COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.12.2002
COM(2002) 768 final

2001/0110 (COD)

OPINION OF THE COMMISSION

pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendment to the Council's common position regarding the 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)

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1. STATE OF PROCEDURE

- The above mentioned proposal [COM(2001) 256 final] was adopted by the Commission on 14th May 2001 and then transmitted to the Council and European Parliament.
- The European Economic and Social Committee gave its Opinion on 12 September 2001.
- The European Parliament approved the proposal with amendments in the first reading on 5 February 2002.
- The Commission rejected the European Parliament's amendments.
- The Council adopted its Common Position on 3 June 2002.
- The European Parliament approved the proposal with an amendment in the second reading on 10 October 2002.

2. OBJECTIVE OF THE DIRECTIVE

The Proposal, which is based on Article 95 of the Treaty, has the following two objectives:

- to preserve the Internal Market by introducing harmonised provisions with regard to the marketing and use of substances classified as carcinogens, mutagens or substances toxic to reproduction (c/m/r);
- to provide a high level of protection of health and the environment by restricting the marketing and use of substances classified as carcinogens, mutagens or substances toxic to reproduction (c/m/r).

3. OPINION OF THE COMMISSION ON THE AMENDMENT PROPOSED BY THE EUROPEAN PARLIAMENT

3.1. Summary of the Commission's position

The Commission cannot accept the amendment proposed by the European Parliament.

3.2. Amendment

The European Parliament proposed that the "Commission should submit as soon as possible a proposal to prohibit the use of products containing such substances, when there is scientific evidence that they are released from these products leading to exposure of the general public".

The current restrictions relating to points 29, 30 and 31 of Annex I of Directive 76/769/EEC as well as the Commission's proposal for the 23rd amendment of Directive 76/769/EEC cover substances and preparations. By including both substances and preparations within the scope of the proposal the situations most likely to lead to exposure of consumers to CMR substances are covered. Examples of preparations used by consumers are glues, detergents, household cleaning products, etc.

It is obvious that CMR substances incorporated in products will pose lower risks than CMR substances in preparations. Therefore, the Commission is of the opinion that the risk assessment procedure should be the essential and necessary basis for restrictions on CMR substances in products.

As regards the general issue of reduction of risks from dangerous substances, the Commission would also draw attention to the important changes which will be brought about under the new chemicals strategy and which are of direct relevance in meeting the objectives sought by the proposed amendment.

These changes will involve the registration of some 30.000 substances through a process where industry will have to submit data including a preliminary risk assessment for each of those substances. In addition, the authorisation procedure which will apply in the case of substances of very high concern, including CMRs, will involve more stringent requirements. The proposals are at an advanced stage of preparation and will soon be presented to the Council and the Parliament.

4. CONCLUSION

Taking account of the above, the Commission delivers a negative opinion on the amendment.