (except for the one production site in Manerbio, Italy).

2.3 Assessment of the extent of the problem

All test results are taken from the documents provided by European Union Trifluralin Task Force (EUTTF) for the summary dossiers (M-II and M-III) for trifluralin in accordance with Article 6 of Commission Regulation (EC) No 451/2000. The studies presented in the dossier were evaluated by the Rapporteur Member State Greece and their acceptability was discussed and documented in the Draft Assessment Report (DAR) of July 2003, followed by a review by Member States (in progress, cf. Introduction). Review of results for this background document rely on the DAR.

2.3.1 Physico-chemical properties

Representative physico-chemical data of trifluralin are presented in Appendix 1.

2.3.2 Abiotic and biotic degradation

Hydrolysis

Trifluralin is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at temperatures up to 52°C. Since < 10% degradation of trifluralin was observed at 50°C, this is equivalent to an environmental half-life > 1 year. Therefore, hydrolysis is not expected to be a significant route of dissipation of trifluralin in the environment.

PHOTODEGRADATION IN WATER

Trifluralin is rapidly photodegraded in sterile aqueous buffer at pH 7 under artificial sun-light at 25 °C with an estimated first-order DT_{50} of 7 hours. Two significant photolysis products are formed, i.e. TR-6 (up to 50% AR) by the oxidative dealkylation of both N-propyl groups and reduction of one of the nitro groups, and TR-15 (up to 32% AR) by cyclisation to form the benzimidazole and dealkylation of the remaining N-propyl group (see Appendix 1, Fig. 3).

Trifluralin rapidly photodegrades in natural water with an estimated DT_{50} value of 1,1 hours. This is likely due to biotic activity and photosensitising compounds found in natural water systems. It should be noted that rapid photolysis in both experiments was seen under conditions that would be expected to facilitate aqueous photolysis, i.e. non-turbid, shallow water with no sediment.

Calculation of photodegradation at a quantum yield of 0,0022 (at 290 nm) results in a rapid transformation half-life between 0,4 and 2,2 d for the month of June at latitudes of 20 to 60°N, respectively (according to ABIWAS; calculations provided by the Umweltbundesamt). The $T/2_{abiotic}$ is therefore < 4 days. Calculations according to US-EPA FIFRA No. 161-2 based on quantum yield of 0,0112 (at 290 nm) resulted in transformation half-lives of 11-12 minutes in summer (latitude 20-60°N) and 0,3-3,1 hours in winter (latitude 20-60°N).

PHOTODEGRADATION IN AIR

The photochemical oxidative degradation half-life of trifluralin in air is rapid (5,3 hours or 0,22 days) using equations of Atkinson and Howard.

AEROBIC BIODEGRADATION IN WATER AND SEDIMENT

Ready biodegradability of trifluralin was investigated with a Modified Sturm Test. After 28 days the cumulative carbon dioxide production of trifluralin solutions at 10 mg/l and 20 mg/l was 7% and 5%, respectively, of their theoretical carbon dioxide production (pass level is 60% of theoretical CO_2 -evolution). The results show that trifluralin is "not readily biodegradable" under the conditions of this test.

This screening test was performed under GLP in 1992 according to EC Directive 84/449EEC Annex V Methods C.-4-C and OECD 301 B. Test item concentrations were in the prescribed range (10-20 mg/l) and also in the range of water solubility. Trifluralin did not inhibit degradation of the reference substance sodium benzoate. This type of test should not be applied to volatile substances, but, whereas the vapour pressure of trifluralin is quite high for a pesticide (0,01 Pa), the Henry's law constant is medium (ca. 0,004) and, therefore, the test can be considered as valid.

In the regulations for pesticide registration a failure of the ready-biodegradability-screening-test requires the performance of a water/sediment study. A further test on "inherent biodegradability" is not required.

A water/sediment study according to the BBA guideline IV 5-1 was conducted under GLP (1993) with two sediments (clayey sand and loamy clay) and associated water samples from the same river for 60 days. Application was made into the water phase. The overall recovery was between 91 and 115% of the total applied radioactivity (AR; mean 101% AR) indicating a valid radiochemical mass balance. Trifluralin showed a rapid dissipation from the water phase to the sediment. A half-life in water could not be calculated accurately ($DT_{50, \text{water}} < 1$ day); half-life in sediment was 4-6 days. The half-life for trifluralin in the total system is calculated to $DT_{50, \text{whole system}}$ 5-6 days due to the formation of bound residues and volatilisation. No mineralisation (CO_2 evolution) was observed and bound residues in the sediment account for 26% of the radioactivity at the end of the test (60 days). 11 to 17% of the radioactivity in the sediment was extractable. However, stable metabolites did not occur with more than 10% AR. It is important to note that 53 to 77% of the initial trifluralin evaporated from the systems within 1 to 2 months (trapped in glycol). The system was not aerated vigorously ("a small current of air passed over the aqueous phase"), but nevertheless volatilisation is supported. Besides that, the Henry's law constant is medium (see Appendix 1).

Two metabolites (TR-4 and TR-13; see Appendix 1, Figure 4) were identified in the sediment at levels of < 10% AR. Maximum levels of TR-4 were observed at day 14 (4 and 9% AR). A significant level of non-identified substances was observed in sandy loam sediment (7% AR at day 14, and 13% AR at the end of the study). Further analysis was not carried out to characterise these metabolites.

In another water/sediment study (1993; GLP), where trifluralin was applied directly to a single sediment (to mimic introduction via run-off), only 2% of applied trifluralin was detected in the water layer at nominal zero-time. The level remained at 2-3% of applied substance thereafter for up to 100 days. This indicates that little or no trifluralin residues will desorb back into the water phase. In this study, non-extractable residues reached 52% after 100 days. Besides small amounts dissipating to the water phase, 5-7% of the trifluralin volatilised and was caught in glycol traps. No radioactivity volatilised as CO_2 , thus, obviously no mineralisation occurred.

In the extractable sediment phase trifluralin declined steadily from 98% AR initially to 4% AR by 100 days. TR-4 occurred as major metabolite, comprising 16% AR at 28 days but $\leq 2\%$ AR at all other times. This metabolite may be considered transient and rapidly degraded. Minor amounts of metabolites were also detected at levels not exceeding 2% AR (TR-5 and TR-13; see Appendix 1, Figures 1 and 4). Other polar metabolites, totalling 11 to 31% AR, were detected from 14 days but assumed to comprise numerous minor components. These metabolites were not analysed further. From this, it was calculated that DT_{50} values in sediment ranged from 16,6 to 18,5 days (first-order kinetics). DT_{50} in the total system was 17,1 days and DT_{90} was 57 days.

In a recent water/sediment study (2004; GLP), trifluralin was also applied to two sediments and incubated for 101 days (mass balance 98% and 101% for the two systems, respectively). Trifluralin was primarily associated with the sediment phase and was not present in the aqueous phase following 17 days of incubation, confirming previous results that little or no trifluralin residues will desorb back into the water phase. Likewise, $\leq 0,4\%$ AR was observed in the CO_2 traps for both systems and no other volatile products were observed. Aeration of the systems was maintained by a gentle air-flow over (but not through) the water layer in the treated test units so as to remove any volatiles into trapping media and to maintain aerobic conditions in the water layer. However, because the sediment is not disturbed by this process, it is common to have anaerobic conditions developing in the sediment layer and was the case in this study, as shown by dissolved oxygen and redox potential measurements. This is generally reflective of the situation out in the field.

In this study metabolites were further characterised. TR-4 reached a maximum of 26-27% AR at 17 days and was 1-11% AR at study termination. TR-7 reached a maximum of 5-21% at 33 days and 0-2% at study termination. A third metabolite, TR-14, reached a maximum of 24-30% AR at 54 days and was 15-28% at study termination. The unidentified ^{14}C , which is the sum of multiple HPLC Peak areas (all less than 5% peak area), ranged from 0% to 23% AR. Non-extractable ^{14}C -residues in sediment increased from 0,1% at Day 0 to 54-77% AR at study termination.

Based on first-order kinetics, the DT_{50} values for trifluralin dissipation from water were 1-2 days (aqueous DT_{90} 3-6 days). The DT_{50} values for degradation in the sediment layer only were 7-15 days (sediment DT_{90} 24-50 days). The DT_{50} values for overall trifluralin degradation (both sediment and water) were 6-15 days (overall DT_{90} 21-50 days).

Because of the formation of bound residues and stable metabolites in the sediment, as well as low mineralisation, trifluralin may be considered persistent in water/sediment systems. The total residue includes TR-4, TR-7 and TR-14 as major metabolites and considerable amounts of non identified other polar metabolites in sediment.

DEGRADATION AND DISSIPATION IN SOIL

Trifluralin (incorporated) was steadily degraded in soil under aerobic conditions according to first-order kinetics (non-GLP test according to EPA Subdiv. N 162-1, 1982). The $DT_{50(\text{lab})}$ ranged from 81-179 days (mean 181 days; 22 °C), with faster degradation being seen in the low organic carbon soils. No major metabolites are formed. Up to seven minor metabolites at < 5% applied radioactivity (AR) each have been identified (see Appendix 1, Fig. 1), together with several other unidentified minor components at < 8% AR in total.

Non-extractable residue levels increased to 33-54% AR by 364 days and were mostly associated with the humin fraction in the majority of the soils. The level of evolved carbon dioxide is estimated to be between 18-32% AR by 364 days. Some trifluralin volatilisation occurred from soil, but this was < 10% AR over the study period, due to the fact that the substance was mixed into the soil.

An older study (1976; non-GLP; according to BBA Merkblatt No. 37) investigated two Speyer soils under laboratory conditions at 22 °C. DT_{50} values were 136-356 days.

The effect of temperature on the aerobic degradation rate of trifluralin has not been investigated experimentally. However, an estimation of the likely degradation rates at 10°C can be made from the data available at 20 °C (22 °C in reality) using a Q_{10} factor of 2,2 (cf. FOCUS 2000).

European and US field studies showed that trifluralin dissipates slowly in soil, with $DT_{50(\text{field})}$ and $DT_{90(\text{field})}$ values for the EC formulation ranging from 35-375 days (mean 164 days) and 116-1246 days (mean 544 days), respectively. Trifluralin was incorporated into the soil in these field trials too. Slower degradation in colder climates is supported by comparing dissipation data between the European and US trials, where temperatures in the European trials were generally lower than in the US, and where dissipation was slower.

In trials on the influence of tillage and other crop management measures (e.g. straw incorporation, fertilisation; non-GLP, non-guideline studies) on the dissipation of trifluralin in soil the following statements were made with respect to volatilisation of trifluralin from soil. $DT_{50(\text{field})}$ values were calculated to be between 300 and 350 days at both sites following the initial soil incorporated application. $DT_{50(\text{field})}$ values were estimated to be lower (< 150 days) following the subsequent pre-emergent applications, without incorporation. The more rapid loss of trifluralin from these subsequent applications was considered to be due to increased losses by volatilisation from the soil surface when trifluralin is not incorporated. Dissipation of trifluralin was increased after incorporation of straw in both field and laboratory tests. The laboratory tests showed that volatilisation is reduced following incorporation of straw, although overall dissipation is increased. The reduced volatilisation is considered to be due to adsorption to the organic material.

Taking all available results from laboratory and field studies into account, it can be concluded that trifluralin is persistent in soil.

ANAEROBIC DEGRADATION

Degradation of trifluralin under anaerobic conditions (non-GLP test according to EPA Subdiv. N 162-2, 1982) is more extensive than under aerobic conditions (32-58% AR after 60 days). One major metabolite, TR-4, up to 13,2% AR was formed in two out of the three soils tested but this metabolite was shown to degrade in one of the soils by the end of the study. The metabolites that could be attributed to anaerobic conditions were TR-4, TR-7, TR-14 and TR-16 (see Appendix 1, Fig. 2). These were formed by sequential reduction of the nitro groups on the parent molecule (TR-4 and TR-7), or by oxidative dealkylation of the N-propyl group on an aerobic metabolite (TR-13) followed by reduction of the nitro group (TR-14). Under anaerobic conditions the levels of evolved volatile components were less significant than under aerobic conditions. However, the levels of non-extractable radioactivity were higher (35-60% AR).

Depending on the soil used in the experiment, anaerobic DT_{50} was determined to be 23 to 54 days (DT_{90} 77-181 days; 22 °C).

REMOVAL FROM SOIL AND DEGRADATION IN AIR

Evaporation of trifluralin from soil was tested in a wind tunnel apparatus at 20°C and about 50% relative humidity (1993; BBA Guideline Part IV, Section 6.1; GLP). Trifluralin evaporates when applied to the surface of soil with an amount of 41-68% of the applied radioactivity after 24 h. However, volatilisation is minimal (< 2% AR) when trifluralin is incorporated into the soil after application. In addition, the calculated photochemical oxidative degradation half-life of trifluralin in air is rapid (0,22 days).

It is critical that the substance is incorporated into the soil shortly after application since otherwise significant volatilisation to air occurs. This is recommended for all crops, except cereals, where the application of products containing trifluralin is made to the soil surface post sowing of the seed and up to the three-leaf stage of crop but before weed emergence.

However, considering the actual agricultural practice of incorporating the substance into the soil, the expected photodegradability in air, calculations on the possible travel distance, and available measurements in air, significant amounts of trifluralin are not expected to be transported to distant locations of the marine environment via the air.

CONCLUSIONS FOR DEGRADATION

Half-life in water for trifluralin was determined in the water/sediment system to be 1-2 days. Half-life in sediment was calculated to be 7-15 days and 6-15 days in the total system. An older study arrived at slightly longer DT_{50} -values. Mineralisation of trifluralin is insignificant (< 1% of the total radioactivity, AR). A significant amount of trifluralin remained in the sediment, furthermore, up to 77% AR was not extractable (bound residues). When applied to the water phase, most of the substance can volatilise from the system (53-77% AR). The short half-life in water does not represent a rapid degradation of trifluralin but rather a transfer to other environmental compartments, mainly sediment. Considerable levels of metabolites (up to 30% at certain points of time, some of them stable) indicate degradation of trifluralin in sediment, especially under anaerobic conditions, besides the formation of bound residues.

Regardless of the short half-life in water and the moderately short half-life in sediment, trifluralin should be considered persistent in the water/sediment systems due to the low degree of mineralisation and the formation of high amounts of bound residues.

Trifluralin is persistent in soil. Hence sediments and soil are major reservoirs for trifluralin and assessment of persistence should be based on these compartments. Therefore, trifluralin must be considered a persistent substance. Fulfilment of the P-criterion is further supported by the identification as "not readily biodegradable".

It should be emphasized that the strong tendency of trifluralin to adsorb to soil, sediment and suspended matter significantly reduces toxicity risks in the water phase, because trifluralin will hardly be present there. On the other hand, trifluralin stays present in the sediment and probably adsorbed to suspended matter. Desorption from sediment to water appears to be low. With a resuspension of sediment and with the freight of suspended matter it could possibly be carried into the marine environment, although likelihood for this pathway is low (cf. Chapter 2.2.2).

Trifluralin rapidly photodegrades in air; this limits the likelihood for a long-range transport - despite the significant volatility of trifluralin from soil if applied superficially. Under favourable conditions, photolysis in water is rapid too, however, hydrolysis appears to be insignificant.

2.3.3 Bioaccumulation in fish

Bioconcentration factors for whole fish are presented in Table 7. Test concentrations are 10 times lower than the LC_{50} values and in the range of water solubility. From the four studies presented, the GLP study from 1996 is considered to provide the most reliable endpoint data for bioaccumulation in fish (BCF 5674, ct_{50} 4,6 days).

In the 28-day flow-through study on bluegill sunfish (*Lepomis macrochirus*), an uptake first-order rate constant (K_1) of 828 ml/g/day led to a whole body bioconcentration factor (BCF) of 5674. Residues were primarily trifluralin plus small amounts of N-dealkylated metabolites, alcohol metabolites and conjugates of alcohol metabolites. On removal to clean water, depuration was rapid with an elimination first-order rate constant (K_2) of 0,15 day⁻¹ (ct_{50} 4,6 d). Trifluralin was the major residue in edible and non-edible tissue, comprising 84-88% of total radioactive residues. Metabolites and their conjugates accounted for around 6-7% of total residues.

Studies reported in the published literature give calculated and measured bioconcentration factors in the range of 2280 to 11 500 for a variety of species. These results are in close agreement with the range of values obtained from the data set of unpublished studies from the dossier.

According to the PBT-criteria laid down in the draft EU/OSPAR marine risk assessment (EC 2003), the bioaccumulation criterion is fulfilled with a BCF above 2000. In case of trifluralin, the most reliable measured BCF is 5674 and a calculated BCF is 2280 (from $\log P_{ow}$ 5,27 according to MEYLAN ET AL. 1999). Both values exceed the cut-off of 2000, therefore, trifluralin meets the B-criterion.

Table 7. Results of bioaccumulation studies with trifluralin in fish

Species	BCF whole fish	Test conditions	Clearance half-life ct_{50} [d] Residues after 14 d	Source Year
<i>Lepomis macrochirus</i>	5674 ^a	28 days uptake; FLO; 2 µg/l trifluralin; GLP	4,6 < 10%	[1] 1996
<i>Lepomis macrochirus</i>	1580 ^b	35 days uptake; FLO; ~ 8 µg/l trifluralin; non-GLP ^c	4,3-5,6	[1] 1973
<i>Lepomis macrochirus</i>	1087-1838 ^a	8 days; STA; 0,5-12,5 mg/kg trifluralin; non-GLP ^d	not calculated	[1] 1985
<i>Pimephales promelas</i>	1750-8870 ^{b,e}	35 days uptake; FLO; 0,3-30 µg/l trifluralin; GLP	not calculated	[1] 1990

[1] EUTTF (2002)

a) Calculated from the uptake rate constant.

b) Calculated from the ratio of concentrations in fish and water.

c) There are major deviations from the OECD Guideline 305E. Therefore, this study is intended to provide supplementary information only.

d) Sediment containing trifluralin was stirred into the test vessels. Concentrations refer to test substance in sediment wet weight. Dissolved trifluralin was detected at a maximum of 1,9 µg/l, declining to 0,6 µg/l. This non-standard study is intended to provide supplementary information only.

e) The low BCF of 1750 was obtained in the high concentration of trifluralin (30 µg/l) and the high BCF of 8870 was obtained in the low concentration of trifluralin (0,3 µg/l).

STA: static test; FLO: flow-through test; GLP: test conducted under "Good Laboratory Practice".

2.3.4 Secondary poisoning

Given the high BCF of trifluralin, an estimate of the potential for secondary poisoning for fish-eating birds and mammals using the estimation method given in the Technical Guidance Document (EC 2003) appears appropriate (Table 8). No specific assessment of the risk to fish as a result of the combined intake of contaminants from water and contaminated food (aquatic organisms) is considered necessary as this is assumed to be covered by the aquatic risk assessment and the risk assessment for secondary poisoning of fish-eating predators.

The risk to fish-eating predators (mammals and/or birds) is calculated as the ratio between the concentration in their food ($PEC_{oral,predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). The concentration in fish is a result of uptake from the aqueous phase (BCF_{fish} 5674) and intake of contaminated food (e.g. worms; $BMF_{fish,default}$ 10). $PNEC_{oral}$ is derived from dietary studies on birds and mammals, although the species tested from these groups are not feeding on fish: $NOEC_{reproduction,bird}$ 1000 mg/kg diet (133 day study) and $NOAEC_{rat}$ 200 mg/kg diet (2 year study). These dietary values are converted with respect to bodyweight (conversion factor birds 8; mammals 20) and divided by an assessment factor (for $NOEC_{birds}$ or $mammals$: 30) resulting in $PNEC_{oral,bird}$ and $PNEC_{oral,mammal}$. Besides these $NOEC$ values, which are considered valid in the context of the assessment under EU-Directive 91/414/EEC, toxicity to birds and mammals is not considered further in the context of this background document.

The $PEC_{surface\ water}$ in Table 8 is the 90th percentile concentration from the COMMPS dataset (0,03 µg/l). Based on this concentration a risk of secondary poisoning is not to be expected for birds and mammals ($PEC/PNEC$ far lower than 1). Considering risks for top predators would imply an additional biomagnification factor of 10 and therefore an increase of the PEC_{oral} by the factor of 10. However, also for top predators, there is no risk indicated by the $PEC/PNEC$ ratio (< 1).

Table 8. Calculations to estimate the risk of secondary poisoning of birds and mammals from trifluralin (calculation according to TGD, EC 2003).

$PEC_{surface\ water}$ [mg/l]	$PEC_{oral\ predator}$ [mg/kg wet fish]	$PNEC_{oral\ bird}$ [mg/kg bw]	$PEC_{oral\ pred.} / PNEC_{oral\ bird}$	$PNEC_{oral\ mammal}$ [mg/kg bw]	$PEC_{oral\ pred.} / PNEC_{oral\ mammal}$
$3,1 * 10^{-5}$	1,76	266,7	0,007	133,3	0,013

(PEC: predicted environmental concentration; PNEC: predicted no-effect concentration.)

2.3.5 Acute and chronic ecotoxicity effects

Some test results on acute and chronic ecotoxicity levels for different trophic levels are presented in Table 9. These test results – together with additional data – were also identified by the Expert Advisory Forum for the Water Framework Directive together.

Table 9. Selected data on the ecotoxicity of trifluralin

Test organism	Trophic level / Habitat	Endpoint / Effect	Test conditions	Endpoint concentration	Source Year
<i>Selenastrum capricornutum</i>	pProd FW	EC ₅₀ GRO-inhibition	7 d; STA ^a ACT; GLP	12,2 µg/l ^b	[1] 1990
<i>Lemna gibba</i>	pProd FW	EC ₅₀ GRO-inhibition	14 d; STA ^a ACT; GLP	43,5 µg/l	[1] 1993
<i>Skeletonema costatum</i>	pProd SW	EC ₅₀ GRO-inhibition	5 d; STA ^a ACT; GLP	28 µg/l	[1] 1993
<i>Chironomus riparius</i>	dCons FW	NOEC Larval develop.	28 d; STA ^c ACT; GLP	250 µg/l nominal	[1] 1996
<i>Hyalella aztecas</i>	dCons FW	NOEC GRO	30 d; STA ^d ACT; GLP	157 mg/kg dw	[1] 1994
<i>Daphnia magna</i>	pCons FW	EC ₅₀ MOR	2 d; REN; ACT; GLP	245 µg/l ^e	[1] 1999
<i>Daphnia magna</i>	pCons FW	NOEC Life-cycle	21 d; REN; ACT; GLP	≥ 50,7 µg/l	[1] 1990
<i>Cancer magister</i>	sCons SW	NOEC REPRO	69 d;	15 µg/l	[2] 1977
<i>Lepomis macrochirus</i>	sCons FW	LC ₅₀ MOR	4 d; FLO; ACT; GLP	89,2 µg/l	[1] 1999
<i>Oncorhynchus mykiss</i>	sCons FW	LC ₅₀ MOR	4 d; FLO; ACT; GLP	88,0 µg/l ^f	[1] 1999
<i>Salmo trutta</i>	sCons FW	NOEC sublethal effects	24h/365d; STA; ACT; non-GLP ^g	25 µg/l nominal	[1] 1985
<i>Cyprinodon variegatus</i>	sCons SW	NOEC Life cycle	166 d; FLO; ACT; non-GLP	1,3 µg/l	[1] 1978
<i>Oncorhynchus mykiss</i>	sCons FW	NOEC ELS	48 d; FLO; ACT; GLP	1,14 µg/l	[1] 1990
<i>Pimephales promelas</i>	sCons FW	NOEC Juvenile GRO ^h	35 d; FLO ACT; GLP	0,3 µg/l	[1] 1992

[1] EUTTF (2002)

[2] Frimmel, F.H. et al. (2001): Ableitung von Qualitätszielen für Kandidatenstoffe der prioritären Liste für die EU-Wasserrahmenrichtlinie. Projektbericht zum Forschungsvorhaben. Substance data sheet for trifluralin.

a) Test results in static test systems are based on measured initial concentrations because trifluralin was not detectable at the end of the tests.

b) The corresponding 72-hour algae EC₅₀ values for the metabolites, TR-6 and TR-15, were > 5,56 mg/l and 1,67 mg/l, respectively.

c) Trifluralin applied to the aqueous phase in the sediment-dweller test. Measured value was 42 µg/l on Day 3. In another test with midge larvae spiking of the sediment resulted in a NOEC of 810 mg/kg dw (measured).

d) Trifluralin applied to the sediment phase in the sediment-dweller test. NOEC based on measured initial concentration.

e) The corresponding 96-hour *Daphnia* EC₅₀ values for the metabolites, TR-6 and TR-15, were 3,52 mg/l and 9,36 mg/l, respectively.

f) The corresponding 96-hour fish LC₅₀ values for the metabolites, TR-6 and TR-15, were 1,00 mg/l and 5,46 mg/l, respectively.

g) 24 hours of exposure to trifluralin and 1 year observation of brown trout. Study not in full compliance with OECD Guideline 215. Initial concentration for the 25 µg/l nominal level was 23 µg/l and 2 µg/l after 24 hours.

h) NOEC based on the occurrence of spinal lesions at 0,7 µg/l.

pProd: primary producers; pCons: primary consumer; sCons: secondary consumer; dCons: detritus and sediment consumer; FW: freshwater species; SW: saltwater species; GRO: Growth, emergence; ELS: Early life-stage test; MOR: Mortality, Immobilisation; REPRO: Reproduction; STA: static test; REN: static-renewal test; FLO: flow-through test; ACT: active substance; GLP: test conducted under "Good Laboratory Practice".

The ecotoxicity data are compiled from the Tier II summaries of the pesticide dossier (information provided by EUTTF). Tests are evaluated in the Draft Assessment Report (DAR) by the Rapporteur Member State in the process of pesticide authorisation under EU-Directive 91/414/EEC. Test results presented in Table 9 are considered valid in the DAR (except for the test with *Cancer magister*, which was unaccounted for in the DAR). Some details on the test conditions are given in column 4 of Table 9. Test results are in the range of the water solubility of trifluralin (about 200 µg/l, cf. Appendix 1).

Trifluralin is very toxic to aquatic organisms (see Table 9). Although a herbicide, fish seem to be particularly sensitive to trifluralin. The lowest chronic endpoint is the 35 d NOEC of 0,3 µg/l for spinal cord deformation in the fathead minnow (*Pimephales promelas*) was derived from a study (1992) in which fish were constantly exposed to trifluralin under flow-through conditions (0,6-50 µg/l nominal). At the end of the 35-day exposure period, survival and total length were significantly reduced at 8,6 and 30 µg/l (measured). Behavioural signs of toxicity were also seen at concentrations down to 3,2 µg/l (measured) but the most sensitive indicator of toxicity was the appearance of crooked ribs and vertebral lesions (leading to compression or deviation of the spine) at concentrations down to 0,7 µg/l (measured). Although the incidences of these effects were concentration dependent, severe abnormalities were primarily observed at the higher exposure levels of 8,6 µg/l and 30 µg/l (measured). At exposure levels of 3,2 µg/l (measured) and below, the severity of vertebral lesions and wavy ribs were generally classed as minimal to slight. The background total incidences of vertebral lesions and wavy ribs in the acetone control fish were 22,8% and 45,5%, respectively, compared to 23,8% and 27,5% in control fish of a similar age.

The second worst-case endpoint is the 2-generation NOEC of 1,3 µg/l on sheepshead minnow (*Cyprinodon variegatus*; 1978), based on a significant reduction in parental fecundity after 166 days exposure to measured trifluralin of 1,3-34,1 µg/l. This is not a significant difference to the endpoint of 1,14 µg/l (measured) after 48-day exposure to the early life-stages of rainbow trout (*Oncorhynchus mykiss*; 1990).

Further information can be obtained from a non-standard laboratory study (1985) conducted with brown trout (*Salmo trutta*) on juvenile fish exposed for 24 hours to nominal trifluralin concentrations of 25-250 µg/l and subsequently held in clean water for up to one year. The fish were periodically sampled over this time, radiologically examined for vertebral lesions and analysed for trifluralin residues. Although no mortality occurred in any of the treatment groups during the exposure period, several fish were prostrate at the 100 and 250 µg/l exposure level and intramuscular haemorrhaging along the spinal column was evident. No adverse effects were observed in the control fish or those exposed to 25 µg/l. Five months post-exposure, mortality rates were 15,4, 59,3 and 100% with frequencies of trifluralin-induced lesions of 3,2%, 95,8% and 100% for the 25, 100 and 250 µg/l exposure levels, respectively. Mortality in the control group was 4,2% with a vertebral lesion frequency of 6,8%. Based on these results, a NOEC for vertebral injury following acute exposure was considered to be 25 µg/L.

These values were all obtained from studies conducted in laboratory water, in the absence of sediment. In view of the rapid dissipation of trifluralin from the water column due to adsorption to sediments, the study with brown trout might even simulate more realistic conditions. However, the 24-hour NOEC of 25 µg/l (nominal) must be interpreted with respect to a reduction of the measured trifluralin concentration in this test to 2 µg/l after 24 hours. Therefore the NOEC based on measured values might well be below 10 µg/l.

On the other hand, additional studies have been conducted with various combinations of trifluralin and suspended sediment. Effect levels were higher than in the water-only experiments described above. Further, two sediment dwelling organisms showed to be less sensitive than fish.

Comparably few tests with saltwater species have been reported, some of which are presented in Table 9. In these tests, the sensitivity of marine species is apparently comparable with the sensitivity of freshwater species of the same taxonomic group.

Considering the toxicity trigger of 0,01 mg/l (10 µg/l) for NOECs (cf. marine Risk Assessment in EC, 2003), the T-criterion is fulfilled for trifluralin.

Several metabolites of trifluralin (see Appendix 1, Figures 1-4) have attracted attention in the soil, water and sediment dissipation tests. TR-4 was a major metabolite in one of the water/sediment systems (up to 27% AR) and also occurred with <10% in soil under anaerobic conditions. Low levels of TR-4 were observed at the respective ends of the experiments, suggesting a further degradation of TR-4 (see Appendix 1, Fig. 2 and 4). The effects of TR-4 were tested on larvae of the midge *Chironomus riparius* sediment-water exposure system (NOEC 0,332 mg a.s./L nominal), earthworms (NOEC (14 d) 100 mg a.s./kg dry soil nominal) and soil microflora activity (< 25% deviation from control values after 29 days up to 2 mg a.s./kg dry soil). In relation to the corresponding PEC-values for sediment and soil, toxicity exposure ratios (TERs) exceeded the trigger values by far, indicating that there is no unacceptable risk by this metabolite.

TR-6 and TR-15 are major products of photolysis of trifluralin in aqueous sterile buffer (see Appendix 1, Fig. 3). Ecotoxicity tests for TR-6 and TR-15 were performed with algae, daphnids and fish resulting in EC₅₀/LC₅₀ values of 1-5 mg/l. These two metabolites are much less toxic than the parent compound trifluralin.

Ecotoxicity data are not available for TR-7 and TR-14, since these metabolites have only recently been identified. However, the risk from these metabolites is considered to be low on the basis of their similarity to the previously tested metabolites. For example, TR-7 is structurally similar to TR-4 and TR-14 is structurally similar to TR-15. Since all three metabolites tested to date are less toxic than the parent, trifluralin, and formed in lower amounts, then the risk from TR-7 and TR-14 is also likely to be low.

Consideration of metabolites does not change the conclusion that the T-criterion is fulfilled for trifluralin.

2.3.6 Carcinogenicity, mutagenicity or harmful reproductive effects

Trifluralin has been subjected to intensive and thorough investigation for genotoxic potential in short-term screening tests. These investigations lead to the conclusion that trifluralin is non-genotoxic. *In vivo*, single oral treatment with trifluralin did not induce chromosome (in two studies) or increases in the frequencies of micronucleated polychromatic erythrocytes or kinetochore positive micronuclei in the bone marrow of mice or sister chromatid exchanges in the hamster bone marrow. On repeated oral administration, trifluralin did not cause chromosome damage in mouse spermatogonial cells or dominant lethal mutations in rats (two studies). *In vitro*, trifluralin failed to cause chromosome damage in hamster ovary cells, UDS in rat hepatocytes or forward mutations in hamster ovary or mouse lymphoma cells. Three Ames tests demonstrated trifluralin's inability to induce bacterial mutations.

With respect to long-term toxicity and carcinogenicity, two studies in B6C3F1 mice are available, among others. The first used a trifluralin test material contaminated with a significant amount of N-nitrosodipropylamine, a known carcinogen. This test material induced malignant liver tumours and benign lung tumours in the females, and may have induced some malignant stomach tumours in the females also. No evidence of carcinogenicity was seen in the males. When a purified trifluralin sample, representative of the commercial material currently available, was tested in B6C3F1 mice, the results convincingly showed an absence of carcinogenic potential. It is clear that the trifluralin molecule is not carcinogenic to the B6C3F1 mouse, and that carcinogenic potential of commercial supplies of trifluralin depends upon specification. The FAO specification for trifluralin includes a maximum content for N-nitroso-di-n-propylamine of 1 mg/kg. Some Member States have set this level for total nitrosamines whilst others have set lower levels, e.g. Italy (0,4 mg/kg to avoid a carcinogenic classification). Technical trifluralin manufactured by members of the European Union Trifluralin Task Force (EUTTF) contains levels much lower than these specifications.

The NOEL in B6C3F1 mouse was 563 ppm in the diet, equivalent to about 40 mg/kg bw/day. At 2250 mg/kg bw/day (approximately 180 mg/kg bw/day) and above, there was reduced growth, anaemic blood changes on erythrocytes and haemoglobin, increased liver weight (without evidence of tissue damage), and progressive glomerulonephrosis in the kidney.

Two studies are available in rats. No evidence of carcinogenic potential was seen in a good quality National Toxicology Programme (NTP) study where Osborne-Mendel rats were fed trifluralin in the diet up to a time-weighted average of 8000 ppm for two years. The second study involved feeding trifluralin in the diet to Fischer 344 rats up to 6500 ppm for two years. Treatment did not affect total tumour incidence in the males and decreased total tumour incidence in the females.

The incidences of benign and malignant thyroid neoplasms were greater than those reported for this strain in the literature, but, in general, there was no evidence of a treatment-related effect. However, there is a dose-related increase in thyroid follicular cell adenomas in male rats only. The males also showed an increased incidence of malignant kidney tumours. The females showed an increase in benign urinary bladder tumours but no increase in malignant tumours. At 813 ppm (about 30-37 mg/kg bw/day), both sexes had considerably increased incidences of renal calculi, and the males showed an increased severity of progressive glomerulonephrosis (PGN) in the kidney. The results are indicative of chronic stress caused by trifluralin on the renal and urinary system. The convincing absence of any genotoxic potential for trifluralin in the short-term screening tests (see above) dictates that the urinary tract tumours in the Fischer rat arose by a non-genotoxic mechanism. The data suggest that early changes in urine content and kidney microscopic appearance do not result from exposure at 50 ppm in the diet, equivalent to a NOEL of 2,6 mg/kg bodyweight/day. In the absence of any of these non-neoplastic changes, no carcinogenic risk would be expected. Besides that, these responses were only observed in Fischer rat and were not reproduced in comparable studies in three other strains of rat or other species.

The weight of evidence suggests that trifluralin is not posing a carcinogenic risk to humans.

Trifluralin has been comprehensively investigated in reproductive toxicity studies, including a three-generation, two two-generation and a one-generation study in rats, and in a limited one-generation dog study. In a number of studies, rats and rabbits were administered trifluralin repeatedly during pregnancy to explore developmental/teratogenic potential. Trifluralin has not caused any adverse effects on reproduction or the developing foetus at doses that were not also toxic to the mothers. Trifluralin therefore has no specific effects on reproductive or developmental processes. The lowest NOEL identified was 5,6 mg/kg bw/day in a two-generation rat reproduction study. In this study, the next highest dose level (40-54 mg/kg bw/day) was associated with maternal toxicity (reduced weight gain during pregnancy and blood changes indicative of anaemia) and effects on the offspring (reduced growth and survival during lactation).

This leads to the conclusion that CMR properties of trifluralin are not significant.

For determination of an ADI (Acceptable Daily Intake) the lowest NOEL from chronic studies has been used and, in the case of trifluralin, this is 2,4 mg/kg bw/day from a study in dogs. By convention, a safety factor of 100 should be applied to this NOEL to produce the ADI: 0,024 mg/kg bw/day.

2.3.7 Endocrine effects

Trifluralin has been put on lists of endocrine disrupting chemicals (see PAN 2001). However toxicology of mammals, birds and fish show that effects related to trifluralin are not specific to endocrine disruption and trifluralin produces no adverse reproductive effects below exposure levels that produce systemic toxicity in mammalian studies.

A single published study with positive measurement of endocrine endpoints in mammals was RAWLINGS ET AL. (1998). In this study, ewes were administered trifluralin by capsule at a dose of 17,5 mg/kg, 2 times per week over a 43 day period during mid breeding season, and measurement of various endocrine endpoints (serum LH, FSH, progesterone, estradiol, thyroxine, insulin, and cortisol; histology of endocrine organs) were made. Statistical increases in cortisol, estradiol and insulin, and a decrease in LH were reported. However, these authors pointed out that the mechanism of effects is unclear and that "a simple stress effect cannot be ruled out". Other studies reported negative results for estrogenic activity in an in vitro E-SCREEN assay with trifluralin.

In fish, the lowest endpoint was determined at 0,3 µg/l from a study on fathead minnows (see Table 8). The most sensitive indicator of toxicity was the appearance of crooked ribs and vertebral lesions (leading to compression or deviation of the spine) at concentrations of 0,7 µg/l. By contrast, no significant deformities were observed in the early life-stage test on rainbow trout, or in the full life-cycle study on sheepshead minnow, conducted at similar exposure levels. In an early life stage-test with the same species reported one year later by COUCH ET AL. (1979), a "heretofore undescribed vertebral dysplasia" was observed amongst the range of adverse effects. Embryos exposed to mean measured trifluralin concentrations of 5,5 to 31 µg/l for 28 days post-hatch developed dysplasia in the form of asymmetrical hypertrophy of the vertebrae (3-20 times normal). Fish exposed for 51 days to 16,6 µg/l, followed by 41 days depuration, showed no further increase in dysplasia but the evidence of original damage that occurred during exposure was still apparent. Serum calcium levels were elevated and fluorosis or mimicry of hypervitaminosis were postulated, somewhat speculatively, as being possible mechanisms of action. In a subsequent study, Couch (1984) exposed embryos and 30-day old sheepshead minnow to trifluralin concentrations of 1-5 µg/L for 19 months. Adverse effects observed were enlarged pituitaries, pseudocysts, congestion of blood vessels and oedema. Most of the fish with enlarged pituitaries also had induced diffuse dysplasia or focal hyperostosis of the vertebrae and other dysplastic vertebral changes.

The occurrence of enlarged pituitaries and vertebral malformations in the same fish, however, does not necessarily mean that these two effects are linked causally. In fact, the evidence from studies with spinal transected fish suggests that they are not related and that the vertebral lesions arise as a result of nerve excitation/muscle spasm. Under field conditions, a plausible explanation is that both abnormalities develop in response to the multiple stressors present in agricultural run-off, suspended sediment being the most likely candidate. The incidence of vertebral abnormalities in fish is not significantly higher in trifluralin-treated areas and there is no evidence to suggest that trifluralin exerts endocrine modulating effects in the environment.

On the basis of the literature review, EUTTF comes to the conclusion that trifluralin does not meet the criteria for classification as an estrogenic or androgenic compound and does not represent a hazard to either human health or wildlife at environmental exposure levels with regard to endocrine effects.

2.3.8 Toxicological effects

Trifluralin has only a very low acute toxicity by oral, dermal and inhalation uptake. The oral LD₅₀ is >5000 mg/kg bw for rats and >2000 mg/kg bw for mice and rabbits, and the dermal LD₅₀ is >2000 mg/kg bw

in rats and rabbits. The four-hour LC₅₀ acute inhalation value has been determined to be > 4,65 mg/l air, which was the maximum concentration achievable (all values for the active substance).

In accordance with EC criteria, trifluralin is not classified on the basis of acute toxicity or skin or eye irritation, but is classified as a skin sensitiser.

This leads to the conclusion that acute toxicological effects to humans are not significant.

2.4 Risk to the environment

Trifluralin meets all PBT criteria. Trifluralin dissipates rapidly from water, but persistence is high in soil and sediment when considering bound residues and low mineralisation. The bioaccumulation potential in terms of the measured bioconcentration factor exceeds the cut-off value of 2000, and trifluralin is very toxic to aquatic organisms (lowest NOEC < 0,01 mg/l). Therefore, trifluralin meets the PBT criteria and poses a potential risk to the marine environment.

Under the intended conditions of use, however, trifluralin will adsorb to soil and sediment rapidly, and therefore will not be directly available to the aquatic organisms. However, sediment dwelling organisms (two of which showed a low sensitivity) might be affected.

Trifluralin adsorbed to sediment and suspended matter may pose a risk to the marine environment if these fractions are transported into the sea from rivers. Desorption from the sediment to water appears to be low. Calculations with ELPOS resulted in a persistence of 18 days and a transport distance of approx. 30 km, which renders riverine transport of trifluralin to the North Sea unlikely, if treated areas are not very close to the coast (run-off is equally low).

If trifluralin is applied to the water phase, a major part may evaporate. Whether this is the case under natural conditions from water bodies is unclear (Henry's law constant is medium). Volatilisation of trifluralin which was worked into the soil is low also. The amount evaporating to air was estimated to be around 64 tonnes per year in Europe. Further, substance which has actually volatilised, is rapidly degraded in air. The travelling distance in air was calculated to be 95 km (ELPOS). This is why an air transport very far beyond the European coast is unlikely. However, trifluralin has been found in the water surface microlayer of the Bering and Chukchi Seas (North Pacific) in concentrations of about 1,1 ng/l.

An evaluation of monitoring data from European rivers in the COMMPS procedure (focus on samples with findings above determination level) yielded a 90th percentile concentration of 0,0306 µg/l. In total, trifluralin was detected in 1,5% of over 30 000 samples from over 4500 sites over several years. Of these, concentrations above 0,1 µg/l were found in 9 samples (0,03%). Although a rapid partition of the substance to the sediment is known to occur, only few sediment samples were analysed for trifluralin. From these few data available the potential risk in sediment can not be evaluated, whereas the risk potential in the water phase seems to be low, as indicated from the monitoring data.

PEC values in surface water resulting by drift directly after application (actual value) were calculated to 11,1 µg a.s./l (1 m), 2,3 µg a.s./l (5 m), and 0,8 µg a.s./l (15 m distance). These concentrations do not prevail in the water, since trifluralin rapidly dissipates from the water phase to the sediment.

Discharge from manufacturing or formulation sites seems to be negligible, although evidence is presently only available for the one manufacturing plant of technical trifluralin in Italy and one major formulation site in France close to the River Rhine. Road transport of trifluralin between these sites undergoes quality assessment and appears not to be a source of environmental contamination with trifluralin.

Acute and chronic human toxicity risks (CMR properties) of trifluralin are not significant and trifluralin can not be considered an endocrine disruptor.

3 Desired reduction

Trifluralin is clearly a PBT substance. Although significant amounts may evaporate into the air from the agricultural use (estimated 64 t/y), photochemical oxidative degradation will rapidly decrease this load before it can be transported far beyond the coasts. An input via substance adsorbed to sediment and suspended matter in rivers is a theoretical risk, but is not considered relevant.

Findings in fresh water have shown a low occurrence, while findings in freshwater sediment are poorly reported and can not yet been fully evaluated. A few measurements (associated with uncertainty) have been reported from North Sea water with concentrations of trifluralin at a low level of 0,02 ng/l. A few (4) measurements in freshwater sediments were reported from France in the range of 66-220 µg/kg (dry or wet weight not indicated). No measurements have been reported so far in the marine sediment.

Therefore measures and actions by OSPAR should be directed, in general, to avoid a potential future entry of trifluralin into the marine environment. A general quest for a reduction of use of trifluralin, based on a risk for the marine environment, does not seem appropriate. Nevertheless, the enforcement of good agricultural practice, i.e. the incorporation of the applied product into the soil in order to avoid evaporation, should be supported.

4 Review of agreed measures and possible substitutes

4.1 Review of agreed national and international measures for the regulation of trifluralin

OSPAR STRATEGY WITH REGARD TO HAZARDOUS SUBSTANCES

Trifluralin was selected in the DYNAMEC process early in 2000. At OSPAR 2002 trifluralin was agreed upon as a priority substance and Germany volunteered in the preparation of the draft background document for October 2003. The draft background document for trifluralin and proposals on action and measures are prepared for decision at OSPAR 2004.

REPORTS ON HAZARDOUS SUBSTANCES FOR THE 5TH NORTH SEA CONFERENCE (1987-2002)

In the Hague Declaration of the 3rd North Sea Conference, trifluralin was put on the list of priority hazardous substances (Annex 1A) with the target of a 50% reduction of inputs via rivers and estuaries. The atmospheric pathway for trifluralin was not included in the Annex 1A list. Regardless of difficulties in reporting, the Progress Report to the 5th International Conference on Protection of the North Sea (5thNSC; 20-21 March 2002 in Bergen, Norway; www.dep.no/md/nsc/report/index-b-n-a.html) indicates in which countries the 50% reduction target has not been achieved between 1985 and 1999/2000 (current sales/use data): Belgium (15,1 t/a), France (1600 t/a), Switzerland (0,5 t/a) and UK (657 t/a). Apart from the Tables 5.3 and 5.4 in Progress Report to the 5thNSC, Switzerland reported a 100% reduction of discharges to water. A 50% reduction has been achieved in Germany (< 102 t/a) and application of trifluralin was discontinued (or was never in use) in Norway, Sweden and The Netherlands. Trifluralin has been banned in Denmark since 1997, but a derogation for use in seed production is in force from 1999 to 2004. The amounts of trifluralin sold in Denmark are as follows: 2000 (581 kg); 2001 (31 kg); 2002 (19 kg).

PLANT PROTECTION PRODUCT DIRECTIVE 91/414/EEC

Trifluralin is presently reviewed under the EU Plant Protection Product Directive 91/414/EEC. The Draft Assessment Report (DAR) was finalised in July 2003 and submitted by the RMS Greece to the European Commission and the European Food Safety Agency. Review of the DAR by EU-Member States is currently in progress. The RMS has responded to comments of Member States in December 2003.

Within the EU, Trifluralin is presently authorised in Austria, Belgium, Finland, France, Germany, Greece, Italy, Ireland, Portugal, Spain and the United Kingdom. In Denmark, Luxembourg, Sweden and The Netherlands, as well as in Norway, trifluralin is not authorised.

WATER FRAMEWORK DIRECTIVE 2000/60/EC

Following the adoption of the Water Framework Directive 2000/60/EC, the European Commission has identified a list of 33 priority substances of which 11 are priority hazardous substances that are of particular concern for the aquatic environment (cf. Decision Number 2455/2001/EC of 20.11.2001, OJ L331 of 15.12.2001, p 1). These substances shall be subject to cessation or phase-out of discharges, emissions and losses into surface, transitional and coastal waters within 20 years of the adoption of measures. Among others, trifluralin is on the list of priority substances and currently under review for identification as possible "priority hazardous substance". A final decision by the Commission is to be expected in summer 2004. The Expert Advisory Forum for the WFD has derived Environmental Quality Standards (EQS) for trifluralin (see Table 10 below), which have to be approved by the European Commission.

QUALITY STANDARDS

In Germany, quality standards for pesticides in drinking water sources were established by a sub-committee on EU Quality Criteria (Länderarbeitsgemeinschaft Wasser – Unterausschuss EU-Qualitätskriterien; LAWA-UA "EUQ") and its predecessors. These national quality standards are derived from ecotoxicological data for the most important trophic levels. Quality standards should not be exceeded, if possible, i.e. they give guidance for protection. In case that actual concentrations exceed the quality standard value, priorities for future measures of water protection may be justified on this basis. The quality standard for trifluralin with respect to aquatic biocoenoses was set to 0,03 µg/l respectively while for drinking water resources a general quality standard of 0,1 µg/l is applied. According to the German Plant Protection Act the concentration for a single pesticide in groundwater must not exceed 0,1 µg/l.

The Expert Group on Quality Standards, a working group under the Expert Advisory Forum for the WFD, endorsed the following Environmental Quality Standards (EQS) for trifluralin (Table 10; Draft Substance Data Sheet of 30 September 2003).

Table 10. Environmental Quality Standards for trifluralin in the context of the Water Framework Directive (as of 30 September 2003)

Ecosystem / Protection Objective	Quality Standard	Quality Standard
Inland waters as well as transitional, coastal and territorial waters	Overall Quality Standard: 0,03 µg/l ^d	Corresponding concentration in SPM: freshwater: 25,2 µg/kg dry wt saltwater: 25,4 µg/kg dry wt
Pelagic Community	Same as Overall Quality Standard	Corresponding concentration in SPM: same as above
Benthic community (freshwater and marine sediment)	3,2 mg/kg dry wt 0,68 mg/kg wet wt.	Corresponding conc. in pore water: 17,3 µg/l ^a
Predators (secondary poisoning)	6,7 mg/kg prey wet wt	Corresponding concentration in water: 0,112 – 1,12 µg/l ^b
Drinking water abstraction	1 µg/l	A1-value for sum of pesticides of CD 74/440/EEC ^c

SPM: Suspended matter.

- 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.
- 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.
- The quality standard of 0,03 µg/l required for the protection of the pelagic community is considered as protective for drinking water abstraction as well. Hence, the derivation of a quality standard addressing drinking water abstraction is not necessary.
- MAC for inland waters is 1 µg/l.

ADMINISTRATIVE RULES CONCERNING SUBSTANCES HAZARDOUS TO WATER

According to German Administrative Rules (Verwaltungsvorschrift wassergefährdende Stoffe GMSMA6, 16, 327, 1996, Appendix 3), trifluralin is classified as "hazardous to water" (Water Hazard Class WHC 2). The classification forms the basis for water protection requirements for industrial plants in which hazardous substances are handled.

In the United Kingdom, trifluralin is a prescribed substance (Red List), where the release into water is prohibited or restricted, under the Environmental Protection (Prescribed Processes and Substances) Regulations of 1991 (GBRSI 472, 1 Apr. 1991). In addition, controls are imposed over the discharge into the public sewers of trade effluents which contain trifluralin in concentrations, which exceed those that would be present regardless of the activities within the premises from which the effluent is discharged, under the Trade Effluents (Prescribed Processes and Substances) Regulations of 1989 (GBRSI 1156, 1 Sep. 1989, amended GBRSI 1629, 1990).

OTHER ADMINISTRATIVE RULES

Administrative rules may be found in the UNEP Legal File (<http://www.chem.unep.ch/irptc/legint.html>).

Classification (Xi) and labelling (Xi: irritant; N: dangerous to the environment) of trifluralin under EC-Council Directive 67/548/EEC was published in 2001 (OJECFC, L225 of 24. August 2001, p. 1ff.).

Maximum residue levels for specified plant products (0,5-3 mg/kg) or other plant products (0,1 mg/kg) were set for trifluralin in Germany under Ordinance on Maximum Limits of Residues (Rückstands-Höchstmengengerordnung) in 1999 (amended 2002).

In Sweden, trifluralin is banned under the Statute-Book of the National Chemicals Inspectorate (Kemikalieinspektionens författningssamling) since 1993, amended 1994, because of its properties as non-readily biodegradable, bioaccumulative and toxic to water-living organisms. Trifluralin has been banned in Denmark since 1997, but a derogation for use in seed production is in force from 1999 to 2004.

The UN World Health Organization (WHO) has issued a limit of 20 µg/l for trifluralin in drinking water in 1993, as this substance is of health significance (Guidelines for drinking-water quality, Volume 1 – Recommendations, amended 1998).

4.2 Choice of substitutes

For its intended uses, trifluralin is a choice among other synthetic pesticides. In the context of good agricultural practice, integrated crop management and the support of ecological farming, there is a general claim for reduction of use of synthetic pesticides and a substitution by non-chemical pest and weed management methods.

5 Choice for action/measures

According to the information available, it has become clear that trifluralin meets the PBT criteria and therefore presents a potential hazard to the marine environment. On the other hand, emission to rivers appears to be low, and, once in the surface water, trifluralin tends to partition to the sediment. The transport of significant amounts of trifluralin via sediment to the marine environment appears to be negligible. A considerable amount evaporates to the air from agricultural application, but photochemical degradation is rapid and transport distances are short, so that coastal areas may be affected only to a negligible extent. A general quest for a reduction in the use of trifluralin, based on a risk for the marine environment, does not seem appropriate. Nevertheless, the enforcement of good agricultural practice (i.e. incorporating the product into the soil as it is applied, in order to avoid evaporation) should be supported.

THE CONCLUSION ON THE AVOIDANCE OF FUTURE RISKS

In order to avoid future risks resulting from production and/or continued or increased use of trifluralin as a plant protection product,

- Contracting Parties should monitor the possible occurrence of trifluralin in surface water and coastal waters, as well as in sediments, in order to identify areas of intensive emission;
- OSPAR should invite Contracting Parties to apply good agricultural practice, and to consider integrated crop management and ecological farming when ever possible. Further, OSPAR should invite Contracting Parties to reduce the levels of use of synthetic pesticides and substitute for them non-chemical pest and weed management methods;
- OSPAR should invite Contracting Parties to check that the operation of plants manufacturing or formulating trifluralin is regulated according to the principles of BAT (Best Available Technology) and that any releases are eliminated, or minimised to the greatest possible extent;
- OSPAR Contracting Parties which are EU Member States should seek appropriate restrictions on trifluralin use within the framework of the 91/414/EC Directive (and via that also within the framework of the EC Water Framework Directive) to promote the achievement of the objective of the OSPAR Hazardous Substances Strategy in respect of trifluralin.

To ensure that the information in this background document and the conclusions reached by OSPAR are taken into account in the approach of the European Community,

- OSPAR should communicate this background document to the European Commission for information.

To ensure that the information in this background document can be considered in the context of other international agreements which deal with hazardous substances, and with which Contracting Parties are associated,

- OSPAR should send copies of this background document to the appropriate bodies dealing with those agreements and invite Contracting Parties who are parties both to OSPAR and those other agreements to promote action to take account of this background document by those other international bodies in a consistent manner.

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EU-Directives quoted

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- 2000/60/EC: Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy
Official Journal No. L 327 of 22/12/2000, p. 1-73.

Appendix 1: Physico-chemical Properties of Trifluralin

Property	Value	Source
Chemical name (IUPAC)	α,α,α -trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine	EUTTF (2002)
CAS-No.	1582-09-8	EUTTF (2002)
EEC No. (EINECS)	216-428-8	EUTTF (2002)
Molecular formula	$C_{13}H_{16}F_3N_3O_4$	EUTTF (2002)
Molecular Mass M [g/Mol]	335,3	EUTTF (2002)
Physical state of matter at 20 °C	crystalline solid at 23.2°C	EUTTF (2002)
Colour / odour	bright orange / vague mothball or faint aniline	EUTTF (2002)
Melting point T_m [°C]	43,0 – 47,5 °C	EUTTF (2002)
Boiling point T_b [°C]	not determined, decomposition	EUTTF (2002)
Solubility in water S [g/l]	$1,94 \cdot 10^{-4}$ (unbuffered 100% pur.) pH 7: $2,21 \cdot 10^{-4}$	EUTTF (2002)
Solubility in hexane [g/kg]	> 250	EUTTF (2002)
log P_{OW}	5,27 at 20 °C (100% pur.)	EUTTF (2002)
Adsorption coefficient log K_{oc} [l/kg]	4,13 (calc.) 3,81 – 4,13 (meas.) no pH-dependency	pckocwin v1.66 EUTTF (2002)
Vapour pressure P [Pa]	$9.5 \cdot 10^{-3}$ Pa at 25°C (100% pur.) $6.1 \cdot 10^{-3}$ Pa at 25°C (96,8% pur.)	EUTTF (2002)
Henry's Law constant [-]	$4,19 \cdot 10^{-3}$ (calc.) $4.12 \cdot 10^{-3}$ (meas. 20°C)	EUTTF (2002)
Volatilisation from water	55-70% in photolysis test Water/sediment test: 60% when applied to water phase (Day 60) 6% when applied to sediment (Day 100)	EUTTF (2002)
Volatilisation from soil	41-68% from soil surface < 2% when incorporated into the soil	EUTTF (2002)
Reactivity with OH-radicals atmospheric half-life [d]	0,22 d (Atkinson & Howard)	EUTTF (2002, 2004)
Hydrolysis [%]	<10% in 5 days (at pH 7; 96,8% pur.)	EUTTF (2002)
Photodegradation in water half-life [h]	7 h (sterile water, 98,6% pur.) 1,1 h (natural water, 99% pur.)	EUTTF (2002)
Toxicological classif. (EU)	Xn, Xi, N (proposed)	EUTTF (2002)
R-Phrases	R36, R40, R43, R50/R53 (proposed)	EUTTF (2002)
S-Phrases	S2, S13, S24, S37, S46 (proposed)	EUTTF (2002)

Metabolic Pathways of Trifluralin

Fig. 1: Proposed metabolic pathway of trifluralin in soil under aerobic conditions.

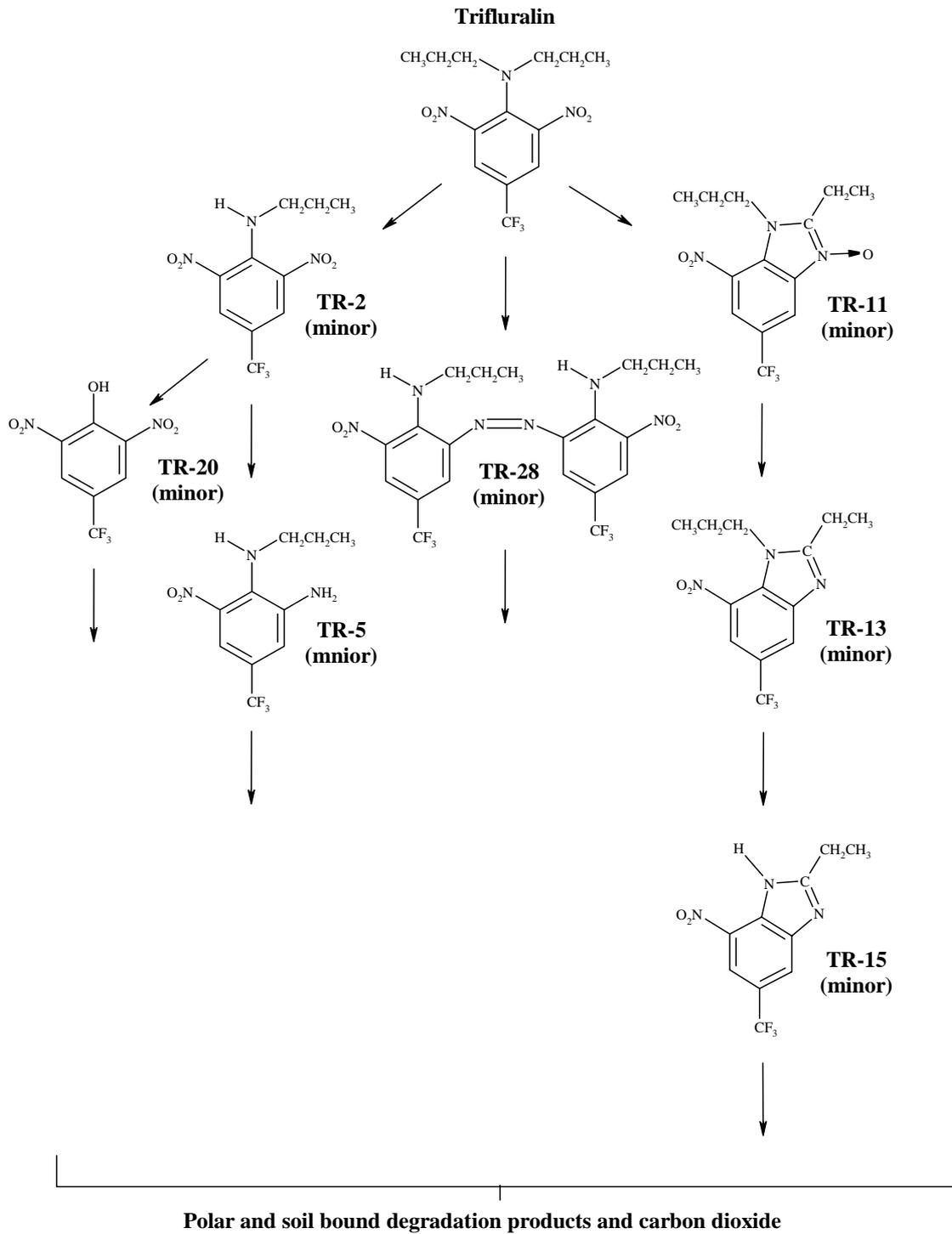


Fig. 2: Proposed metabolic pathway of trifluralin in soil under anaerobic conditions.

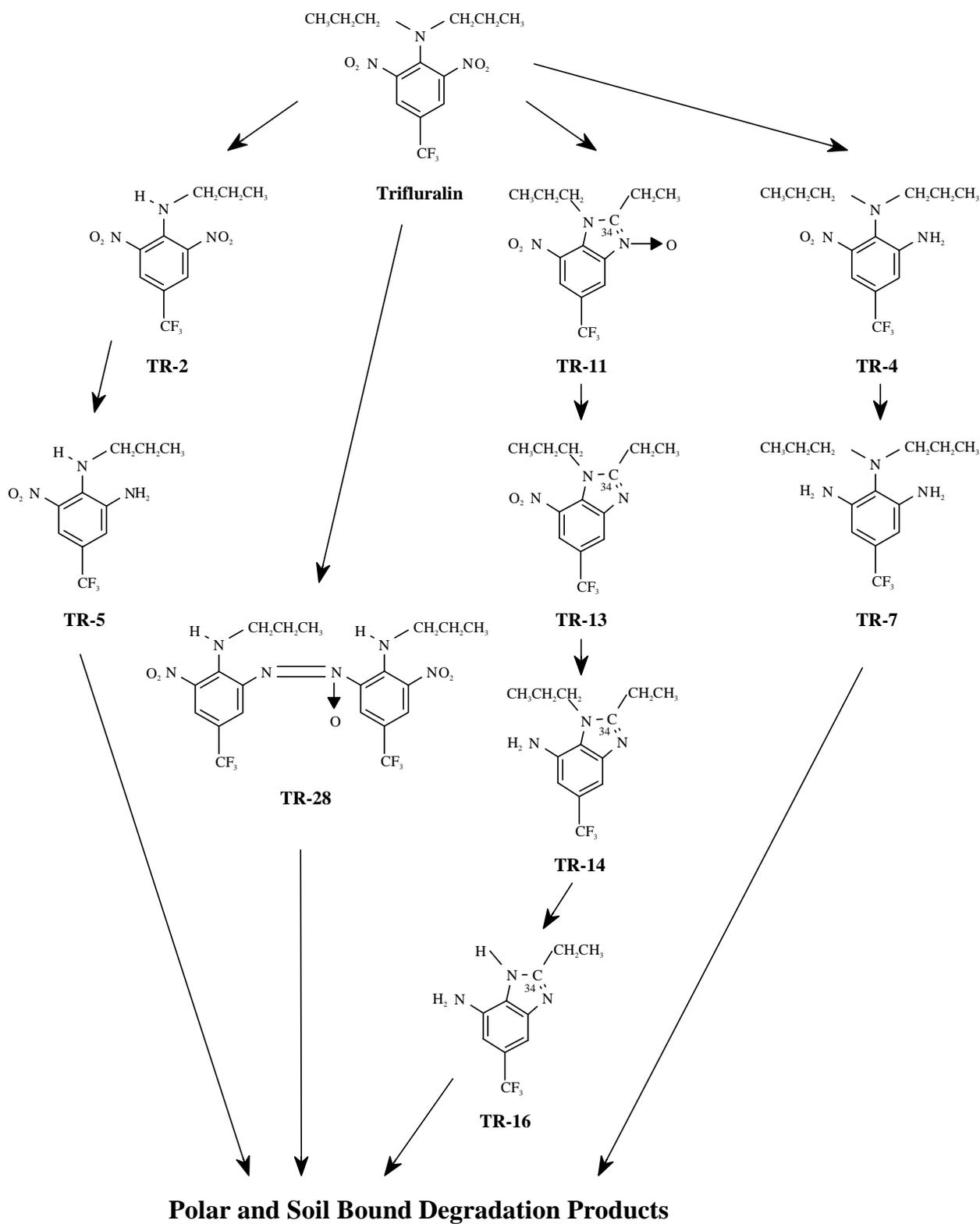


Fig. 3: Proposed degradation pathway for the photolysis of trifluralin in aqueous sterile buffer solution.

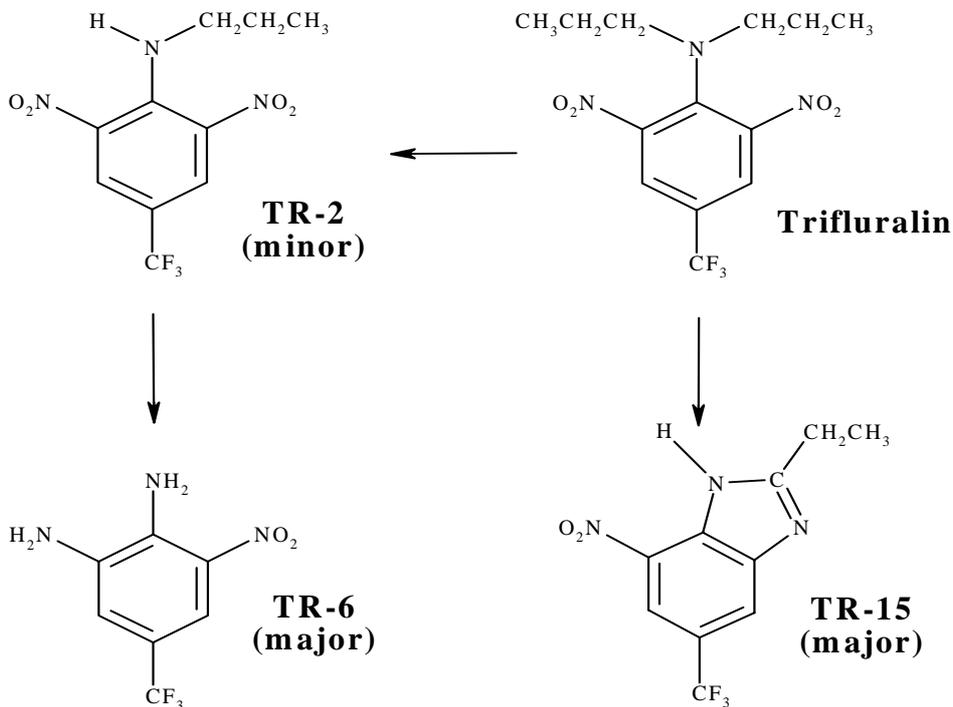
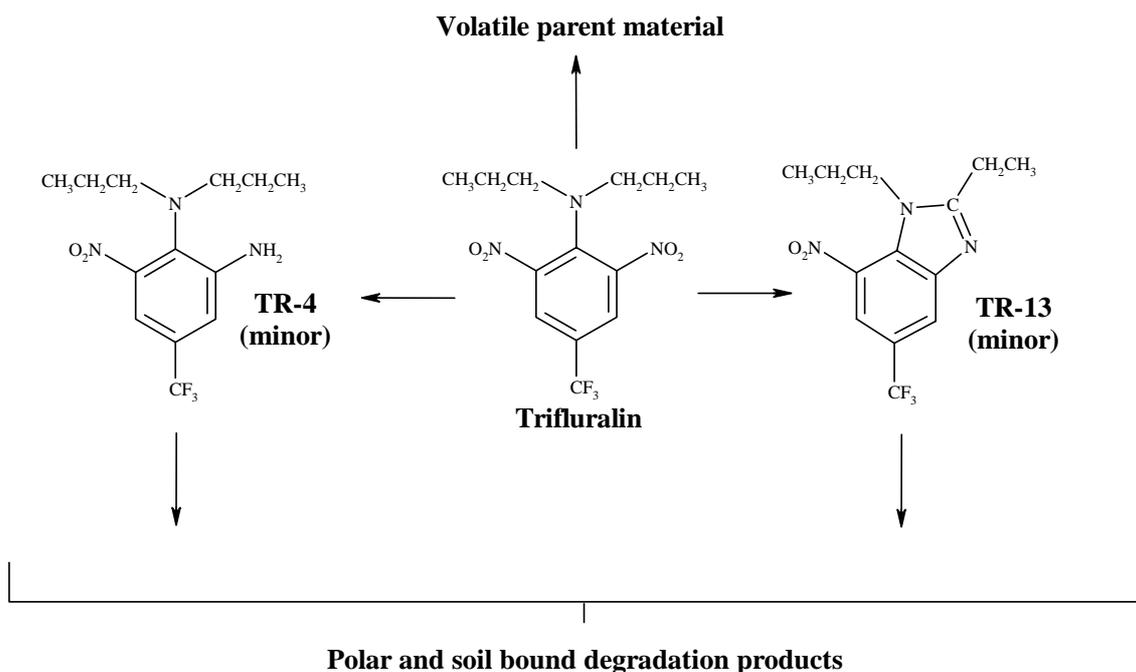


Fig. 4: Proposed degradation pathway for trifluralin in a water/sediment system. A recent water/sediment-study (2004) indicated the occurrence of TR-7 (via TR-4) and TR-14 (via TR-13) as major metabolites in sediment.



Note: The metabolite TR-4 is considered minor in the water phase and major in the sediment of the water/sediment system.

Appendix 2: Monitoring Strategy for Trifluralin

As part of the Joint Assessment and Monitoring Programme (*reference number 2003-22*), OSPAR 2005 adopted a revised Agreement on Monitoring Strategies for OSPAR Chemicals for Priority Action (*reference number 2004-14*) to implement the following monitoring for tracking progress towards the objectives of the OSPAR Hazardous Substances Strategy (*reference number 2003-21*) with regard to trifluralin. The monitoring strategy for trifluralin will be updated as and when necessary, and redirected in the light of subsequent experience.

The sources of trifluralin have been detailed in the Background Document. A number of relevant controls on marketing and/or use as well as on emissions and/or discharges, quality standards and residue levels for trifluralin are applied at national level or have been agreed in the EU and other international forums. These measures have been highlighted in chapter 4 of the Background Document. Evidence from reports on the implementation of such measures will be used to make an initial judgement of the extent to which the amounts of these substances emitted or discharged are reduced.

Trifluralin is still in use in some Contracting Parties as a herbicide and is manufactured and formulated in the EU. Point sources are regarded as insignificant. Emissions from agricultural use are considered as main diffuse source though emission data are not available but can be estimated from consumption figures and mode of application. OSPAR will compile, with the assistance from industry, production and sales figures for the substance in the OSPAR Convention area and seek to estimate the amounts imported into, or exported from, the European Community/European Economic Area.

The Background Document reports that trifluralin has been found in surface waters and river sediments of several Contracting Parties as well as in marine water and sediment of certain locations of the North Sea and the Baltic Sea. It has been detected in Arctic fog and the Bering and Chukchi Sea thereby indicating the possibility of its long-range atmospheric transport. Trifluralin is a volatile substance which evaporates mainly to air (70%) when applied to soil but may evaporate also to water bodies. It dissipates rapidly from water, but is persistent in soil and sediment where it may directly affect sediment dwelling organisms. It is bioaccumulative and toxic for aquatic organisms, especially fish. Trifluralin is not monitored under OSPAR monitoring programmes. Concentrations in water will be monitored under the EC Water Framework Directive.

To confirm atmospheric transport, a one-off survey of concentrations of trifluralin in the air in the Arctic is proposed to be carried out by Arctic Contracting Parties or through the Arctic Monitoring and Assessment Programme (AMAP).

Direct discharges and inputs of trifluralin to rivers via drainage and run-off appear to be low or negligible and leaching to ground water is not expected. OSPAR will use data reported by Contracting Parties under Water Framework Directive to calculate riverine inputs in order to detect inputs during application periods of trifluralin.

For concentrations in the marine environment, a one-off survey is proposed to screen the occurrence of trifluralin in all matrices. For concentrations of water, use can be made of the data reported under the Water Framework Directive. The survey would best concentrate on regions with high consumption. Experiences from national one-off surveys such as in Germany could help organizing an OSPAR one-off survey.

TRIFLURALIN MONITORING STRATEGY	
<i>Implementation of actions and measures</i>	<ul style="list-style-type: none"> • Examination of progress in the implementation of regulations on marketing and/or use or emission and/or discharge which have been agreed, or are endorsed, by the Background Document
<i>Concentration in air</i>	<ul style="list-style-type: none"> • One-off survey of concentrations in the air in the Arctic by Arctic Contracting Parties or through the Arctic Monitoring and Assessment Programme
<i>Discharges and losses to water</i>	<ul style="list-style-type: none"> • No monitoring
<i>Production/use/sales/figures</i>	<ul style="list-style-type: none"> • Collect, with assistance from industry, data on quantities produced and sold in countries of the OSPAR Convention area • Estimate quantities imported into, and exported from, the OSPAR Convention Area
<i>Atmospheric inputs</i>	<ul style="list-style-type: none"> • No monitoring
<i>Riverine inputs</i>	<ul style="list-style-type: none"> • Calculation of inputs from EC WFD information
Maritime area:	
<i>Concentrations in sediments</i>	<ul style="list-style-type: none"> • One-off survey (hot-spots) will be carried out
<i>Concentrations in water</i>	<ul style="list-style-type: none"> • No monitoring
<i>Concentrations in biota</i>	<ul style="list-style-type: none"> • One-off survey (hot-spots) will be carried out