

**Proposal for a Directive of the European Parliament and of the Council amending, for the twenty-fifth 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 (substances classified as carcinogens, mutagens or substances toxic to reproduction — c/m/r)**

(2002/C 126 E/18)

(Text with EEA relevance)

COM(2002) 70 final — 2002/0040(COD)

*(Submitted by the Commission on 12 February 2002)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF  
THE EUROPEAN UNION,

reproduction and preparations containing them should not  
be placed on the market for use by the general public.

Having regard to the Treaty establishing the European  
Community, and in particular Article 95 thereof,

(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>(4)</sup> establishes, in the form of an  
Appendix concerning points 29, 30 and 31 of Annex I to  
Directive 76/769/EEC, 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.

Having regard to the proposal from the Commission,

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

(5) Directive 94/60/EC envisaged that the said list would be  
extended shortly 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, which  
contains substances classified as carcinogenic, mutagenic  
or toxic to reproduction of category 1 or 2 <sup>(5)</sup>.

Acting in accordance with the procedure laid down in Article  
251 of the Treaty <sup>(1)</sup>,

Whereas:

(1) Council Directive 76/769/EEC <sup>(2)</sup> lays down restrictions on  
the marketing and use of certain dangerous substances and  
preparations.

(6) Commission Directive 2001/59/EC, which was adopted on  
6 August 2001 and adapted to technical progress for the  
twenty-eighth time Directive 67/548/EEC, and more  
particularly Annex I thereto, contains two substances  
newly classified as carcinogenic category 1, nineteen  
substances newly classified as carcinogenic category 2,  
five substances newly classified as mutagenic category 2,  
one substance newly classified as toxic to reproduction  
category 1 and sixteen substances newly classified as  
toxic to reproduction category 2.

(2) The measures provided for in this Directive fall within the  
framework of the action plan in Decision No 646/96/EC of  
the European Parliament and of the Council of 29 March  
1996 adopting an action plan to combat cancer within the  
framework for action in the field of public health (1996 to  
2000) <sup>(3)</sup>, which has been extended until the end of 2002  
by Decision No 521/2001/EC.

(7) Those substances should be added to the list in the  
appendix to Annex I to Directive 76/769/EEC.

(3) In order to improve health protection and consumer safety,  
substances classified as carcinogenic, mutagenic or toxic to

(8) The risks and advantages of the substances newly classified,  
by Commission Directive 2001/59/EC, as carcinogenic,  
mutagenic and toxic to reproduction of category 1 or 2  
have been taken into account.

<sup>(1)</sup> 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.

<sup>(2)</sup> OJ L 262, 27.9.1976, p. 201. Directive as last amended by  
Commission Directive 2001/91/EC (OJ L 286, 29.10.2001, p. 27).

<sup>(3)</sup> OJ L 95, 16.4.1996, p. 9. Decision as amended by Decision  
No 521/2001/EC (OJ L 79, 17.3.2001, p. 1).

<sup>(4)</sup> OJ L 365, 31.12.1994, p. 1.

<sup>(5)</sup> OJ L 196, 16.8.1967, p. 1. Directive as last amended by  
Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

(9) 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>(1)</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 (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) <sup>(2)</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. The substances listed in the Annex to this Directive in point 1(c) shall be deleted from list 2 of point 29 of Annex I to Directive 76/769/EEC.

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

<sup>(2)</sup> 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).

#### 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 2002 [nine months after the date of its entry into force]. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 31 March 2003 [twelve months after the date of the entry into force of this Directive].

2. When Member States adopt these 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 third day following that of its publication in the *Official Journal of the European Communities*.

#### Article 4

This Directive is addressed to the Member States.

### ANNEX

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

1. The lists under the heading 'Point 29 — Carcinogens' are amended as follows:

(a) In the list for category 1, the following are added:

| Substances  | Index number | EC number     | CAS number   | Notes |
|---|--------------|---------------|--------------|-------|
| Butane [containing $\geq 0,1$ % Butadiene (203-450-8)] [1]    | 601-004-01-8 | 203-448-7 [1] | 106-97-8 [1] | C, S  |
| Isobutane [containing $\geq 0,1$ % Butadiene (203-450-8)] [2] |              | 200-857-2 [2] | 75-28-5 [2]  |       |
| 1,3-Butadiene;<br>Buta-1,3-diene                              | 601-013-00-X | 203-450-8     | 106-99-0     | D     |

(b) In the list for category 2, the following are added:

| Substances                                  | Index number | EC number | CAS number | Notes |
|---|--------------|-----------|------------|-------|
| Beryllium oxide                             | 004-003-00-8 | 215-133-1 | 1304-56-9  | E     |
| Sodium chromate                             | 024-018-00-3 | 231-889-5 | 7775-11-3  | E     |
| Trichloroethylene;<br>Trichloroethene       | 602-027-00-9 | 201-167-4 | 79-01-6    |       |
| $\alpha$ -Chlorotoluene;<br>Benzyl chloride | 602-037-00-3 | 202-853-6 | 100-44-7   | E     |

| Substances  | Index number | EC number  | CAS number  | Notes |
|---|--------------|--|---|-------|
| 2,3-Dibromopropan-1-ol;<br>2,3-Dibromo-1-propanol   | 602-088-00-1 | 202-480-9  | 96-13-9   | E     |
| Propylene oxide;<br>1,2-Epoxypropane;<br>Methyloxirane  | 603-055-00-4 | 200-879-2  | 75-56-9   | E     |
| Phenyl glycidyl ether;<br>2,3-Epoxypropyl phenyl ether;<br>1,2-Epoxy-3-phenoxypropane   | 603-067-00-X | 204-557-2  | 122-60-1  | E     |
| Furan   | 603-105-00-5 | 203-727-3  | 110-00-9  | E     |
| R-2,3-Epoxy-1-propanol  | 603-143-00-2 | 404-660-4  | 57044-25-4  | E     |
| (R)-1-Chloro-2,3-epoxypropane   | 603-166-00-8 | 424-280-2  | 51594-55-9  |       |
| 2,3-Dinitrotoluene  | 609-050-00-3 | 210-013-5  | 602-01-7  | E     |
| 3,4-Dinitrotoluene  | 609-051-00-9 | 210-222-1  | 610-39-9  | E     |
| 3,5-Dinitrotoluene  | 609-052-00-4 | 210-566-2  | 618-85-9  | E     |
| 2,5-Dinitrotoluene  | 609-055-00-0 | 210-581-4  | 619-15-8  | E     |
| 6-Hydroxy-1-(3-isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile   | 611-057-00-1 | 400-340-3  | 85136-74-9  |       |
| (6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1,3,5-triazin-2,4-diyl)bis[(amino-1-methylethyl)-ammonium] formate  | 611-058-00-7 | 402-060-7  | 108225-03-2   |       |
| Trisodium-[4'-(8-acetyl-amino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)biphenyl-1,3',3'',1'''-tetraolato-O, O', O'', O''']copper(II)  | 611-063-00-4 | 413-590-3  | —   |       |
| Phenylhydrazine [1]<br>Phenylhydrazinium chloride [2]<br>Phenylhydrazine hydrochloride [3]<br>Phenylhydrazinium sulphate (2:1) [4]  | 612-023-00-9 | 202-873-5 [1]<br>200-444-7 [2]<br>248-259-0 [3]<br>257-622-2 [4] | 100-63-0 [1]<br>59-88-1 [2]<br>27140-08-5 [3]<br>52033-74-6 [4] | E     |
| A mixture of: N-[3-hydroxy-2-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide;<br>N-[2,3-Bis-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide;<br>Methacrylamide;<br>2-Methyl-N-(2-methyl-acryloylaminomethoxy-methyl)-acrylamide;<br>N-(2,3-Dihydroxypropoxymethyl)-2-methylacrylamide | 616-057-00-5 | 412-790-8  | —   |       |

(c) In the list for category 2, the following are deleted:

| Substances  | Index number | EC number     | CAS number   | Notes |
|---|--------------|---------------|--------------|-------|
| Butane [containing $\geq 0,1$ % Butadiene (203-450-8)] [1]    | 601-004-01-8 | 203-448-7 [1] | 106-97-8 [1] | C, S  |
| Isobutane [containing $\geq 0,1$ % Butadiene (203-450-8)] [2] |              | 200-857-2 [2] | 75-28-5 [2]  |       |
| 1,3-Butadiene;<br>Buta-1,3-diene                              | 601-013-00-X | 203-450-8     | 106-99-0     | D     |

2. Under the heading 'Point 30 — Mutagens' in the list for category 2, the following are added:

| Substances  | Index number | EC number     | CAS number   | Notes |
|---|--------------|---------------|--------------|-------|
| Sodium chromate   | 024-018-00-3 | 231-889-5     | 7775-11-3    | E     |
| Butane [containing $\geq 0,1$ % Butadiene (203-450-8)] [1]                          | 601-004-01-8 | 203-448-7 [1] | 106-97-8 [1] | C, S  |
| Isobutane [containing $\geq 0,1$ % Butadiene (203-450-8)] [2]                       |              | 200-857-2 [2] | 75-28-5 [2]  |       |
| 1,3-Butadiene<br>Buta-1,3-diene   | 601-013-00-X | 203-450-8     | 106-99-0     | D     |
| Propylene oxide;<br>1,2-Epoxypropane;<br>Methyloxirane                              | 603-055-00-4 | 200-879-2     | 75-56-9      | E     |
| 1,3,5-Tris-[(2S and 2R)-2,3-epoxypropyl]-<br>1,3,5-triazine-2,4,6-(1H,3H,5H)-trione | 616-091-00-0 | 423-400-0     | 59653-74-6   | E     |

3. The lists under the heading 'Point 31 — Toxic to reproduction' are amended as follows:

(a) In the list for category 1, the following is added:

| Substances     | Index number | EC number | CAS number | Notes |
|----------------|--------------|-----------|------------|-------|
| 2-Bromopropane | 602-085-00-5 | 200-855-1 | 75-26-3    | E     |

(b) In the list for category 2, the following are added:

| Substances  | Index number | EC number | CAS number  | Notes |
|---|--------------|-----------|-------------|-------|
| Flusilazole (ISO);<br>Bis(4-fluorophenyl)-(methyl)-(1H-1,2,4-triazol-<br>1-ylmethyl)-silane   | 014-017-00-6 | —         | 85509-19-9  | E     |
| A mixture of: 4-[[Bis-(4-fluorophenyl)-<br>methylsilyl]methyl]-4H-1,2,4-triazole;<br>1-[[Bis-(4-fluorophenyl)methyl-silyl]<br>methyl]-1H-1,2,4-triazole | 014-019-00-7 | 403-250-2 | —           | E     |
| Bis(2-methoxyethyl) ether   | 603-139-00-0 | 203-924-4 | 111-96-6    |       |
| R-2,3-Epoxy-1-propanol  | 603-143-00-2 | 404-660-4 | 57044-25-4  | E     |
| Fluazifop-butyl (ISO);<br>Butyl (RS)-2-[4-(5-trifluoromethyl-<br>2-pyridyloxy)phenoxy]propionate  | 607-304-00-8 | 274-125-6 | 69806-50-4  |       |
| Vinclozolin (ISO);<br>N-3,5-Dichlorophenyl-5-methyl-5-vinyl-<br>1,3-oxazolidine-2,4-dione   | 607-307-00-4 | 256-599-6 | 50471-44-8  |       |
| Methoxyacetic acid  | 607-312-00-1 | 210-894-6 | 625-45-6    | E     |
| Bis(2-ethylhexyl) phthalate;<br>Di-(2-ethylhexyl) phthalate;<br>DEHP  | 607-317-00-9 | 204-211-0 | 117-81-7    |       |
| Dibutyl phthalate;<br>DBP   | 607-318-00-4 | 201-557-4 | 84-74-2     |       |
| (±) Tetrahydrofurfuryl (R)-2-[4-(6-chloroquin-<br>oxalin-2-yloxy)phenyloxy]propionate   | 607-373-00-4 | 414-200-4 | 119738-06-6 | E     |

| Substances  | Index number | EC number | CAS number  | Notes |
|---|--------------|-----------|-------------|-------|
| Flumioxazin (ISO);<br>N-(7-Fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-<br>2H-1,4-benzoxazin-6-yl)cyclohex-<br>1-ene-1,2-dicarboxamide | 613-166-00-X | —         | 103361-09-7 |       |
| (2RS,3RS)-3-(2-Chlorophenyl)-2-(4-fluorophe-<br>nyl)-[(1H-1,2,4-triazol-1-yl)-methyl]oxirane                                      | 613-175-00-9 | 406-850-2 | 106325-08-0 |       |
| N, N-Dimethylacetamide  | 616-011-00-4 | 204-826-4 | 127-19-5    | E     |
| Formamide   | 616-052-00-8 | 200-842-0 | 75-12-7     |       |
| N-Methylacetamide   | 616-053-00-3 | 201-182-6 | 79-16-3     |       |
| N-Methylformamide   | 616-056-00-X | 204-624-6 | 123-39-7    | E     |