



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 21 janvier 2003**

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**STATEMENT OF THE COUNCIL'S REASONS**

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**Subject : Common position adopted by the Council with a view to the adoption of 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)**

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**STATEMENT OF THE COUNCIL'S REASONS**

## **I. INTRODUCTION**

1. On 12 February 2002, the Commission presented a proposal for a European Parliament and Council Directive amending for the 25th 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)<sup>1</sup>.

The proposal is based on Article 95 of the Treaty.

2. The European Parliament adopted its Opinion at first reading on 11 June 2002.<sup>2</sup>
3. The Economic and Social Committee delivered its opinion on 29 May 2002<sup>3</sup>
4. On 21 janvier 2003, 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 of 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 spring 2002. The Council's Common Position is in substance identical to the Commission's proposal.
2. On 11 June 2002, the European Parliament adopted 5 amendments, proposing to extend the restrictions to articles and requesting the Commission to present proposals to this effect by the end of 2002. In addition, the Parliament proposed to end the exemption for CMR substances in cosmetics.

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<sup>1</sup> OJ C 126 E, 28.05.2002, p. 398 .

<sup>2</sup> OJ: not yet published.

3. As concerns amendments 5 and 3&6, second part, the Council, in general, shares the concern of the European Parliament in relation to CMR substances in articles/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 articles 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 these amendments by the Parliament and has rejected them.

Finally, it should be noted that the issue of chemicals in products will be addressed in the context of the development of a new chemicals policy. 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 articles.

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<sup>3</sup> OJ C 221, 17.09.2002, p. 8.

4. In relation to amendments 1, 2 and 3&6, first part, the Council agrees with the aim of the Parliament of ensuring that the CMR substances restricted under the Dangerous Substances Directive should be subject to the same restrictions in cosmetic products. However, the Council is of the opinion that CMR substances in cosmetics should be dealt with in the framework of the Cosmetics Directive (Directive 76/768/EEC) and therefore cannot accept the amendmemts proposed by the Parliament.

It should be recalled that in the context of the 7th amendment of the Cosmetics Directive, the Parliament and the Council have, subject to final approval, agreed that all CMR substances, category 1 and 2, should be banned.

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