

**DIRECTIVE 2003/34/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 26 May 2003**

**amending for the 23rd time Council Directive 76/769/EEC 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)**

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 <sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(3)</sup>, in the light of the joint text approved by the Conciliation Committee on 17 March 2003,

Whereas:

- (1) Under Article 14 of the Treaty, an area without internal frontiers is to be established in which the free movement of goods, persons, services and capital is ensured.
- (2) On 29 March 1996 the European Parliament and the Council adopted Decision No 646/96/EC adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000) <sup>(4)</sup>.
- (3) 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. The Commission should submit as soon as possible a proposal to prohibit the use of products containing such substances, when there is scientific evidence that they are released from these products leading to exposure of, and risk to, 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 <sup>(5)</sup> establishes, in the form of an Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC <sup>(6)</sup>, 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 provides that the Commission will submit to the European Parliament and Council a proposal to extend this list not later than six months 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 the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances <sup>(7)</sup>, which contains substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2.
- (6) Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25th time Council Directive 67/548/EEC <sup>(8)</sup>, which in particular adapts Annex I thereto, contains 20 substances newly classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2, and Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC <sup>(9)</sup>, which in particular adapts Annex I thereto, contains two substances newly classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2. These substances should be added to points 29, 30 and 31 of the Appendix to Annex I to Directive 76/769/EEC.
- (7) The risks and advantages of the substances thus newly classified have been taken into account.
- (8) This Directive is to 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 <sup>(10)</sup>, and individual directives based thereon, in particular Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work <sup>(11)</sup>,

<sup>(1)</sup> OJ C 213 E, 31.7.2001, p. 263.

<sup>(2)</sup> OJ C 311, 7.11.2001, p. 7.

<sup>(3)</sup> Opinion of the European Parliament of 5 February 2002 (OJ C 284 E, 21.11.2002, p. 88), Council Common Position of 3 June 2002 (OJ C 197 E, 20.8.2002, p. 1) and Decision of the European Parliament of 10 October 2002 (not yet published in the Official Journal), Decision of the European Parliament of 27 March 2003 and Council Decision of 8 April 2003.

<sup>(4)</sup> OJ L 95, 16.4.1996, p. 9. Decision repealed by Decision No 1786/2002/EC of the European Parliament and of the Council (OJ L 271, 9.10.2002, p. 1).

<sup>(5)</sup> OJ L 365, 31.12.1994, p. 1.

<sup>(6)</sup> OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 2003/11/EC of the European Parliament and of the Council (OJ L 42, 15.2.2003, p. 45).

<sup>(7)</sup> OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p.1).

<sup>(8)</sup> OJ L 355, 30.12.1998, p. 1. Directive as amended by Commission Decision 2000/368/EC (OJ L 136, 8.6.2000, p. 108).

<sup>(9)</sup> OJ L 136, 8.6.2000, p. 1.

<sup>(10)</sup> OJ L 183, 29.6.1989, p. 1.

<sup>(11)</sup> OJ L 196, 26.7.1990, p. 1. Directive as last amended by Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66).

HAVE ADOPTED THIS DIRECTIVE:

*Article 3*

*Article 1*

The substances listed in the Annex shall be added to those listed in the Appendix, under points 29, 30 and 31 respectively, of Annex I to Directive 76/769/EEC.

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

*Article 2*

1. Member States shall adopt and publish not later than 15 July 2004 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

*Article 4*

This Directive is addressed to the Member States.

They shall apply these measures from 15 January 2005.

Done at Brussels, 26 May 2003.

2. When Member States adopt these measures, they shall contain a reference to this Directive or 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.

*For the European Parliament*

*For the Council*

*The President*

*The President*

P. COX

G. DRYS

## ANNEX

**Point 29 — Carcinogens: category 2**

Substances	Index number	EC number	CAS number
Cobalt dichloride	027-004-00-5	231-589-4	7646-79-9
Cobalt sulphate	027-005-00-0	233-334-2	10124-43-3
Cadmium fluoride	048-006-00-2	232-222-0	7790-79-6
Chrysene	601-048-00-0	205-923-4	218-01-9
Benzo[e]pyrene	601-049-00-6	205-892-7	192-97-2
2,2'-Bioxirane; 1,2:3,4-diepoxybutane	603-060-00-1	215-979-1	1464-53-5
2,3-Epoxypropan-1-ol; glycidol	603-063-00-8	209-128-3	556-52-5
2,4-Dinitrotoluene [1]; dinitrotoluene [2]; dinitrotoluene, technical grade	609-007-00-9	204-450-0 [1] 246-836-1 [2]	121-14-2 [1] 25321-14-6 [2]
2,6-Dinitrotoluene	609-049-00-8	210-106-0	606-20-2
Hydrazine-tri-nitromethane	609-053-00-X	414-850-9	—
Azobenzene	611-001-00-6	203-102-5	103-33-3
o-Dianisidine based azo dyes; 4,4'-diaryloxy-3,3'-dimethoxybiphenyl dyes with the exception of those mentioned elsewhere in Annex I to Directive 67/548/EEC	611-029-00-9	—	—
o-Tolidine based dyes; 4,4'-diaryloxy-3,3'-dimethylbiphenyl dyes, with the exception of those mentioned elsewhere in Annex I to Directive 67/548/EEC	611-030-00-4	—	—
1,4,5,8-Tetraaminoanthraquinone; C.I. Disperse Blue 1	611-032-00-5	219-603-7	2475-45-8

**Point 30 — Mutagens: category 2**

Substances	Index number	EC number	CAS number
Cadmium fluoride	048-006-00-2	232-222-0	7790-79-6
Cadmium chloride	048-008-00-3	233-296-7	10108-64-2
2,2'-Bioxirane; 1,2:3,4-diepoxybutane	603-060-00-1	215-979-1	1464-53-5

**Point 31 — Toxic to reproduction: category 2**

Substances	Index number	EC number	CAS number
Cadmium fluoride	048-006-00-2	232-222-0	7790-79-6
Cadmium chloride	048-008-00-3	233-296-7	10108-64-2
2,3-Epoxypropan-1-ol; glycidol	603-063-00-8	209-128-3	556-52-5
2-Methoxypropanol	603-106-00-0	216-455-5	1589-47-5
4,4'-isobutylethylidenediphenol; 2,2-bis (4'-hydroxyphenyl)-4-methylpentane	604-024-00-8	401-720-1	6807-17-6
2-Methoxypropyl acetate	607-251-00-0	274-724-2	70657-70-4
Tridemorph (ISO); 2,6-dimethyl-4-tridecylmorpholine	613-020-00-5	246-347-3	24602-86-6
Cycloheximide	613-140-00-8	200-636-0	66-81-9