

**DIRECTIVE 2001/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 19 June 2001**

amending, for the twenty-first 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, as regards substances classified as carcinogens, mutagens or substances toxic to reproduction

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 Economic and Social Committee ⁽²⁾,

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

Whereas:

- (1) Article 14 of the Treaty provides for the establishment of an area without internal frontiers 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 646/96/EC adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000) ⁽⁴⁾.
- (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 fourteenth time Directive 76/769/EEC ⁽⁵⁾ establishes, in the form of an Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC ⁽⁶⁾, a list containing substances classified as carcinogenic, mutagenic or toxic to reproduction in 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 ⁽⁷⁾, which contains substances classified as carcinogenic, mutagenic or toxic to reproduction in category 1 or 2.

- (6) Commission Directive 97/69/EC of 5 December 1997 adapting for the twenty-third time Directive 67/548/EEC, and more particularly Annex I thereto, to technical progress, contains one substance newly classified as carcinogenic in category 2 and Commission Directive 98/73/EC ⁽⁸⁾ of 18 September 1998 adapting for the twenty-fourth time Directive 67/548/EEC ⁽⁹⁾, and more particularly Annex 1 thereto, to technical progress, contains one substance newly classified as carcinogenic in category 2 and one substance newly classified as toxic to reproduction in category 2. These substances should be added to the Appendix concerning points 29 and 31 of Annex I to Directive 76/769/EEC.
- (7) The risks and advantages of the substances newly classified, by Directives 97/69/EC and 98/73/EC, as carcinogenic in category 2 or toxic to reproduction in category 2 have been taken into account.
- (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 ⁽¹⁰⁾, 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 (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽¹¹⁾.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

⁽¹⁾ OJ C 116 E, 26.4.2000, p. 54.

⁽²⁾ OJ C 140, 18.5.2000, p. 1.

⁽³⁾ 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.

⁽⁴⁾ OJ L 95, 16.4.1996, p. 9.

⁽⁵⁾ OJ L 365, 31.12.1994, p. 1.

⁽⁶⁾ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 1999/77/EC (OJ L 207, 6.8.1999, p. 18).

⁽⁷⁾ OJ 196 J, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2000/33/EC (OJ L 136, 8.6.2000, p. 90).

⁽⁸⁾ OJ L 343, 13.12.1997, p. 19.

⁽⁹⁾ OJ L 305, 16.11.1998, p. 1.

⁽¹⁰⁾ OJ L 183, 29.6.1989, p. 1.

⁽¹¹⁾ 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).

1. In the introduction, the Note R below shall be added:

'Note R:

The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter, less two standard errors, greater than 6µm.'

2. The substances listed in the Annex to this Directive shall be added to those substances listed in the Appendix concerning points 29 and 31.

Article 2

1. The Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 July 2002. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 18 January 2003.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such 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 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 Luxembourg, 19 June 2001.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

M. WINBERG

ANNEX

Point 29 — Carcinogens: category 2

Substances	Index number	EC number	CAS number	Notes
4-chloraniline	612-137-00-9	203-401-0	106-47-8	
Refractory ceramic fibres; Special Purpose Fibres, with the exception of those specified elsewhere in Annex I to Directive 67/548/EEC; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O + K ₂ O + CaO + MgO + BaO) content less or equal to 18 % by weight]	650-017-00-8			R

Point 31 — Toxic to reproduction: category 2

Substances	Index number	EC number	CAS number	Notes
6-(2-chloroethyl)-6(2-methoxyethoxy)-2,5,7,10-tetraoxa-6-silaundecane; etacelasil	014-014-00-X	253-704-7	37894-46-5	