



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 07.01.1998
COM(97) 738 final

98/ 0005 (COD)

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

**amending for the 18th
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**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION AND CONTEXT

European Parliament and Council Directive 94/60/EC¹ amending for the 14th time of Directive 76/769/EEC² (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) adds a list of substances classified as category 1 or 2 carcinogens, mutagens or substances toxic to reproduction (c/m/r) to Annex I of Directive 76/769/EEC. It stipulates that these substances may not be used in substances or preparations placed on the market for sale to the general public. The c/m/r-classification of these substances has been defined in Annex I of Directive 67/548/EEC³ on classification, packaging and labelling of dangerous substances. This Annex is regularly updated by way of adaptation to technical progress.

Directive 94/60/EC also imposes on the Commission the obligation to submit further proposals to the European Parliament and Council to add additional c/m/r substances to Annex I of Directive 76/769 no later than six months after the publication of new classifications as c/m/r (categories 1 and 2) in the framework of Council Directive 67/548/EEC. The European Parliament and Council Directive 97/.../EC⁴, 16th amendment to Directive 76/769/EEC, updates and consolidates the Appendix of c/m/r-substances to Annex I to the Directive.

Commission Directive 96/54/EC⁵ (22nd adaptation) added 16 new c/m/r substances to Annex I of Directive 67/548/EEC. Out of these substances 14 are category 2 carcinogens, 7 are category 2 mutagens, one is category 1 toxic to reproduction substance and one is category 2 toxic to reproduction substance. The appendix to points 29, 30 and 31 is proposed to be supplemented by these substances.

¹ OJ No L 365, 31.12.1994, p. 1.

² OJ No L 262, 27.9.1976, p. 201, Directive as last amended by Directive 94/60/EC (OJ No L 365, 31.12.1994, p.1).

³ OJ No 196, 16.8.1967, p. 1/67, Directive as last amended by Commission Directive 94/69/EC (OJ No L 381, 31.12.1994, p.1).

⁴ OJ No L

⁵ OJ No L 248, 30.9.1996, p. 1.

2. JUSTIFICATION FOR PROPOSAL AND CONSIDERATIONS OF SUBSIDIARITY

What are the objectives of the proposal in relation to the Community's obligations ?

In the context of the programme 'Europe against cancer' an action plan has been launched by the Council (Decisions 90/238/Euratom, ECSC, EEC⁶ and 93/362/EEC⁷) to focus the attention on substances and preparations considered to be carcinogens. Due to the fact that use of chemicals by consumers cannot be controlled safety can only be ensured by prohibiting use by consumers of c/m/r substances and preparations. Following the adoption of the Directive 94/60/EC the Commission is required to propose Directives prohibiting use by consumers of substances newly classified as c/m/r categories 1 or 2.

The objectives of the proposal are to preserve the Internal Market and to protect the health of the consumers.

Does the initiatives arise out of an exclusive Community competence or a shared competitiveness?

The action to preserve the Internal Market for dangerous substances falls within the exclusive competence of the Community. This competence was established by Council Directive 76/769/EEC.

What are the courses of action available to the Community?

The only course of action available is a proposal for an amendment to Directive 76/769/EEC, the eighteenth amendment, providing for harmonised rules on the use of substances and preparations classified as category 1 or 2 c/m/r's.

Are uniform rules necessary? Is it not sufficient to establish targets to be implemented by Member States?

The proposed 18th amendment establishes uniform rules for the circulation of substances and preparations classified as c/m/r. It also guarantees high level of protection of health and safety of consumers. The proposed 18th amendment is the only way to meet these goals. Targets would be insufficient.

3. RATIONALE OF THE PROPOSAL

The proposed 18th amendment would extend the appendix of c/m/r substances to Annex I to Directive 76/769 by adding the substances classified as c/m/r category 1 or category 2 in the 22nd adaptation to technical progress of Directive 67/548/EEC. Use by consumers of all these substances is thus prohibited.

⁶ OJ No L 137, 30.5.1990, p. 31.

⁷ OJ No L 150, 22.6.1993, p. 43.

4. COSTS AND BENEFITS

4.1 Costs

None of the 16 substances are known to be placed on the market for consumer uses. The proposed Directive should not pose any problems to the industry or trade.

4.2 Benefits

The proposed ban will ensure that the carcinogenic substances and preparations are not placed on the market for consumer use either now or in the future. The benefit of the proposal is to protect the health of consumers.

5. PROPORTIONALITY

The 18th amendment would yield benefits in terms of protecting the health of consumers. This would be achieved at no costs.

6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT 18TH AMENDMENT

Advice on the preparation of the proposal was sought through several meetings involving experts from Member States and industry. Industry, represented CEFIC (European Chemical Industry Council) and ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) did not present any remarks on the proposal.

7. CONFORMITY WITH THE TREATY

This proposal is intended to facilitate a high level of protection of health of the consumers and is therefore in conformity with Article 100 A § 3 of the Treaty.

The proposal does not call for any special provisions of the kind referred to in Article 7 c of the Treaty.

It is in conformity with Article 3 b.

8. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 100 A of the Treaty, the Codecision Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

Proposal for an European Parliament and Council Directive amending for the 18th 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 THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100 a thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure referred to in Article 189 b of the Treaty ³,

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;

Whereas the operation of the internal market should also gradually improve the quality of life, health protection and consumer safety; whereas the measures proposed by this Directive are in line with the Council Resolution of 9 November 1989 on future priorities for relaunching consumer protection policy⁴;

Whereas the Council and the Representatives of the Governments of the Member States, meeting within the Council, adopted Decision 90/238/Euratom, ECSC, EEC⁵ concerning a 1990 to 1994 action plan in the context of the 'Europe against Cancer' programme;

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;

Whereas Directive 94/60/EC⁶ of the European Parliament and Council of 20 December 1994 amending for the 14th time Council Directive 76/769/EEC of 27 July 1976 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

1 OJ No C

2 OJ No C

3 Opinion of the European Parliament of

4 OJ No C 294, 23.11.1989, p. 1.

5 OJ No L 137, 30.5.1990, p. 31.

6 OJ No L 365, 31.12.1994, p. 1.

and preparations⁷ introduces a list in the form of an appendix to points 29, 30 and 31 of Annex I to Directive 76/769/EEC containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2, whereas such substances and preparations should no be placed on the market for use by the general public;

Whereas Directive 94/60/EC foresees that the Commission will submit to the European Parliament and Council a proposal to extend this list within six months after publication of an adaptation to technical progress if Annex I to Council Directive 67/548/EEC (8) of 27 June 1967 containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2;

Whereas the Commission Directive 96/54/EC⁹ of 30 July 1996 adapting for the 22nd time Council Directive 67/548/EEC, and more particularly Annex I thereto, to technical progress, contains 16 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 to annex I to Directive 76/769/EEC.

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:

Whereas this Directive does not affect Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC¹⁰ of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, and individual directives based thereon, in particular Council Directive 90/394/EEC¹¹ 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),

⁷ OJ No L 262, 27.9.1976, p. 201, Directive as last amended by Council Directive 94/60/EC (OJ No L 365, 31.12.1994, p.1)

⁸ OJ No L 196, 16.8.1967, p. 1, Directive as last amended by Directive 96/56/EC of the European Parliament and the Council (OJ No L 236, 18.9.1996, p.35).

⁹ OJ No L 248, 30.9.1996, p. 1.

¹⁰ OJ No L 183, 29.6.1989, p. 1.

¹¹ OJ No L 196, 26.7.1990, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The substances listed in the Annex to this Directive supplement those substances listed in the appendix to 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 one year after the date of its adoption and shall forthwith inform the Commission thereof.

They shall apply these provisions as from.....

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

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. Wherever possible, dangerous substances are designated by their EINECS (European Inventory of Existing Commercial Chemical Substances) or ELINCS (European List of Notified Chemical Substances) names. Entries not listed in EINECS or ELINCS are designated using an internationally recognised 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 to Directive 67/548/EEC. Substances are listed in the Appendix according to this index number.

EC number:

For each substances 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 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 Abstract Service (CAS) numbers have been defined for substances to help in their identification.

Point 29 - Carcinogens: category 2

Substances	Index number	EC number	CAS number
Potassium dichromate	024-002-00-6	231-906-6	7778-50-9
Ammonium dichromate	024-003-00-1	232-143-1	7789-09-5
Sodium dichromate	024-004-00-7	234-190-3	10588-01-9
Sodiumdichromate, dihydrate	024-004-01-4	234-190-3	7789-12-0
Chromyl dichloride; chromic oxychloride	024-005-00-2	239-056-8	14977-61-8
Potassium chromate	024-006-00-8	232-140-5	7789-00-6
Chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in this Annex	024-017-00-8	-	-
Bromoethylene	602-024-00-2	209-800-6	593-60-2
5-Allyl-1,3-benzodioxole; safrole	605-020-00-9	202-345-4	94-59-7
Benzidine based azo dyes; 4,4'-diarylazobiphenyl dyes, with the exception of those specified elsewhere in this Annex	611-024-00-1	-	-
Disodium 4-amino 3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate; C.I. Direct Black 38	611-025-00-7	217-710-3	1937-37-7
Tetrasodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate]; C.I. Direct Blue 6	611-026-00-2	220-012-1	2602-46-2
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate); C.I. Direct Red 28	611-027-00-8	209-358-4	573-58-0
Toluene-2,4-diammonium sulphate; 4-methyl- <i>m</i> -phenylenediamine sulphate	612-126-00-9	265-697-8	65321-67-7

Point 30 -Mutagens: category 2

Substances	Index number	EC number	CAS number
Potassium dichromate	024-002-00-6	231-906-6	7778-50-9
Ammonium dichromate	024-003-00-1	232-143-1	7789-09-5
Sodium dichromate	024-004-00-7	234-190-3	10588-01-9
Sodiumdichromate, dihydrate	024-004-01-4	234-190-3	7789-12-0
Chromyl dichloride; chromic oxychloride	024-005-00-2	239-056-8	14977-61-8
Potassium chromate	024-006-00-8	232-140-5	7789-00-6
1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1 <i>H</i> , 3 <i>H</i> , 5 <i>H</i>)-trione; TGIC	615-021-00-6	219-514-3	2451-62-9

Point 31 -Toxic to reproduction: category 1

Substances	Index number	EC number	CAS number
1,2-Dibromo-3-chloropropane	602-021-00-6	202-479-3	96-12-8

//

Point 31 -Toxic to reproduction: category 2

Substances	Index number	EC number	CAS number
bis(2-Methoxyethyl)phthalate	607-228-00-5	204-212-6	117-82-8

19

ISSN 0254-1475

COM(97) 738 final

DOCUMENTS

EN

10 06 05 14

Catalogue number : CB-CO-97-754-EN-C

ISBN 92-78-29932-4

Office for Official Publications of the European Communities
L-2985 Luxembourg