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(Acts whose publication is obligatory)

DIRECTIVE 97/56/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 October 1997

amending for the 16th time 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

THE EUROPEAN PARLIAMENT AND COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a 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 189b of the Treaty [3],

(1) Whereas measures should be adopted for the smooth operation of the internal market; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

(2) Whereas the operation of the internal market should also gradually improve the quality of life, health protection and consumer safety; whereas the measutres proposed by this Directive are in line with the Council resolution of 9 November 1989 on future priorities for relaunching consumer protection policy [4];

(3) Whereas the Council and the representatives of the Governments of the Member States, meeting within the Council, adopted Decision 90/238/Euratom, ECSC, EEC concerning a 1990 to 1994 action plan in the context of the 'Europe against Cancer' programme [5];

(4) Whereas, 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;

(5) Whereas 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 on the approximation of the laws, regulations and administrative provision of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations [6] introduces a list in the form of an appendix to points 29, 30 and 31 of Annex I to Directive 76/769/EEC [7] containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2; whereas such substances and preparations which contain them may not be placed on the market for sale to the general public;

(6) Whereas the Commission will be submitting to the European Parliament and the Council a proposal to extend this list within six months after

[1] OJ C 383, 19. 12. 1996, p. 1.
[2] OJ C 133, 28. 4. 1997, p. 38.
[3] Opinion of the European Parliament of 16 January 1997 (OJ C 33, 3. 2. 1997, p. 75), Council common position of 9 June 1997 (OJ C 234, 1. 8. 1997, p. 1) and Decision of the European Parliament of 15 July 1997 (OJ L 286, 22. 9. 1997). Council Decision of 15 September 1997.
[4] OJ C 294, 22. 11. 1989, p. 1.
[5] OJ L 137, 30. 5. 1990, p. 31.
[6] OJ L 365, 31. 12. 1994, p. 1.
[7] OJ L 262, 27. 9. 1976, p. 201. Directive as last amended by Directive 97/16/EC of the European Parliament and of the Council (OJ L 116, 6. 5. 1997, p. 31).

publication of an adaptation to technical progress of Annex I to Directice 67/548/EEC [1] containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2;

(7) Whereas the risks and advantages of the substances newly classified as carcinogenic, mutagenic and toxic to reproduction of category 1 or 2 have been taken into account;

(8) Whereas Commission Directives 93/101/EC [2] and 94/69/EC [3] adapting for the 20th and 21st times Directive 67/548/EEC, and more particularly Annex I thereto, to technical progress contain over 800 substances newly classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2; whereas these substances should be added to points 29, 30 and 31 of the Appendix of Annex I to Directive 76/769/EEC;

(9) Whereas, for reasons of transparency and clarity, with regard to points 29, 30 and 31, Annex I to Directive 76/769/EEC should be amended and the Appendix in Annex I to the said Directive should be replaced by a consolidated appendix;

(10) Whereas this Directive does not affect Community legislation laying down minimum requirements for the protection of workers contained in Directive 89/391/EEC [4] and individual directives bases thereon, in particular Directive 90/394/EEC [5],

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

1. In the column entitled 'Conditions of restriction', the second paragraph relating to points 29, 30 and 31 shall be replaced by the following:

'Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations must be marked legibly and indelibly as follows: "Restricted to professional users".'.

2. The Appendix shall be replaced by the text contained in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish before 4 December 1998 the laws, regulations and administrative provisions necessary to comply with this Directive: They shall forthwith inform the Commission thereof.

They shall apply these provisions as from 1 March 1999.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such 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 is addressed to the Member States.

Done at Brussels, 20 October 1997.

For the European Parliament	*For the Council*
The President	*The President*
J. M. GIL-ROBLES	F. BODEN

[1] Council Directive 67/548/EEC of 27 June 1967 of the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16. 8. 1967, p. 1). Directive as last amended by Directive 96/56/EC of the European Parliament and of the Council (OJ L 236, 18. 9. 1996, p. 35).

[2] OJ L 13, 15. 1. 1994, p. 1.

[3] OJ L 381, 31. 12. 1994, p. 1.

[4] 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 (OJ L 183, 29. 6. 1989, p. 1).

[5] Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (OJ L 196, 26. 7. 1990, p. 1).

ANNEX

'Appendix

Foreword

Explanations of column headings

Substances:

The name is the same as that used for the substance in Annex I to Directive 67/548/EEC. Whenever possible dangerous substances are designated by their Einecs (European Inventory of Existing Commercial Chemical Substances) of Elincs (European List of Notified Chemical Substances) names. Other entries not listed in Einecs or Elincs are designated using an internationally recognized chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases.

Index number:

The index number is the identification code given to the substance in Annex I of Directive 67/548/EEC. Substances are listed in the Appendix according to this index number.

EC number:

For each substance listed in the European Inventory of Existing Commercial Chemical Substances (Einecs) there is an identification code. The code starts at 200-001-8.

For each new substance notified under the Directive 67/548/EEC an identification code has been defined and published in the European List of Notified Chemical Substances (Elincs). The code starts at 400-010-9.

CAS number:

Chemical Abstracts Service (CAS) numbers have been defined for substances to help in their identification.

Notes:

The full text of the notes can be found in the foreword of Annex I of Directive 67/548/EEC.

The notes to the taken into account for the purposes of this Directive are as follows:

Note J:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (Einecs No 200-753-7).

Note K:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (Einecs No 203-450-8).

Note L:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346.

Note M:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (Einecs No 200-028-5).

Note N:

The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

Note P:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (Einecs No 200-753-7).

Point 29 — Carcinogens: category 1

Substances	Index number	EC number	CAS number	Notes
Chromium trioxide	024-001-00-0	215-607-8	1333-82-0	
Zinc chromates including zinc potassium chromate	024-007-00-3			
nickel monoxide	028-003-00-2	215-215-7	1313-99-1	
nickel dioxide	028-004-00-8	234-823-3	12035-36-8	
dinickel trioxide	028-005-00-3	215-217-8	1314-06-3	
nickel sulphide	028-006-00-9	240-841-2	16812-54-7	
nickel subsulphide	028-007-00-4	234-829-6	12035-72-2	
diarsenic trioxide; arsenic trioxide	033-003-00-0	215-481-4	1327-53-3	
arsenic pentoxide; arsenic oxide	033-004-00-6	215-116-9	1303-28-2	
arsenic acid and its salts	033-005-00-1			
lead hydrogen arsenate	082-011-00-0	232-064-2	7784-40-9	
benzene	601-020-00-8	200-753-7	71-43-2	
vinyl chloride; chloroethylene	602-023-00-7	200-831-0	75-01-4	
Bis (chloromethyl) ether	603-046-00-5	208-832-8	542-88-1	
Chloromethyl methyl ether; chlorodimethyl ether	603-075-00-3	203-480-1	107-30-2	
2-naphthylamine; beta-naphthylamine	612-022-00-3	202-080-4	91-59-8	
benzidine; 4,4′-diaminobiphenyl; biphenyl-4,4′-ylenediamine	612-042-00-2	202-199-1	92-87-5	
salts of benzidine	612-070-00-5			
salts of 2-naphthylamine	612-071-00-0			
biphenyl-4-ylamine; xenylamine; 4-aminobiphenyl	612-072-00-6	202-177-1	92-67-1	
salts of biphenyl-4-ylamine; salts of xenylamine; salts of 4-aminobiphenyl	612-073-00-1			
Tar, coal; Coal tar (The by-product from the destructive distillation of coal. Almost black semisolid. A complex combination of aromatic hydro-carbons, phenolic compounds, nitrogen bases and thiophene.)	648-081-00-7	232-361-7	8007-45-2	

Substances	Index number	EC number	CAS number	Notes
Tar, coal, high-temp.; Coal tar (The condensation product obtained by cooling, to approximately ambient temperature, the gas evolved in the high temperature (greater than 700 °C (1292 °F)) destructive distillation of coal. A black viscous liquid denser than water. Composed primarily of a complex mixture of condensed ring aromatic hydrocarbons. May contain minor amounts of phenolic compounds and aromatic nitrogen bases.)	648-082-00-2	266-024-0	65996-89-6	
Tar, coal, low-temp.; Coal oil (The condensation product obtained by cooling, to approximately ambient temperature, the gas evolved in low temperature (less than 700 °C (1292 °F)) destructive distillation of coal. A black viscous liquid denser than water. Composed primarily of condensed ring aromatic hydrocarbons, phenolic compounds, aromatic nitrogen bases, and their alkyl derivatives.)	648-083-00-8	266-025-6	65996-90-9	
Tar brown-coal; (An oil distilled from brown-coal tar. Composed primarily of aliphatic, naphthenic and one- to three-ring aromatic hydrocarbons, their alkyl derivates, heteroaromatics and one- and two-ring phenols boiling in the range of approximately 150 °C to 360 °C (302 °F to 680 °F).)	648-145-00-4	309-885-0	101316-83-0	
Tar, brown-coal, low temp.; (A tar obtained from low temperature carbonization and low temperature gasification of brown coal. Composed primarily of aliphatic, naphthenic and cyclic aromatic hydrocarbons, heteroaromatic hydrocarbons and cyclic phenols.)	648-146-00-X	309-886-6	101316-84-1	
Coke (coal tar), high temperature pitch	648-157-00-X		140203-12-9	
Coke (coal tar), mixed coal-high temperature pich	648-158-00-5		140203-13-0	
Coke (coal tar) low temperature, high temperature pitch	648-159-00-0		140413-61-2	
Distillates (petroleum), light paraffinic; Unrefined or mildly refined baseoil (A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C_{15} through C_{30} and produces a finished oil with a viscosity of less than 100 SUS at 100 °F (19 cS at 40 °C). It contains a relatively large proportion of saturated aliphatic hydrocarbons normally present in this distillation range of crude oil.)	649-050-00-0	265-051-5	64741-50-0	
Distillates (petroleum), heavy paraffinic; Unrefined or mildly refined baseoil (A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C_{20} through C_{50}, and produces a finished oil with a viscosity of at least 100 SUS at 100 °F (19 cSt at 40 °C). It contains a relatively large proportion of saturated aliphatic hydrocarbons.)	649-051-00-6	265-052-0	64741-51-1	