

COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a
COUNCIL DIRECTIVE

amending Directive 76/464/EEC on pollution caused by
certain dangerous substances discharged into the
aquatic environment of the Community

(presented by the Commission)

**Proposal for a Council Directive amending Directive 76/464/EEC
on pollution caused by certain dangerous substances
discharged into the aquatic environment of the Community**

EXPLANATORY MEMORANDUM

I On 3 and 4 May 1976, the Council adopted Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (1). In this Directive is stated in Article 12 that the Council shall take a decision (within nine months) acting unanimously on any Commission proposal concerning the limit values and quality objectives of the substances from the List I of the Annex to Directive 76/464/EEC. For each substance of this List not only the limit values and quality objectives were proposed by the Commission and discussed in the Council, but also all general legal and technical provisions.

These general provisions were discussed for each substance the Council was dealing with. The discussion in the Council took very long time. In ten years the limit values and quality objectives for only 3 substances (4 Directives) were approved by the Council.

In order to speed the procedure the Commission proposed a "framework" Directive setting out the general legal provisions applicable to all the substances in List I in the Annex to Directive 76/464/EEC and containing a set of general technical provisions in its Annexes.

(1) O.J. L 129 of 18.05.1976, p. 23

This Directive was adopted by the Council on 12 June 1986, as Directive 86/280/EEC on limit values and quality objectives for discharges of certain dangerous substances included in List I of the Annex to Directive 76/464/EEC. Although the mechanism set out in Directive 86/280/EEC signified an improvement with regard to the implementation of Article 6 of Directive 76/464/EEC the procedure under which limit values and quality objectives had to be fixed has been assumed not to be swift enough (1).

During discussions of the first modification (2) to Directive 86/280/EEC on limit values and quality objectives for discharges of certain dangerous substances included in List I of the Annex to Directive 76/464/EEC in the Committee of the Environment, Public Health and Consumer Protection of the European Parliament, it was proposed that at one stage future additions to the Annexes of Directive 86/280/EEC be adopted in the Council by qualified majority. The Commission did recognise the force behind this idea, but stressed that on that purpose it would be more appropriate to present a single amendment to Article 12 of the framework Directive 76/464/EEC in accordance with Article 130S.

On 12 April 1988 at the Plenary Session of the European Parliament the Commission confirmed its willingness to amend the framework Directive 76/464/EEC in accordance with the wish of the European Parliament and undertook to make appropriate amendments in accordance with Article 130S of the EEC Treaty.

One of the conclusions of the Ministerial Seminar on future Community water policy held in Frankfurt on 27 and 28 June 1988 is as follows :

(1) O.J. L 181 of 04.07.1986, p.16
(2) O.J. L 158 of 25.06.1988, p. 35

"Most delegations urged that, in order to speed up progress, the identification of substances to be included in the Black List should be decided by unanimity and that the values to be subsequently applied should be decided by qualified majority following Article 130S, second indent."

In order to fulfill the obligation following from this conclusion the Commission worked out the present proposal for an amendment of Article 12 of Directive 76/464/EEC on the basis of Article 130S, second paragraph of the EEC Treaty, and has requested National Experts to provide it with advice on the List of priority substances.

Such a List has already been requested by the Environmental Council at its meeting on 21 March 1988.

During the meeting of the National Experts on 29 June 1988 a List of substances was unanimously agreed as the List of priority substances.

During the meeting of National Experts on 31 January 1989, the Commission stated that insufficient ecotoxicological evidence had been found to include 3-Chlorotoluene and Chloroprene in the first priority List as proposed by the National Experts.

Furthermore two substances are under discussion in the Council and therefore they were also excluded from the present proposal.

- II. The Commission suggests that the procedure under Article 130S second indent shall first be applicable to the following list of substances :

Substances	Ecotoxi- cological study	Technical study	Advice of Scientific Advisory Committee
1. Trifluralin (124)	x	x	0
2. Endosulfan (76)	x	x	0
3. Simazine (106)	x	x	x
4. Triorganotin comp.			
- Tributyltin oxide (115)	x	x	x
- Triphenyltin acetate (125)	x	x	x
- Triphenyltin chloride (126)	x	x	x
- Triphenyltin hydroxide (127)	x	x	x
5. Atrazine* (131)	0	x	0
6. Organophosphorous substances :			
- Azinphos-ethyl (5)	0	x	0
- Azinphos-methyl (6)	0	x	0
- Fenitrothion (80)	x	x	x
- Fenthion (81)	x	x	x
- Malathion (89)	x	x	x
- Parathion and Parathion-methyl (100)	x	x	x
- Dichlorvos (70)	0	x	0

x = available

0 = envisaged (available 1990)

*) Atrazine is not mentioned in the original "List of 129 substances". The main reason for this was that the use of this substance was estimated to be low in EEC Member States at that time.

(this footnote continues on the next page)

The list is based on the original "List of 129 substances" (1) and contains four substances and two groups of substances. These substances are chosen mainly on the basis of their ecotoxicological properties (toxicity, mutagenicity, carcinogenicity, teratogenicity, bioaccumulation and persistence) but also the production and figure on use are taken into account as well as their presence in the Community surface waters.

For some of these substances the Ecotoxicological and Technical studies are already available and for others the study is envisaged for the end of 1989 and for 1990.

Although the advice of the Scientific Advisory Committee is not yet available for all of these substances, the Commission considers that there is already sufficient evidence to assume that the substances listed below are priority candidates for the following reason :

*) However, in the last few years it has become obvious that Atrazine is extensively used as a herbicide. Considering its similarity with Simazine (which was already proposed for the inclusion in the Annexes in Directive 88/280/EEC) in terms of chemical structure and physical properties the Group of National Experts agreed to include Atrazine in the List of priority substances.

(1) O.J. C 176 of 14.07.1982, p. 3

1. TRIFLURALIN (N° 124) : CAS-1582-09-8

1.1 PRODUCTION AND USE (Ref. 1)

1.1.1 Production

The installed production capacity of trifluralin within the Community is reported to be 10.300 tonnes/year. The main producers are situated in Italy (3 plants) and Germany (1 plant). The production capacity in the EEC is estimated to be 17 % of the world production capacity.

1.1.2 Use

Trifluralin is a key herbicide for weed control. The market, after having grown steadily for many years, seems now to be relatively steady. The expected growth of annual demand is estimated between 1 and 3 %. Worldwide consumption was estimated around 25.000 tonnes in 1983.

1.2 ECOTOXICOLOGICAL EVALUATION (Ref. 2)

Classification of trifluralin is under discussion in the Committee on classification of existing chemicals (Directive 67/548/EEC) (1).

1.2.1 Toxicity

1.2.1.1 Acute toxicity

Despite its low water solubility (<1 milligram.l⁻¹ at 27°C) and its high absorption potential to soils, trifluralin may pose a great hazard to aquatic flora and fauna.

(1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.67, p. 1)

Trifluralin displays very high acute toxicity to aquatic invertebrates and fish species :

LC ₅₀ (48 h) for <u>Daphnia magna</u>	0,115-0,327 milligram.l ⁻¹
LC ₅₀ (48 h) for <u>Cyprina (Ostracoda)</u>	0,06 milligram.l ⁻¹
LC ₅₀ (48 h) for rainbow trout	0,006-0,240 milligram.l ⁻¹

In contrast to its aquatic toxicity, trifluralin displays low mammalian toxicity after acute exposure :

LD ₅₀ for rat (oral)	5-36	gram/kg body weight
LD ₅₀ for mouse (oral)	5	gram/kg body weight
LD ₅₀ for newborn rat (oral)	0,5	gram/kg body weight

1.2.1.2 Chronic toxicity

The toxicity of trifluralin has been studied in Daphnia magna (3 generations). The maximum acceptable toxicant concentration (MATC) 0,0024-0,0072 milligram.l⁻¹.

Fathead Minnow (Pimephales promelas) (1 life cycle) shows MATC of 0,0015-0,0165 milligram.l⁻¹.

Trifluralin also exhibits high chronic toxicity in marine organisms and sublethal effects in one fish species

(C. variegatus) occurred at levels as low as 0,001-0,005 milligram.l⁻¹ (exposure time : 19 months).

Chronic toxicity data for mammals are insufficient.

1.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

There is insufficient data to evaluate carcinogenicity. IARC has not evaluated trifluralin. Although there is some evidence for the in vivo clastogenicity in mammals, the confusion caused by presence of nitrosamine prevents any firm conclusion.

Trifluralin exhibits no mutagenic activity in a number of test systems (Ref. 11).

At high doses embryotoxicity was observed.

The substance does not seem to be teratogenic.

1.2.2 Persistence

Trifluralin is rapidly lost from surface waters and a half-life of less than one hour has been reported. Photodecomposition appears to be the major route of degradation, but evaporation may be of importance under certain conditions.

Trifluralin in general has persistence in soil between 3-18 weeks depending on the soil type.

1.2.3 Bioaccumulation

Trifluralin is lipophilic and displays high bioconcentration factors (up to 5.750 in fish). However, its potential for bioaccumulation is constrained by its low persistence in aquatic systems, together with a tendency to be adsorbed to sediments.

1.2.4 Advice of the Scientific Advisory Committee

Will be available in March 1990.

2. ENDOSULFAN (N° 76) : CAS-115-29-7

2.1 PRODUCTION AND USE (Ref. 3)

2.1.1 Production

There is only one manufacturer of endosulfan within the EEC. The plant is located in Germany and produces about 7.000 tonnes/year (1986).

Endosulfan is formulated in Germany (1.500 tonnes/year), France (2.000 tonnes/year), Italy (100-150 tonnes/year), Netherlands (30 tonnes/year), United Kingdom (5 tonnes/year), Spain (200 tonnes/year) and Portugal (4 tonnes/year).

2.1.2 Use

The substance is used in arboriculture, silviculture and agriculture as an insecticide. In the EEC, it is mainly used for the cultivation of potatoes, maize, tabac, tomatoes, various other vegetables and also in cultivation of fruit trees.

The total consumption is estimated to be 500-600 tonnes/year.

2.2. ECOTOXICOLOGICAL EVALUATION (Ref. 4)

Classification of endosulfan is under discussion in the Committee on classification of existing chemicals (Directive 67/548/EEC) (1).

2.2.1 Toxicity

2.2.1.1 Acute toxicity

Endosulfan is very toxic to aquatic fauna. Fish are extremely sensitive, LC_{50} varying between 0,000.09- 0,004 milligram.l⁻¹. For certain crustaceans still lower LC_{50} values were reported (0,000.04 milligram.l⁻¹).

In contrast, endosulfan is moderately toxic to birds and mammals.

LD ₅₀ for pheasant	50-100 milligram/kg body weight
LD ₅₀ for mouse	5-10 milligram/kg body weight
LD ₅₀ for rat	80-110 milligram techn. (in oil)/kg body weight

(1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.67, p. 1)

2.2.1.2 Chronic toxicity

Chronic toxicity data for aquatic organisms are insufficient.

In feeding trials rats receiving 30 milligram/kg diet for two years and dogs 30 milligram/kg diet for one year showed no ill-effect (Ref. 9).

2.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

No mutagenic effects were reported. Teratogenicity was reported with administration of high doses. Endosulfan has been declared not carcinogenic.

2.2.2 Persistence

It is reported that the half-life in flowing waters varies between 4 and 15 days. In contrast, under anaerobic conditions, persistence is pH dependent (T 1/2 of 5 weeks for pH = 7 and T 1/2 of 5 months for pH = 5.5).

2.2.3 Bioaccumulation

Bioconcentration factors between 11-2.500 were reported in various aquatic organisms.

2.2.4 Advice of the Scientific Advisory Committee

Will be available in March 1990.

3. SIMAZINE (N° 106) : CAS-122-34-9

3.1 PRODUCTION AND USE (Ref. 1)

3.1.1 Production

Installed production capacity is recorded to be 15.000 tonnes/year. There are 3 production plants in the EEC, situated in Italy and the United Kingdom. The exact production figure for the EEC is unknown but it is assumed to be 2.500-7.000 tonnes/year.

3.1.2 Use

Simazine is a pre-emergence herbicide used for control of weeds in deep-rooted crops, such as citrus, olives, vineyards, coffee, tea, cacao. Its major use is on maize.

Two different sources estimate uses in Europe to vary from 4.000-7.000 tonnes/year.

3.2 ECOTOXICOLOGICAL EVALUATION (Ref. 2)

Classification of simazine is under discussion in the Committee on classification of existing chemicals (Directive 67/548/EEC) (1).

3.2.1 Toxicity

(1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.67, p. 1)

3.2.1.1 Acute toxicity

Simazine is toxic to aquatic organisms. Tests have shown a wide range of sensitivity for different algae species; toxicity levels as low as 0,006 milligram.l⁻¹ are reported for the most sensitive species, with most of the data being in the range 0,1-1,0 milligram.l⁻¹.

For fish, it was shown to be moderately toxic (96 h LC₅₀ varies between 2,5 and 28,6 milligram.l⁻¹). For one species (Roccus saxatilis) an LC₅₀ of 0,25 milligram.l⁻¹ has been reported. Mammalian acute toxicity is reported to be low (LD₅₀ rat > 5 gram/kg body weight).

3.2.1.2 Chronic toxicity

For long term exposures of 8 to 30 days, safe limits ranging between 0,1-1 milligram.l⁻¹ were suggested for some aquatic vertebrates, although for some sensitive species an LC₅₀ of 1 milligram.l⁻¹ has been reported.

Chronic toxicity data are very scarce for mammals. In two years feeding studies a no effect level (NOEL) of 100 and 150 milligram/kg diet were established in rats and dogs.

3.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

The studies available seem to show that simazine has no reproductive effects, it is not teratogenic, it may be genotoxic and no conclusion can therefore be drawn in relation to its carcinogenicity.

3.2.2 Persistence

Some studies indicate that simazine displays low persistence in the aquatic environment, with a short half-life (<1 month). However, other investigations report that half-life is sufficiently long to result in the accumulation of simazine from one season's treatment to the next.

3.2.3 Bioaccumulation

Simazine has a low bioconcentration factor (<1-55) and in general is not expected to accumulate in aquatic organisms.

3.2.4 Advice of the Scientific Advisory Committee

The advice on Simazine was delivered on 28 March 1988 (Ref. CSTE/88/17/COM) and confirms the decision to include this substance in List I.

4. TRIORGANOTIN COMPOUNDS

TRIBUTYLTIN OXIDE (N° 115)	CAS-56-35-9
TRIPHENYLTIN ACETATE (N° 125)	CAS-900-95-8 : TPhTAc)
CHLORIDE (N°126)	CAS-639-58-7 : TPhTCl)
HYDROXIDE (N°127)	CAS-76-87-9 : TPhTOH)

These substances will hereafter be called collectively TPhTs.

4.1 PRODUCTION AND USE (Study will be available at the end of 1989)

4.1.1 Production

The EC production of all tributyltin compounds (including tributyltin oxide) was estimated in 1986 as being 3.500 tons. According estimation from industry the production of triphenyltin compounds (including triphenyltin fluoride) reached the last years 2.500 tons/year.

4.1.2 Use

Tributyltin oxide has a major use as a biocide and is used in wood preservatives (20 %) and particularly in antifouling paints (70 %). The netto counted EEC use in 1986 was 2.500 tons.

Potential new uses have been reported in the area of tropical disease control.

TPhTs are used in agriculture (745 - 1.680 tons in 1987) and as an antifouling agent (quantity estimated was 100 tons/year). TPhTCl is also used as intermediate for the production of TPhTOH and TPhTAc.

4.2 ECOTOXICOLOGICAL EVALUATION (Ref. 5, 6)

4.2.1 Toxicity

4.2.1.1 Acute toxicity

Tributyltin oxide is highly toxic to various aquatic biota. At 0,0001 milligram.l⁻¹ it is reported to inhibit the growth of algae Skeletonema costatum.

In Pacific oyster spat (Crassostrea gigas) metabolic effects are reported down to 0,000.01 milligram.l⁻¹.

With fish, LC₅₀ values generally range from 0,02-0,06 milligram.l⁻¹.

Tributyltin oxide has an acute oral LD₅₀ for rats of the order of 150-250 mg/kg body weight. However, low doses in the diet of rats affect the immune system, with atrophy of the thymus and lymphoid glands. Similar phenomena have recently been reported in fish.

TPhTs are also highly toxic to aquatic organisms. Inhibitory effects on algal metabolisms occur down to ca. 0,001 milligram.l⁻¹.

For freshwater molluscs, LC₅₀ range between 0,02 and 0,4 milligram TPhTs l⁻¹ and for crustacea from 0,01 to 0,08 milligram TPhTs l⁻¹. For fish, LC₅₀ of below 0,4 milligram.l⁻¹ are reported for TPhTAc, and for TPhTOH of below 0,1 milligram.l⁻¹.

The acute oral LD₅₀ of TPhTAc for rats is 0,1-0,5 gram/kg body weight and probably similar for the other TPhTs.

4.2.1.2 Chronic toxicity

Mussel larvae (Mytilus spp.) are reported to have an LC₅₀ 15 days as low as 0,0001 milligram.l⁻¹ towards tributyltin oxide. Long-term toxicity data for TPhTs are lacking.

4.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

There are no reports of carcinogenesis, no evidence of teratogenesis and no conclusive evidence of mutagenesis action with tributyltin oxide.

From reported data it would appear that there is no conclusive evidence that TPhTs are either carcinogenic or mutagenic. There are no data for teratogenicity.

4.2.2 Persistence

Organotins are degraded by hydrolysis, oxidation, photolysis and biota, but the half-life is dependent upon the presence of microflora and ranges for tributyltin oxide in natural waters from 4 days to 35 weeks.

4.2.3 Bioaccumulation

The occurrence of bioaccumulation of tributyltin oxide in aquatic organisms has been established. Bioconcentration factor ranges from 1.000-10.000 between differing species and from 500-4.400 between differing organs.

TPHTs should be considered as moderately bioaccumulative.

4.2.4 Advice of the Scientific Advisory Committee

The advice on tributyltin oxide and TPHTs was delivered on 27 October 1988 (Ref. CSTE/88/41/COM and CSTE/88/61/COM respectively) and confirms the decision to include these substances in List I.

5. ATRAZINE (N° 131) : CAS-1912-24-9

5.1 PRODUCTION AND USE (Study will be available at the end of 1989)

5.1.1 Production

Atrazine is/or can be produced by four plants in Europe .
The formulation (mixing of active ingredients with solvents and/or inert fillers) of atrazine is carried out by 3-6 factories in the EEC.

5.1.2 Use

Atrazine is widely used as herbicide in agriculture and for non-agricultural applications :

- in agricultural uses (often confined to a very short period of the year), on maize and sorghum;
- in non-agricultural uses to control weeds on roadsides and railway tracks.

Data on use are lacking.

5.2 ECOTOXICOLOGICAL EVALUATION (Study will be available at the end of 1989)

Atrazine is still a matter of discussion in the Committee on classification of existing chemicals (Directive 67/548/EEC) (1).

5.2.1 Toxicity

5.2.1.1 Acute toxicity

The acute toxicity for aquatic organisms is rather high :

<u>Skeletona costatum</u>	EC ₅₀ (48 hours) - growth	0,265 milligram.l ⁻¹
<u>Daphnia magna</u>	EC ₅₀ - growth	0,5 milligram.l ⁻¹
<u>Daphnia magna</u>	LC ₅₀ (48 hours)	6,9 milligram.l ⁻¹
<u>Gammarus frascatus</u>	LC ₅₀ (48 hours)	5,7 milligram.l ⁻¹
<u>Salmo gairdneri</u> (rainbow trout)	LC ₅₀ (24 hours) No effect level (96 hours)	12,6 0,1 milligram.l ⁻¹

Acute toxicity for mammals is low :

LD ₅₀ for rat	2.500-3.000 mg/kg body weight
LD ₅₀ for mouse	750 mg/kg body weight

(1) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.67, p. 1)

5.2.1.2 Chronic toxicity

Bluegill EC₅₀ (long-term exposure) - equilibrium 0,2 milligram.l⁻¹

Rat No effect level (2 years) 100-1.000 mg/kg body weight

5.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

Data are not conclusive on mutagenicity and teratogenicity. Preliminary evaluation of data on carcinogenicity indicate that the substance can be assumed as not carcinogenic.

5.2.2 Persistence

Persistence of atrazine in surface waters is estimated to be high (half-life 4,3 months).

5.2.3 Bioaccumulation

Bioaccumulation seems to be low.

5.2.4 Advice of the Scientific Advisory Committee

In view of the Council Directive 80/778/EEC relating to the quality of water intended for human consumption, the Scientific Advisory Committee advised on 30.04.1987 that a maximum admissible concentration of 0,0001 milligram.l⁻¹ should continue to be applied to individual pesticides (e.i. atrazine) in drinking water (Ref. CSTE/87/71/COM) as a general principle. The advice of the Committee on the environmental impact of atrazine on the aquatic environment will be available at the end of 1990.

6. ORGANOPHOSPHORUS SUBSTANCES

AZINPHOS-ETHYL	(N° 5)	: CAS-2642-71-9
AZINPHOS-METHYL	(N° 6)	: CAS-86-50-0
DICHLORVOS	(N° 70)	: CAS-62-73-7
FENITROTHION	(N° 80)	: CAS-122-14-5
FENTHION	(N° 81)	: CAS-55-38-9
MALATHION	(N° 89)	: CAS-121-75-5
PARATHION AND	(N° 100)	: CAS-56-38-2
PARATHION-METHYL		: CAS-298-00-0

6.1 PRODUCTION AND USE (Studies will be available at the end of 1989)

6.1.1 Production

The estimated EEC production figures are as follows :

azinphos-ethyl	550-850 tons/year
azinphos-methyl	550-850 tons/year
dichlorvos	500 tons/year
fenitrothion	-
fenthion	1.000-1.500 tons/year
malathion	11.000 tons/year
parathion and	
parathion-methyl	12.000 tons/year

6.1.2 Use

Azinphos-ethyl is used as insecticide on a large range of crops. The estimated uses was 150-300 tons/year.

Azinphos-methyl is used as acaricide with an extensive field of action in quantities estimated as being 100-150 tons/year.

Dichlorvos is used as a household and fumigant, especially against Diptera and mosquitoes, for the protection of stored products, for crop protection against sucking and chewing insects and in veterinary applications. For 1989, the estimated use in EEC is about 100 tons.

Fenitrothion is a contact insecticide effective against a wide range of pests. The counted use in EEC countries in 1989 is < 300 tons.

The major use of fenthion seems to be the control of mosquitoes and midges in tropical countries. Furthermore it is used against fruit flies, leaf hoppers and cereal bugs - in EEC countries in quantities of 700-1.000 tons/year.

Malathion is an insecticide widely used all over the world to control insect pests in agriculture, silviculture and home gardens. It is one of the most important organo-phosphorus insecticide employed, the netto counted EEC use is < 1.000 tons/year.

Parathion and parathion-methyl are both broad spectrum contact insecticides which are used in particular for the control of insects on cotton, small grains and vegetables. The use of these insecticides in the EEC is counted to be < 2.000 tons/year.

6.2 ECOTOXICOLOGICAL EVALUATION

Azinphos-ethyl	(Studies will be available at the end of 1990)
Azinphos-methyl	"
Dichlorvos	"
Fenitrothion	(Ref. 7)
Fenthion	(Ref. 7)
Malathion	(Ref. 8)
Parathion and	(Ref. 7)
Parathion-methyl	

Classification of these substances is under discussion in the Committee on classification of existing chemicals (Directive 67/548/EEC) (1).

(1) Council Directive 67/548/EEC of 27 June 1967 on the

6.2.1 Toxicity

6.2.1.1 Acute toxicity

According to laboratory studies azinphos-ethyl is very toxic to aquatic and terrestrial organisms.

LC₅₀ (24 hours) for fish of several species varies from
0,001 to 0,1 milligram.l⁻¹
LC₅₀ for crustaceans varies from 0,003 to 0,004 milligram.l⁻¹
LD₅₀ (oral) for rat 12 mg/kg body weight.

According to laboratory studies azinphos-methyl is also very toxic to aquatic and terrestrial organisms.

LC₅₀ (24 hours) for fish of several species varies from
0,0047 to 8 milligram.l⁻¹
LC₅₀ (96 hours) 0,0004 to 4,3 milligram.l⁻¹
LC₅₀ for crustaceans varies from 0,0001 to 0,05 milligram.l⁻¹
LD₅₀ (oral) rat varies from 11 to 16 mg/kg body weight.

According to laboratory studies dichlorvos is extremely toxic to aquatic organisms, especially crustaceans and insects.

EC₅₀ (48 hours) for Daphnia pulex 0,000.06 milligram.l⁻¹
No effect level (NOEL-96 hours) for Lepomis macrochirus 0,1 milligram.l⁻¹.

The substance is very toxic to terrestrial organisms and to birds :

LD₅₀ (oral) for rat 56 mg/kg body weight.

approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.67, p. 1)

According to laboratory studies fenitrothion displays - with exception of the groups mentioned hereunder - acute toxicity levels for aquatic biota between 1 and 10 milligram.l⁻¹. Acute LC₅₀'s for many species of crustacean and insect larvae are as low as 0,001-0,010 milligram.l⁻¹; for some fish species 50 % of the eggs are killed by exposure 0,06 milligram.l⁻¹ fenitrothion. Oral LD₅₀'s for mammals range from 220 to 1.850 milligram/kg body weight, birds however are more sensitive (LD₅₀'s for pheasant and quail range from 70 to 140 milligram/kg body weight).

According to laboratory studies fenthion is toxic to aquatic biota. For algae, most groups of invertebrates, fish and amphibians, acute toxicities range from 0,1 to 7 milligram.l⁻¹. Crustaceans and insect larvae are very sensitive to the pesticide : for many species LC₅₀'s and EC₅₀'s are 0,0005-0,005 milligram.l⁻¹, and even as low as 0,000.02 milligram.l⁻¹ for some species of marine shrimp. LD₅₀'s for mammals range from 100 to 500 milligram/kg body weight (compared with 2 to 28 milligram/kg body weight for birds).

According to laboratory studies parathion is very toxic to freshwater, estuarine and marine biota. Acute effects occur at 0,001 to 6 milligram.l⁻¹ depending on the group of biota. Insects and particularly crustaceans are extremely sensitive to acute parathion intoxication.

The substance is also very toxic to terrestrial mammals; for male rats the oral LD₅₀ is about 7,6 milligram/kg body weight and for females 3,5 milligram/kg body weight.

The range of toxic concentrations of parathion-methyl is very wide. The insects (the target group for the pesticide) are very sensitive (acute LC_{50} range 0,002-0,085 milligram.l⁻¹ but crustaceans are even more sensitive (LC_{50} range between 0,0001-0,05 milligram.l⁻¹). There are no significant differences in toxicity between freshwater and marine biota. It is also very toxic to terrestrial mammals and man. Average oral LD_{50} 's are 11-16 mg/kg body weight for rats and the lethal dose for adult man ingesting this pesticide is less than 1.800 milligram.

According to laboratory studies malathion has either very low toxicity or extremely high toxicity, depending on the sensitivity of the aquatic biota. In the freshwater environment, the LC_{50} (96 hours) was found to be as low as 0,001 milligram.l⁻¹ for several species of various groups of insects and crustaceans. For the zoal stages of some marine crab species the LC_{50} (96 hours) is 0,001 milligram.l⁻¹.

Oral LD_{50} 's for rats reported in the literature range from 885 to 1.375 milligram/kg body weight. The lowest dose reported to cause a lethal effect to humans was 50 milligram/kg body weight.

6.2.1.2 Chronic toxicity

There were no symptoms of poisoning found in rats receiving 2,5 milligram azinthos-methyl/kg diet for 2 years. In 90 days no intoxication was showed in trial rats receiving either 1000 milligram dichlorvos per kg diet or 2 milligram azinthos-ethyl per kg diet.

Although no chronic data on aquatic toxicity for dichlorvos are available for the most sensitive groups of biota, it is presumed, by analogy with experiments with fish larvae carried out with dichlorvos, that MATCs are at least one order of magnitude lower than acute effect levels; consequently NOEL levels to crustaceans and insects are probably at the 10 nanogram.l⁻¹ or lower.

With regard to sublethal and chronic effects some fish species react negatively to fenitrothion in concentrations of 0,01 milligram.l⁻¹.

Fenthion's data based on sublethal doses used in chronic toxicity trials indicate that physiological activity can be impaired at 0,05 milligram.l⁻¹ in fish and even at 0,001 milligram.l⁻¹ in copepods.

Chronical exposure induces mortality in rats at doses of 5 milligram/kg body weight and reproduction success is influenced by doses of 10 milligram/kg body weight.

In 1-year feeding trials dogs receiving 50 milligram/kg diet showed no loss of weight or food consumption (Ref. 9).

As far as chronic effects of parathion are concerned, levels ranging from 0,0001 up to 0,005 milligram.l⁻¹ are reported to be lethal for freshwater crustaceans. For insects, concentrations of 0,0002 milligram.l⁻¹ up to 0,002 milligram.l⁻¹ seem to be lethal after 2-3 weeks exposure of the organisms.

In 90-days feeding trials rats receiving 5 milligram of parathion-methyl/kg diet showed no symptoms of poisoning (Ref. 9).

Chronic toxicity data on insects and crustaceans confirm the susceptibility of these biota to malathion; some fish species are affected by chronic exposure to 0,05 milligram.l⁻¹ of the insecticide.

Chronic effects in rabbits were detected at levels of 120 milligram technical grade malathion/kg body weight. In 21 months feeding trials, rats receiving 100 mg technical grade malathion/kg diet showed normal weight gain (Ref. 9).

6.2.1.3 Mutagenicity, carcinogenicity and teratogenicity

For azinphos-ethyl no data have been recorded for mutagenicity, carcinogenicity and teratogenicity.

For azinphos-methyl only a few data have been recorded which show some mutagenic effects to microorganisms. Carcinogenicity tests on rats were negative however there is a suspicion of neoplastic effects on mice.

Following available data fenitrothion does not seem to have mutagenic and carcinogenic properties, but has shown to be teratogenic to embryos of amphibians at relatively low concentrations (0,3-3 milli-gram.l⁻¹).

Dichlorvos shows mutagenic properties; dichloroacetaldehyde, the major metabolite of dichlorvos in mammals in vivo was discovered to be mutagenic. Carcinogenicity studies gave mostly positive results in short term experiments but was not confirmed by long term trials, so the evidence is not considered as conclusive to date. Dichlorvos may have a (slight) teratogenic potential, though most studies gave negative results.

Fenthion has no mutagenic potential, but has been shown to be able to induce malignant tumors in male mice, but not in females, nor male or female rats. The teratogenic potential of the compound is only expressed at high doses (e.g. in milligram/kg in the offspring of mice).

Malathion and the intermediate oxidation product malaoxon do not seem to have oncogenic or teratogenic potency. Malathion has, however, been found to be mutagenic in several types of experiments on E. coli and on mammalian cells.

Convincing scientific evidence showing that parathion is carcinogenic or mutagenic is not available, so that further studies are desirable. The substance can induce teratogenic effects in birds, malformation in mammals and aquatic organisms, but only at concentrations above those encountered in the environment.

Experimental data (in mice and rats) on the carcinogenic potential of parathion-methyl indicate that the compound is not oncogenic (Ref. 10). The mutagenic effects are organism dependent (e.g. positive gene mutations were obtained in vitro experiments with E. coli and Saccharomyces cerevisiae and negative for S. typhimurium).

Teratogenic effects can be induced in birds and mice, but only in very high doses.

6.2.2 Persistence

Azinphos-methyl has a low persistence in surface water (from hours to days) and moderate in soil (months).

Degradation occurs through chemical and biological hydrolysis and oxidation. Also photodegradation plays a role.

Degradation of azinphos-ethyl probably occurs through photodegradation and chemical and biological hydrolysis.

Dichlorvos has a low persistence (half-life in aquatic environment range from less than one day to several days). It is degraded abiotically (by hydrolysis and by photodegradation) and biologically.

Fenitrothion is rather rapidly (a few days up to maximum 1-2 weeks) eliminated from the terrestrial and aquatic biota by photolysis and hydrolysis, but mainly by bacterial degradation.

Fenthion's elimination from the aquatic environments occurs relatively quickly (from a few days to 4 weeks) by photolysis, hydrolysis but mainly by bacterial degradation.

Malathion is quickly eliminated from the aquatic environment (a few days) by hydrolysis.

In the aquatic environment, parathion and parathion-methyl are rapidly degraded by microorganisms (half-lives between 2-8 days and 2-4 days respectively).

6.2.3 Bioaccumulation

Bioaccumulation data for azinphos-ethyl and azinphos-methyl on aquatic organisms are not reported in the literature. The bioaccumulation factors for these substances calculated (from log P) are 3.000 and 400 respectively.

The bioaccumulation factor for dichlorvos is low (log Pow 1,55), which would exclude the possibility of serious accumulation in organisms.

Fenitrothion bioaccumulates to a moderate extent, but depuration is relatively rapid (a few days) when contamination ceases.

Despite its high bioaccumulation potential, fenthion is not considered to accumulate in the aquatic food chain, because of its rapid metabolism by plants as well as animals.

Malathion is rapidly metabolized by plants and by animals and, as a consequence, has not been found to accumulate to any serious extent in biota.

Despite a moderate bioaccumulation potential in aquatic organisms, parathion and parathion-methyl are removed by 50 % from the biota in a few days and eliminated totally in a few weeks.

6.2.4 Advice of the Scientific Advisory Committee

Advice on the following substances will be available in March 1990.

- Azinphos-ethyl
- Azinphos-methyl
- Dichlorvos

Advice on the following substances were delivered by the Committee and confirm the decision to include these substances in List I :

- Fenitrothion (Ref. CSTE/87/67/COM)
- Fenthion (Ref. CSTE/87/65/COM)
- Malathion (Ref. CSTE/87/103/COM)
- Parathion and
Parathion-methyl (Ref. CSTE/87/69/COM)

CONCLUSION

Based on the proposal of the Parliament and on the result of the Ministerial Seminar, the Commission proposes an amendment to Directive 76/464/EEC according to Article 130S of the EEC Treaty.

This amendment intends that Article 12 of Directive 76/464/EEC will be amended to enable the Council to take decision acting by qualified majority with regard to the determination of limit values and quality objectives pursuant to Article 6 of Directive 76/464/EEC for the substances included in the family and group of substances within List I of the Annex to Directive 76/464/EEC.

The Commission suggests that the procedure under Article 130S, second indent, of the EEC Treaty, shall first be applicable to the sixteen substances mentioned in this Explanatory Memorandum (point II) and Article 2 of the proposed modification.

Any future selection of substances from List I of Directive 76/464/EEC for the purpose of fixing limit values and quality objectives will be adopted by the Council acting unanimously and the determination of limit values and quality objectives for these substances will be adopted by the Council by qualified majority.

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Proposal for a
COUNCIL DIRECTIVE

amending Directive 76/464/EEC on pollution caused by
certain dangerous substances discharged into the
aquatic environment of the Community

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

Having regard to Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (1), and in particular Articles 6 and 12 thereof,

Having regard to the proposal from the Commission (2),

Having regard to the opinion of the European Parliament (3),

Having regard to the opinion of the Economic and Social Committee (4),

Whereas, in order to protect the aquatic environment of the Community against pollution caused by certain dangerous substances, Article 3 of Directive 76/464/EEC introduces a system of prior authorization laying down emission standards for discharges of the substances in List I in the Annex thereto; whereas Article 6 of the said Directive provides for laying down limit values for such emission standards and quality objectives for the aquatic environment affected by discharges of these substances;

(1) OJ No L 129, 18.5.1976, p. 23.

(2)

(3)

(4)

Whereas pollution through discharges of the various dangerous substances within List I must be eliminated; whereas the Council should, within specific time limits and on a proposal from the Commission, adopt limit values which the emission standards should not exceed, methods of measurement, and the time limits with which existing dischargers should comply;

Whereas Member States should apply these limit values, except where a Member State can prove to the Commission, in accordance with a monitoring procedure set up by the Council, that the quality objectives established by the Council, on a proposal from the Commission, are being met and continuously maintained throughout the area which might be affected by the discharges because of the action taken, among others, by that Member State;

Whereas, to enable Member States to demonstrate that the quality objectives are being met, provision should be made for reports to the Commission for each quality objective chosen and applied;

Whereas Member States should seek to ensure that the measures taken pursuant to this Directive do not have the effect of increasing soil or air pollution;

Whereas substances and groups of substances are listed in List I in the Annex to Directive 76/464/EEC because of their persistence, toxicity and bioaccumulation;

Whereas it is necessary to make the procedure establishing limit values and quality objectives for dangerous substances more efficient in order to achieve quickly common Community-wide standards for those substances belonging to List I in the Annex to Directive 76/464/EEC; whereas the setting of limit values and quality objectives should, for reasons of time and efficiency, be carried out by the Council acting by qualified majority pursuant to the second paragraph of Article 130s;

Whereas trifluralin, endosulfan, simazine, triorganotin compounds (i.e. tributyltin oxide, triphenyltin acetate, triphenyltin chloride, triphenyltin hydroxide), atrazine and Organophosphorus substances (i.e. azinphos-ethyl, azinphos-methyl, fenitrothion, fenthion, malathion, parathion and parathion-methyl, dichlorvos) have been chosen mainly on the basis of the criteria adopted in Directive 76/464/EEC;

Whereas, since pollution due to the discharge of these substances into the aquatic environment is caused by a large number of industries, it is necessary to lay down specific limit values for discharges according to the type of industry concerned and to lay down quality objectives for the aquatic environment into which these substances are discharged,

HAS ADOPTED THIS DIRECTIVE :

Article 1

The first subparagraph of Article 12(1) of Directive 76/464/EEC is hereby replaced by the following:

"The Council acting by qualified majority and after consulting the European Parliament and the Economic and Social Committee shall, within nine months, take a decision on any Commission proposal made pursuant to Article 6 and on the proposals concerning the methods of measurement applicable."

Article 2

The following substances belonging to List I of the Annex to Directive 76/464/EEC will be considered on a priority basis for the purpose of fixing limit values and quality objectives :

- Trifluralin
- Endosulfan
- Simazine
- Triorganotin compounds :
 - * Tributyltin oxide
 - * Triphenyltin acetate
 - * Triphenyltin oxide
 - * Triphenyltin hydroxide
- Atrazine
- Organophosphorus substances :
 - * Azinphos-ethyl
 - * Azinphos-methyl
 - * Fenitrothion
 - * Fenthion
 - * Malathion
 - * Parathion and Parathion-methyl
 - * Dichlorvos

Article 3

1. Member States shall bring into force the measures necessary to comply with this Directive by 31 December 1991. They shall forthwith inform the Commission thereof.

The provisions adopted pursuant to the first subparagraph shall make express reference to this Directive.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.

The Commission shall inform the Member States accordingly.

Article 4

This Directive is addressed to the Member States.

Done at

For the Council

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