

I

(Information)

COUNCIL

COMMON POSITION (EC) No 45/2002

adopted by the Council on 3 June 2002

with a view to the adoption of a Directive 2002/.../EC of the European Parliament and of the Council of ... 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)

(2002/C 197 E/01)

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 ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

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) On 29 March 1996 the European Parliament and the Council adopted 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) ⁽⁴⁾.

(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 ⁽⁵⁾ establishes, in the form of an Appendix concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC ⁽⁶⁾, a list containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2. Such substances and preparations containing them 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 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽⁷⁾, 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 ⁽⁸⁾, and more particularly Annex I thereto, to technical progress, contains 20 substances newly classified as carcinogenic, mutagenic or toxic to reproduction of 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 ⁽⁹⁾, and more particularly Annex I thereto, to technical progress, contains two substances newly classified as carcinogenic, mutagenic or toxic to reproduction of 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.

⁽¹⁾ OJ C 213 E, 31.7.2001, p. 263.

⁽²⁾ OJ C 311, 7.11.2001, p. 7.

⁽³⁾ Opinion of the European Parliament of 5 February 2002 (not yet published in the Official Journal), Council Common Position of 4 June 2002 and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ L 95, 16.4.1996, p. 9. Decision as last amended by Decision No 521/2001/EC (OJ L 79, 17.3.2001, p. 1).

⁽⁵⁾ OJ L 365, 31.12.1994, p. 1.

⁽⁶⁾ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2001/91/EC (OJ L 286, 30.10.2001, p. 27).

⁽⁷⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

⁽⁸⁾ OJ L 355, 30.12.1998, p. 1. Directive as amended by Commission Decision 2000/368/EC (OJ L 136, 8.6.2000, p. 108).

⁽⁹⁾ OJ L 136, 8.6.2000, p. 1.

(7) The risks and advantages of the substances thus newly classified 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 ⁽¹⁾, 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 ⁽²⁾,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The substances listed in the Annex shall be added to those listed in the Appendix, under points 29, 30 and 31 respectively, of Annex I to Directive 76/769/EEC.

Article 2

1. Member States shall adopt and publish not later than ...(*) the laws, regulations and administrative provisions

necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these measures from ...(**)

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

For the European Parliament
The President

For the Council
The President

⁽¹⁾ OJ L 183, 29.6.1989, p. 1.

⁽²⁾ OJ L 196, 26.7.1990, p. 1. Directive as last amended by Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66).

(*) 12 months after the entry into force of this Directive.

(**) 18 months after the entry into force of this Directive.

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[e]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'-diaryldazo-3,3'-dimethoxybiphenyl dyes with the exception of those mentioned elsewhere in Annex I to Directive 67/548/EEC	611-029-00-9	—	—
<i>o</i> -Tolidine based dyes; 4,4'-diaryldazo-3,3'-dimethylbiphenyl dyes, with the exception of those mentioned elsewhere in Annex I to Directive 67/548/EEC	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

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 14 May 2001, the Commission presented a proposal for a European Parliament and Council Directive amending for the 23rd 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 — CMR) ⁽¹⁾.

The proposal is based on Article 95 of the Treaty.

2. The European Parliament adopted its opinion at first reading on 5 February 2002 ⁽²⁾.
3. The Economic and Social Committee delivered its opinion on 12 September 2001 ⁽³⁾.
4. On 3 June 2002, the Council adopted its common position in accordance with Article 251 of the Treaty.

II. AIM

The aim of the Commission's proposal is to add to Annex I to Directive 76/769/EEC a list of substances classified as category 1 or 2 carcinogens, mutagens or substances toxic to reproduction. The proposal stipulates that these substances may not be used in substances and preparations placed on the market for sale to the general public.

III. ANALYSIS OF THE COMMON POSITION

1. The Council has been examining the proposal since the middle of 2001. The Council's common position is identical to the Commission's proposal.
2. On 5 February 2002, the European Parliament adopted 2 amendments, proposing to extend the restrictions to products and requesting the Commission to present proposals to this effect before 30 June 2002.
3. In general, the Council shares the concern of the European Parliament in relation to CMR substances in products. However, the Council cannot agree to an extension of the scope of application of the Directive as proposed by the Parliament without basing it on scientific evaluation or a risk assessment. According to the current legislative framework, it is for the Member States and the Commission to determine, on the basis of a risk assessment, whether substances and preparations and products containing them pose a risk to public health or the environment. In this respect, it should be recalled that a very high number of CMR substances exists and that these are contained in an indefinite number of products. A product-based approach to CMR substances would thus, under the current legislative framework, be impossible to apply in practice.

Furthermore the Council considers that the proposed restrictions on certain CMR substances and preparations containing them provide adequate measures to limit the use of those CMR substances, and that these measures should be adopted without delay. Consequently, the Council cannot endorse the two amendments by the Parliament and has rejected them.

IV. CONCLUSION

The Council considers that the measures foreseen in the common position offer a balanced solution based on the Community risk assessment procedure, ensuring a high level of health and consumer protection.

⁽¹⁾ OJ C 213 E, 31.7.2001, p. 263.

⁽²⁾ Not yet published in the Official Journal.

⁽³⁾ OJ C 311, 7.11.2001, p. 7.

Further, the Council recalls the Council Conclusions on the Strategy for a Future Chemical Policy adopted on 7/8 June 2001, in particular points 9 and 19 of these, where the Council:

- 'Reaffirms its commitment to the development of a new chemicals policy and a new Community system for the management of chemicals (substances and preparations) including how the issue of chemicals in products will be addressed in legislation';

and

- 'Recognises that there is a need to shift to industry, including downstream users, the responsibility to generate knowledge about chemical substances and to assess and manage the risks arising from their use, enabling the authorities to focus on chemicals of highest priority'.

It is the view of the Council that the envisaged measures in the new chemicals policy will considerably improve the effectiveness of the management of risks relating to dangerous substances, including CMR substances, in products.
