

**DIRECTIVE 2003/36/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 26 May 2003**

amending, for the 25th 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)

(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 ⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) Council Directive 76/769/EEC ⁽⁴⁾, 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) ⁽⁵⁾.
- (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.
- (4) Directive 94/60/EC of the European Parliament and of the Council of 20 December 1994 amending for the 14th time Directive 76/769/EEC ⁽⁶⁾, 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 containing them 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 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽⁷⁾, which lists substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2.

(6) Commission Directive 2001/59/EC ⁽⁸⁾, which adapted to technical progress for the 28th time Council Directive 67/548/EEC, and more particularly Annex I thereto, lists two substances newly classified as carcinogenic category 1, 19 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 16 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 Directive 2001/59/EC, as carcinogenic, mutagenic and toxic to reproduction of category 1 or 2 have been taken into account.

(9) This Directive shall apply 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 work ⁽⁹⁾, 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 ⁽¹⁰⁾,

⁽¹⁾ OJ C 126 E, 28.5.2002, p. 398.

⁽²⁾ OJ C 221, 17.9.2002, p. 8.

⁽³⁾ Opinion of the European Parliament of 11 June 2002 (not yet published in the Official Journal), Council Common Position of 21 January 2003 (OJ C 64 E, 18.3.2003, p. 6) and European Parliament Decision of 10 April 2003 (not yet published in the Official Journal).

⁽⁴⁾ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2002/62/EC (OJ L 183, 12.7.2002, p. 58).

⁽⁵⁾ OJ L 95, 16.4.1996, p. 9. Decision repealed on 31 December 2002 by Decision No 1786/2002/EC (OJ L 271, 9.10.2002, p. 1).

⁽⁶⁾ OJ L 365, 31.12.1994, p. 1.

⁽⁷⁾ 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).

⁽⁸⁾ OJ L 225, 21.8.2001, p. 1.

⁽⁹⁾ OJ L 183, 29.6.1989, p. 1.

⁽¹⁰⁾ 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).

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.

Article 2

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 25 June 2004. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 25 December 2004.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 May 2003.

For the European Parliament

The President

P. COX

For the Council

The President

G. DRYS

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 $\geq 0,1$ % Butadiene (203-450-8)] [1]	601-004-01-8	203-448-7 [1]	106-97-8 [1]	C, S
Isobutane [containing $\geq 0,1$ % 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
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	

Substances	Index number	EC number	CAS number	Notes
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]	612-023-00-9	202-873-5 [1]	100-63-0 [1]	E
Phenylhydrazinium chloride [2]		200-444-7 [2]	59-88-1 [2]	
Phenylhydrazine hydrochloride [3]		248-259-0 [3]	27140-08-5 [3]	
Phenylhydrazinium sulphate (2:1) [4]		257-622-2 [4]	52033-74-6 [4]	
A mixture of: N-[3-hydroxy-2-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide; N-[2,3-Bis-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide; methacrylamide; 2-methyl-N-(2-methyl-acryloylamino-methoxymethyl)-acrylamide; N-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 $\geq 0,1\%$ Butadiene (203-450-8)] [1]	601-004-01-8	203-448-7 [1]	106-97-8 [1]	C,S
Isobutane [containing $\geq 0,1\%$ 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

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 $\geq 0,1\%$ Butadiene (203-450-8)] [1]	601-004-01-8	203-448-7 [1]	106-97-8 [1]	C, S
Isobutane [containing $\geq 0,1\%$ Butadiene (203-450-8)] [2]		20-857-2 [2]	75-28-5 [2]	
1,3-Butadiene buta-1,3-diene	601-013-00-X	203-450-8	106-99-0	D
Propylene oxide; 1,2-epoxypropane; Methyloxirane	603-055-00-4	200-879-2	75-56-9	E
1,3,5-tris-[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-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)methyl-silyl]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	603-143-002	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