



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.01.2000  
COM(1999) 746 final

2000/0006 (COD)

Proposal for a

**EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE**

**amending for the 21<sup>st</sup> 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<sup>1</sup> amending for the 14<sup>th</sup> time Directive 76/769/EEC<sup>2</sup> (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/EEC<sup>3</sup> 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 97/56/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 97/69/EC<sup>5</sup> (23<sup>rd</sup> adaptation) added 1 substance newly classified as carcinogenic category 2 to Annex I of Directive 67/548/EEC and Commission Directive 98/73/EC<sup>6</sup> (24<sup>th</sup> adaptation) added 1 substance newly classified as carcinogenic category 2 and 1 substance newly classified as toxic for reproduction category 2. It is proposed to add these substances to the appendix to points 29 and 31.

### 2. JUSTIFICATION FOR PROPOSAL AND CONSIDERATIONS OF SUBSIDIARITY

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<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

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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, Directive as last amended by Directive 94/60/EC (OJ L 365, 31.12.1994, p. 1).

<sup>3</sup> OJ L 196, 16.8.1967, p. 1/67, Directive as last amended by Commission Directive 94/69/EC (OJ L 381, 31.12.1994, p. 1).

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

<sup>5</sup> OJ L 343, 13.12.1997, p. 19.

<sup>6</sup> OJ L 305, 16.11.1998, p. 1.

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

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 twenty-first 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 21<sup>st</sup> 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 21<sup>st</sup> amendment is the only way to meet these goals. Targets would be insufficient.

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

The proposed 21<sup>st</sup> 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 23<sup>rd</sup> and 24<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**

None of the 3 substances is known to be placed on the market for consumer uses. Refractory ceramic fibres could however, although extremely rare and unlikely, be obtained by the general public for hobby use. 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 21<sup>st</sup> 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 21<sup>ST</sup> AMENDMENT**

Advice on the preparation of the proposal was sought through several meetings involving experts from Member States and industry. Industry, represented by CEFIC (European Chemical Industry Council) and CERAME-UNI did not oppose the proposal, in so far as it does not concern articles containing the substances.

## **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 95§3 of the Treaty.

The proposal does not call for any special provisions of the kind referred to in Article 15 of the Treaty.

It is in conformity with Article 5.

## **8. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE 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 14<sup>th</sup> 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

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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.

dangerous substances and preparations<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 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 Directive 67/548/EEC<sup>14</sup>, which contains substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2.
- (6) Commission Directive 97/69<sup>15</sup> adapting for the 23<sup>rd</sup> time Directive 67/548/EEC, and more particularly Annex I thereto, to technical progress, contains 1 substance newly classified as carcinogenic category 2 and Commission Directive 98/73/EC<sup>16</sup> adapting for the 24<sup>th</sup> time Directive 67/548/EEC, and more particularly Annex 1 thereto, to technical progress, contains 1 substance newly classified as carcinogenic category 2 and 1 substance newly classified as toxic to reproduction category 2. These substances should be added to points 29 and 31 of the Appendix to Annex I to Directive 76/769/EEC.
- (7) The risks and advantages of the substances newly classified, by Directive 96/54/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 the 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work.

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<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).

<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 343, 13.12.1997, p. 19

<sup>16</sup> OJ L 305, 16.11.1998, p. 1.

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

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

The substances listed in Annex to this Directive shall be added to those substances listed in the appendix concerning points 29 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 December 2001 [one year after the date of its entry into force]. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 July 2002 [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

<b>Substances</b>	<b>Index number</b>	<b>EC number</b>	<b>CAS number</b>
4-chloroaniline	612-137-00-9	203-401-0	106-47-8
Refractory ceramic fibres	650-017-00-8		

Point 31 – Toxic to reproduction: category 2

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