



COMMISSION OF THE EUROPEAN COMMUNITIES

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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)**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### 1. INTRODUCTION AND CONTEXT

European Parliament and Council Directive 94/60/EC amending for the fourteenth time 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 and preparations<sup>1</sup> 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<sup>2</sup>. 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 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>3</sup>. This Annex is regularly updated by way of adaptation to technical progress.

Directive 94/60/EC also invites the Commission to submit further proposals to the European Parliament and Council to add additional c/m/r substances to Annex I of Directive 76/769/EEC 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 97/56/EC<sup>4</sup>, 16<sup>th</sup> amendment to Directive 76/769/EEC, updates and consolidates the Appendix of c/m/r-substances to Annex I to the Directive.

Commission Directive 98/98/EC<sup>5</sup>, 25<sup>th</sup> adaptation to Directive 67/548/EEC, added 13 substances newly classified as carcinogenic category 2, 3 substances newly classified as mutagenic category 2, and 7 substances newly classified as toxic to reproduction category 2 to Annex I of Directive 67/548/EEC and Commission Directive 2000/32/EC<sup>6</sup>, 26<sup>th</sup> adaptation to Directive 67/548/EEC, added 1 substance newly classified as carcinogenic category 2 and 1 substance newly classified as toxic to reproduction category 2. It is proposed to add these substances to the appendix to points 29, 30 and 31 respectively.

### 2. JUSTIFICATION FOR PROPOSAL

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

Within the framework for action in the field of public health, the European Parliament and the Council have adopted an action plan to combat cancer (Decision n° 646/96/EC<sup>7</sup>). 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 invited to propose measures governing substances newly classified as c/m/r categories 1 or 2.

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

<sup>2</sup> OJ L 262, 27.9.1976, p. 201.

<sup>3</sup> OJ L 196, 16.8.1967, p. 1.

<sup>4</sup> OJ L 333, 4.12.1997, p. 1.

<sup>5</sup> OJ L 355, 30.12.1998, p.1

<sup>6</sup> OJ L 136, 8.6.2000, p.1

<sup>7</sup> OJ L 95, 16.4.1996, p. 9.

The aim of the proposal is to preserve the Internal Market. When Member States adopt national provisions restricting the marketing and use of c/m/r substances and preparations there will be obstacles to trade because of different development of national legislation. It is therefore necessary to improve the conditions for the functioning of the Internal Market to the benefit of the protection of the health and safety of consumers.

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

### **3. RATIONALE OF THE PROPOSAL**

The proposed twenty third amendment would extend the appendix of c/m/r substances to Annex I to Directive 76/769/EEC by adding the substances classified as c/m/r category 1 or category 2 in the 25<sup>th</sup> and 26<sup>th</sup> adaptations to technical progress of Directive 67/548/EEC. Use by consumers of all these substances is thus prohibited.

### **4. COSTS AND BENEFITS**

#### **4.1. Costs**

The costs are estimated to be low due to the limited use of those substances by the general public.

#### **4.2. Benefits**

The proposed ban will ensure that the carcinogenic and mutagenic substances and substances toxic to reproduction 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 twenty third amendment would yield benefits in terms of protecting the health of consumers. This would be achieved at low costs.

### **6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT 23<sup>RD</sup> AMENDMENT**

Advice on the preparation of the proposal was sought through several meetings involving experts from Member States and industry. Industry was represented by CEFIC (European

Chemical Industry Council), CEPE (European Council of the Paint, Printing Ink and Artists' Colours Industry), Eurométaux and CONCAWE (the oil companies' European organisation for environment, health and safety).

## **7. CONFORMITY WITH THE TREATY**

This proposal is intended to preserve the Internal Market and at the same time ensure a high level of protection of health of the consumers and is therefore in conformity with Article 95(3) of the Treaty.

## **8. EUROPEAN PARLIAMENT AND ECONOMIC AND SOCIAL COMMITTEE**

In compliance with Article 95 of the Treaty, the Codecision Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

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**(Text with EEA relevance)**

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>8</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>9</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>10</sup>,

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)<sup>11</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.
- (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<sup>12</sup> establishes, in the form of an Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC<sup>13</sup>, a list containing substances classified as carcinogenic, mutagenic or toxic to

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<sup>8</sup> OJ C

<sup>9</sup> OJ C

<sup>10</sup> Opinion of the European Parliament of

<sup>11</sup> OJ L 95, 16.4.1996, p. 9.

<sup>12</sup> OJ L 365, 31.12.1994, p. 1.

<sup>13</sup> 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).

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<sup>14</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 twenty fifth time Council Directive 67/548/EEC<sup>15</sup>, 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<sup>16</sup>, 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.
- (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<sup>17</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>18</sup>.

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

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<sup>14</sup> 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 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).

<sup>15</sup> OJ L 355, 30.12.1998, p. 1

<sup>16</sup> OJ L 136, 8.6.2000, p. 1

<sup>17</sup> OJ L 183, 29.6.1989, p. 1.

<sup>18</sup> OJ L 196, 26.7.1990, p. 1.

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.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## 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[ <i>e</i> ]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'-diarylaazo-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'-diarylaazo-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