

# **Dangerous substances and preparations: cancerogens, mutagens and toxic, c/m/r category 1 or 2 (29th amend. Directive 76/769/EEC)**

2004/0225(COD) - 07/10/2004 - Legislative proposal

**PURPOSE :** to amend for the twenty-ninth 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 carcinogen, mutagen or toxic to reproduction - c/m/r).

**PROPOSED ACT :** Directive of the European Parliament and of the Council.

**CONTENT :** European Parliament and Council Directive 94/60/EC amending for the fourteenth time Directive 76/769/EEC of 27 July 1976 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 introduced a list of substances classified as category 1 or 2 carcinogen, mutagen or toxic to reproduction (c/m/r) in the Appendix of Annex I to Directive 76/769/EEC. It stipulates in points 29, 30 and 31 of Annex I of Directive 76/769/EEC that these substances may not be used in substances or preparations placed on the market for sale to the general public. These are substances which have previously been listed as carcinogen, mutagen or toxic to reproduction (c/m/r) in Annex I of 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. Annex I of Directive 67/548/EEC is regularly updated by way of adaptations to technical progress.

Directive 94/60/EC also provides that the Commission will submit to the European Parliament and Council, no later than six months after publication of an adaptation to technical progress of Annex I to Council Directive 67/548/EEC, a proposal for a Directive governing the substances newly classified as carcinogenic, mutagenic and toxic to reproduction in categories 1 and 2, so as to update the Appendix of Annex I to Directive 76/769/EEC.

Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the twenty-ninth time Council Directive 67/548/EEC, and more particularly Annex I thereto, inserted 146 entries containing substances newly classified as carcinogenic category 1, 21 entries containing substances newly classified as carcinogenic category 2, 152 entries containing substances newly classified as mutagenic category 2, and 24 entries containing substances newly classified as toxic to reproduction category 2 in Annex I of Directive 67/548/EEC. It is proposed to update the Appendix of Annex I to Directive 76/769/EEC in order to govern these substances newly classified in the framework of Directive 67/548/EEC.

This twenty-ninth amendment will insert 346 entries containing substances newly classified or re-classified under Commission Directive 2004/73/EC in the Appendix of Annex I to Directive 76/769/EEC. However, among these 346 entries, 304 contain substances which were already subject to a restriction for sale to the general public due to an earlier classification as c/m/r substance of category 1 or 2. Therefore, only 42 of these entries relate to substances that will be subject for the first time to the restriction for sale to the general public provided in points 29, 30 and 31 of Annex I of Directive 76/769/EEC.

Among the 146 entries containing substances newly classified as carcinogenic category 1, 145 cover substances which were previously classified as carcinogenic category 2. Therefore, the list relating to

carcinogens category 2 needs to be amended accordingly.

In addition, a number of entries in the Appendix of Annex I to Directive 76/769/EEC need to be amended to update the content of the column entitled "Notes". This update concerns four entries related to substances classified as carcinogenic category 1, 36 entries related to substances classified as carcinogen category 2, six entries related to substances classified as mutagen category 2, two entries related to substances classified as toxic to reproduction category 1 and three entries related to substances classified as toxic to reproduction category 2.