

Proposal for a Directive of the European Parliament and of the Council amending for the twenty-third 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)

(2001/C 213 E/14)

(Text with EEA relevance)

COM(2001) 256 final — 2001/0110(COD)

(Submitted by the Commission on 14 May 2001)

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,

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

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

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) The European Parliament and the Council adopted on 29 March 1996 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) ⁽¹⁾.

(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.

(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/EEC ⁽²⁾ establishes, in the form of an

Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC ⁽³⁾, 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 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 relating to the classification, packaging and labelling of dangerous substances ⁽⁴⁾, 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 twenty-fifth time Council Directive 67/548/EEC ⁽⁵⁾, and more particularly Annex I thereto, to technical progress, contains 20 substances newly classified as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, and Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the twenty-sixth time Council Directive 67/548/EEC ⁽⁶⁾, and more particularly Annex I thereto, to technical progress, contains 2 substances newly classified as carcinogenic, mutagenic or toxic to reproduction 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 newly classified, by Directives 98/98/EC and 2000/32/EC, as carcinogenic, mutagenic and toxic to reproduction of category 1 or 2 have been taken into account.

⁽³⁾ OJ L 262, 27.9.1976, p. 201. Directive last amended by Commission Directive 99/77/EC (OJ L 207, 6.8.1999, p. 18).

⁽⁴⁾ 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 (OJ L 196, 16.8.1967, p. 1). Directive as last amended by Directive 99/33/EC of the European Parliament and Council of 10 May 1999 (OJ L 199, 30.7.1999, p. 57).

⁽⁵⁾ OJ L 355, 30.12.1998, p. 1.

⁽⁶⁾ OJ L 136, 8.6.2000, p. 1.

⁽¹⁾ OJ L 95, 16.4.1996, p. 9.

⁽²⁾ OJ L 365, 31.12.1994, p. 1.

(8) 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 work ⁽¹⁾, 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 ⁽²⁾,

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.

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 July 2002 [one year

after the date of its entry into force]. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 January 2003 [18 months after the date of the entry into force of this Directive].

2. When Member States adopt those 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 twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

⁽¹⁾ OJ L 183, 29.6.1989, p. 1.

⁽²⁾ OJ L 196, 26.7.1990, p. 1.

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
<i>o</i> -Dianisidine based azo dyes; 4,4'-diaryldiazo-3,3'-dimethoxybiphenyl dyes with the exception of those mentioned elsewhere in Annex I to Directive 67/548	611-029-00-9	—	—
<i>o</i> -Tolidine based dyes; 4,4'-diaryldiazo-3,3'-dimethylbiphenyl dyes, with the exception of those mentioned elsewhere in Annex I to Directive 67/548	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