



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending, for the twenty-fifth time, Council Directive 76/769/EEC
on the approximation of the laws, regulations and administrative provisions
of the Member States relating to restrictions on the marketing and use
of certain dangerous substances and preparations (substances classified as carcinogens,
mutagens or substances toxic to reproduction – c/m/r)**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION AND CONTEXT

European Parliament and Council Directive 94/60/EC amending for the fourteenth time Directive 76/769/EEC of the 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations¹ adds a list of substances classified as category 1 or 2 carcinogens, mutagens or substances toxic to reproduction (c/m/r) to Annex I of Directive 76/769/EEC². It stipulates that these substances, or preparations containing them, may not be placed on the market for sale to the general public. The c/m/r-classification of these substances has been defined in Annex I of Council Directive 67/548/EEC of the 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances³. This Annex is regularly updated by way of adaptation to technical progress.

Directive 94/60/EC also invites the Commission to submit further proposals to the European Parliament and Council to add additional c/m/r substances to Annex I of Directive 76/769/EEC no later than six months after the publication of new classifications as c/m/r (categories 1 and 2) in the framework of Council Directive 67/548/EEC. The European Parliament and Council Directive 97/56/EC, sixteenth amendment to Directive 76/769/EEC⁴, updates and consolidates the Appendix of c/m/r-substances to Annex I to the Directive. The Commission put forward a Proposal to add additional c/m/r substances to Annex I of Directive 76/769/EEC as a consequence of Commission Directive 98/98/EC⁵ adapting for the twenty-fifth time Directive 67/548/EEC.

Commission Directive 2001/59/EC of 6 August 2001 adapting for the twenty-eighth time Directive 67/548/EEC⁶, and more particularly Annex I thereto, to technical progress, added two substances newly classified as carcinogenic category 1, nineteen substances newly classified as carcinogenic category 2, five substances newly classified as mutagenic category 2, one substance newly classified as toxic to reproduction category 1 and sixteen substances newly classified as toxic to reproduction category 2 to Annex I of Directive 67/548/EEC. It is proposed to add these substances to the appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC.

2. JUSTIFICATION FOR PROPOSAL

What are the objectives of the proposal in relation to the Community's obligations?

Within the framework for action in the field of public health, the European Parliament and the Council have adopted an action plan to combat cancer (Decision N° 646/1996⁷). Due to the fact that use of chemicals by consumers cannot be controlled, safety can only be ensured by

¹ OJ L 365, 31.12.1994, p. 1.

² OJ L 262, 27.9.1976, p. 201.

³ OJ L 196, 16.8.1967, p. 1.

⁴ OJ L 333, 4.12.1997, p. 1.

⁵ OJ L 355, 30.12.1998, p. 1.

⁶ OJ L 225, 21.8.2001, p. 1.

⁷ OJ L 95, 16.4.1996, p. 9.

prohibiting use by consumers of c/m/r substances and preparations. Following the adoption of the Directive 94/60/EC the Commission is invited to propose measures governing substances newly classified as c/m/r categories 1 or 2.

The aim of the proposal is to preserve the Internal Market. When Member States adopt national provisions restricting the marketing and use of c/m/r substances and preparations there will be obstacles to trade because of differences in legislation between Member States. The Draft Proposal aims to improve the conditions for the functioning of the Internal Market to the benefit of the protection of the health and safety of consumers.

What are the courses of action available to the Community?

The only course of action available is to make a proposal for an amendment to Directive 76/769/EEC, the twenty-fifth amendment, providing for harmonised rules on the use of substances and preparations classified as category 1 or 2 c/m/r's.

Are uniform rules necessary? Is it not sufficient to establish targets to be implemented by Member States?

The proposed twenty-fifth amendment establishes uniform rules for the circulation of substances and preparations classified as c/m/r. It also guarantees a high level of protection of health and safety of consumers. The proposed twenty-fifth amendment is the only way to meet these goals. Targets would be insufficient.

3. RATIONALE OF THE PROPOSAL

The proposed twenty-fifth amendment would extend the appendix of c/m/r substances to Annex I to Directive 76/769 by adding the substances classified as c/m/r category 1 or category 2 in the twenty-eighth adaptation to technical progress of Directive 67/548/EEC. Use by consumers of all these substances is thus prohibited.

4. COSTS AND BENEFITS

4.1. Costs

The costs are estimated to be low due to the limited use of those substances by the general public.

4.2. Benefits

The proposed ban will ensure that the carcinogenic and mutagenic substances and substances toxic to reproduction and preparations are not placed on the market for consumer use either now or in the future. The benefit of the proposal is to protect the health of consumers.

5. PROPORTIONALITY

The twenty-fifth amendment would yield benefits in terms of protecting the health of consumers. This would be achieved at no cost.

6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT TWENTY-FIFTH AMENDMENT

Advice on the preparation of the proposal was sought through two meetings involving experts from Member States and industry. Industry was represented by CEFIC (European Chemical Industry Council) and Eurométaux.

7. CONFORMITY WITH THE TREATY

This proposal is intended to preserve the Internal Market and at the same time ensure a high level of protection of health of the consumers and is therefore in conformity with Article 95(3) of the Treaty.

8. EUROPEAN PARLIAMENT AND ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 95 of the Treaty, the Codecision Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

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mutagens or substances toxic to reproduction – c/m/r)**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ⁸,

Having regard to the opinion of the Economic and Social Committee ⁹,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ¹⁰,

Whereas:

- (1) Council Directive 76/769/EEC ¹¹ lays down restrictions on the marketing and use of certain dangerous substances and preparations.
- (2) The measures provided for in this Directive fall within the framework of the action plan in Decision No 646/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000) ¹², which has been extended until the end of 2002 by Decision No 521/2001/EC.
- (3) In order to improve health protection and consumer safety, substances classified as carcinogenic, mutagenic or toxic to reproduction and preparations containing them should not be placed on the market for use by the general public.

⁸ OJ C xx.

⁹ OJ C xx.

¹⁰ Opinion of the European Parliament of 14 November 2000 (not yet published in the Official Journal), Council Common Position of 12 March 2001 (OJ C 142, 15.5.2001, p. 1) and European Parliament Decision of 16 May 2001.

¹¹ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2001/91/EC (OJ L 286, 29.10.2001, p. 27).

¹² OJ L 95, 16.4.1996, p. 9. Decision as amended by Decision No 521/2001/EC (OJ L 79, 17.3.2001, p. 1).

- (4) Directive 94/60/EC of the European Parliament and of the Council of 20 December 1994 amending for the fourteenth time Directive 76/769/EEC¹³ establishes, in the form of an Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC, a list containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2. Such substances and preparations should not be placed on the market for use by the general public.
- (5) Directive 94/60/EC envisaged that the said list would be extended shortly after publication of an adaptation to technical progress of Annex I to Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances, which contains substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2¹⁴.
- (6) Commission Directive 2001/59/EC, which was adopted on 6 August 2001 and adapted to technical progress for the twenty-eighth time Directive 67/548/EEC, and more particularly Annex I thereto, contains two substances newly classified as carcinogenic category 1, nineteen substances newly classified as carcinogenic category 2, five substances newly classified as mutagenic category 2, one substance newly classified as toxic to reproduction category 1 and sixteen substances newly classified as toxic to reproduction category 2.
- (7) Those substances should be added to the list in the appendix to Annex I to Directive 76/769/EEC.
- (8) The risks and advantages of the substances newly classified, by Commission Directive 2001/59/EC, as carcinogenic, mutagenic and toxic to reproduction of category 1 or 2 have been taken into account.
- (9) This Directive applies without prejudice to Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work¹⁵, and individual directives based thereon, in particular Council Directive 90/394/EEC of the 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)¹⁶,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The substances listed in the Annex to this Directive shall be added to those substances listed in the appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC. The substances listed in the Annex to this Directive in point 1(c) shall be deleted from list 2 of point 29 of Annex I to Directive 76/769/EEC.

¹³ OJ L 365, 31.12.1994, p. 1.

¹⁴ OJ L 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

¹⁵ OJ L 183, 29.6.1989, p. 1.

¹⁶ OJ L 196, 26.7.1990, p. 1. Directive as last amended by Council Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66).

Article 2

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 31 December 2002 [nine months after the date of its entry into force]. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 31 March 2003 [twelve months after the date of the entry into force of this Directive].

2. When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

The Appendix to Annex I to Directive 76/769/EEC is amended as follows:

(1) The lists under the heading “Point 29 – Carcinogens” are amended as follows:

(a) In the list for category 1, the following are added:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
Butane [containing ≥ 0.1 % Butadiene (203-450-8)] [1]	601-004-01-8	203-448-7 [1]	106-97-8 [1]	C, S
Isobutane [containing ≥ 0.1 % Butadiene (203-450-8)] [2]		200-857-2 [2]	75-28-5 [2]	
1,3-Butadiene; Buta-1,3-diene	601-013-00-X	203-450-8	106-99-0	D

(b) In the list for category 2, the following are added:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
Beryllium oxide	004-003-00-8	215-133-1	1304-56-9	E
Sodium chromate	024-018-00-3	231-889-5	7775-11-3	E
Trichloroethylene; Trichloroethene	602-027-00-9	201-167-4	79-01-6	
α -Chlorotoluene; Benzyl chloride	602-037-00-3	202-853-6	100-44-7	E
2,3-Dibromopropan-1-ol; 2,3-Dibromo-1-propanol	602-088-00-1	202-480-9	96-13-9	E
Propylene oxide; 1,2-Epoxypropane; Methyloxirane	603-055-00-4	200-879-2	75-56-9	E
Phenyl glycidyl ether; 2,3-Epoxypropyl phenyl ether; 1,2-Epoxy-3-phenoxypropane	603-067-00-X	204-557-2	122-60-1	E
Furan	603-105-00-5	203-727-3	110-00-9	E
R-2,3-Epoxy-1-propanol	603-143-00-2	404-660-4	57044-25-4	E
(R)-1-Chloro-2,3-epoxypropane	603-166-00-8	424-280-2	51594-55-9	
2,3-Dinitrotoluene	609-050-00-3	210-013-5	602-01-7	E
3,4-Dinitrotoluene	609-051-00-9	210-222-1	610-39-9	E

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
3,5-Dinitrotoluene	609-052-00-4	210-566-2	618-85-9	E
2,5-Dinitrotoluene	609-055-00-0	210-581-4	619-15-8	E
6-Hydroxy-1-(3-isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile	611-057-00-1	400-340-3	85136-74-9	
(6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1,3,5-triazin-2,4-diyl)bis[(amino-1-methylethyl)ammonium] formate	611-058-00-7	402-060-7	108225-03-2	
Trisodium-[4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)biphenyl-1,3',3'',1'''-tetraolato-O, O', O'', O''']copper(II)	611-063-00-4	413-590-3	-	
Phenylhydrazine [1] Phenylhydrazinium chloride [2] Phenylhydrazine hydrochloride [3] Phenylhydrazinium sulphate (2:1) [4]	612-023-00-9	202-873-5 [1] 200-444-7 [2] 248-259-0 [3] 257-622-2 [4]	100-63-0 [1] 59-88-1 [2] 27140-08-5 [3] 52033-74-6 [4]	E
A mixture of: <i>N</i> -[3-hydroxy-2-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide; <i>N</i> -[2,3-Bis-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide; Methacrylamide; 2-Methyl- <i>N</i> -(2-methylacryloylamino-methoxymethyl)-acrylamide; <i>N</i> -(2,3-Dihydroxypropoxymethyl)-2-methylacrylamide	616-057-00-5	412-790-8	-	

(c) In the list for category 2, the following are deleted:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
Butane [containing ≥ 0.1 % Butadiene (203-450-8)] [1] Isobutane [containing ≥ 0.1 % Butadiene (203-450-8)] [2]	601-004-01-8	203-448-7 [1] 200-857-2 [2]	106-97-8 [1] 75-28-5 [2]	C, S
1,3-Butadiene; Buta-1,3-diene	601-013-00-X	203-450-8	106-99-0	D

(2) Under the heading “Point 30 – Mutagens” in the list for category 2, the following are added:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
Sodium chromate	024-018-00-3	231-889-5	7775-11-3	E
Butane [containing ≥ 0.1 % Butadiene (203-450-8)] [1] Isobutane [containing ≥ 0.1 % Butadiene (203-450-8)] [2]	601-004-01-8	203-448-7 [1] 200-857-2 [2]	106-97-8 [1] 75-28-5 [2]	C, S
1,3-Butadiene Buta-1,3-diene	601-013-00-X	203-450-8	106-99-0	D
Propylene oxide; 1,2-Epoxypropane; Methyloxirane	603-055-00-4	200-879-2	75-56-9	E
1,3,5-Tris-[(2 <i>S</i> and 2 <i>R</i>)-2,3- epoxypropyl]-1,3,5-triazine-2,4,6- (1 <i>H</i> ,3 <i>H</i> ,5 <i>H</i>)-trione	616-091-00-0	423-400-0	59653-74-6	E

(3) The lists under the heading “Point 31 – Toxic to reproduction” are amended as follows:

(a) In the list for category 1, the following is added:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
2-Bromopropane	602-085-00-5	200-855-1	75-26-3	E

(b) In the list for category 2, the following are added:

SUBSTANCES	INDEX NUMBER	EC NUMBER	CAS NUMBER	NOTES
Flusilazole (ISO). Bis(4-fluorophenyl)-(methyl)-(1H-1,2,4-triazol-1-ylmethyl)-silane	014-017-00-6	-	85509-19-9	E
A mixture of: 4-[[Bis-(4-fluorophenyl)-methylsilyl]methyl]-4H-1,2,4-triazole; 1-[[Bis-(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole	014-019-00-7	403-250-2	-	E
Bis(2-methoxyethyl) ether	603-139-00-0	203-924-4	111-96-6	
R-2,3-Epoxy-1-propanol	603-143-00-2	404-660-4	57044-25-4	E
Fluazifop-butyl (ISO); Butyl (RS)-2-[4-(5-trifluoromethyl-2-pyridyloxy)phenoxy]propionate	607-304-00-8	274-125-6	69806-50-4	
Vinclozolin (ISO); N-3,5-Dichlorophenyl-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione	607-307-00-4	256-599-6	50471-44-8	
Methoxyacetic acid	607-312-00-1	210-894-6	625-45-6	E
Bis(2-ethylhexyl) phthalate; Di-(2-ethylhexyl) phthalate; DEHP	607-317-00-9	204-211-0	117-81-7	
Dibutyl phthalate; DBP	607-318-00-4	201-557-4	84-74-2	
(+/-) Tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	607-373-00-4	414-200-4	119738-06-6	E
Flumioxazin (ISO); N-(7-Fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboxamide	613-166-00-X	-	103361-09-7	
(2RS,3RS)-3-(2-Chlorophenyl)-2-(4-fluorophenyl)-[(1H-1,2,4-triazol-1-yl)-methyl]oxirane	613-175-00-9	406-850-2	106325-08-0	
N, N-Dimethylacetamide	616-011-00-4	204-826-4	127-19-5	E
Formamide	616-052-00-8	200-842-0	75-12-7	
N-Methylacetamide	616-053-00-3	201-182-6	79-16-3	
N-Methylformamide	616-056-00-X	204-624-6	123-39-7	E