




Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2002/0040(COD) Procedure completed
Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)	
Subject 4.20.05 Health legislation and policy 4.60.04.02 Consumer security	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health, Consumer Policy		20/02/2002
		V/ALE SCHÖRLING Inger	
	Former committee responsible		
	 Environment, Public Health, Consumer Policy		20/02/2002
		V/ALE SCHÖRLING Inger	
Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	2480	21/01/2003
	Competitiveness (Internal Market, Industry, Research and Space)	2451	30/09/2002
European Commission	Commission DG Internal Market, Industry, Entrepreneurship and SMEs	Commissioner	

Key events			
12/02/2002	Legislative proposal published	COM(2002)0070	Summary
27/02/2002	Committee referral announced in Parliament, 1st reading		
23/05/2002	Vote in committee, 1st reading		Summary
23/05/2002	Committee report tabled for plenary, 1st reading	A5-0181/2002	
11/06/2002	Decision by Parliament, 1st reading	T5-0284/2002	Summary
30/09/2002	Debate in Council	2451	
21/01/2003	Council position published	15703/2/2002	Summary
30/01/2003	Committee referral announced in Parliament, 2nd reading		
25/03/2003	Vote in committee, 2nd reading		Summary
25/03/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0099/2003	
10/04/2003	Debate in Parliament		

10/04/2003	Decision by Parliament, 2nd reading	T5-0180/2003	Summary
26/05/2003	Final act signed		
26/05/2003	End of procedure in Parliament		
25/06/2003	Final act published in Official Journal		

Technical information

Procedure reference	2002/0040(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16387

Documentation gateway

Legislative proposal	COM(2002)0070 , OJ C 126 28.05.2002, p. 0398 E	12/02/2002	EC	Summary
Committee draft report	PE301.048	16/04/2002	EP	
Amendments tabled in committee	PE301.048/AM	14/05/2002	EP	
Committee report tabled for plenary, 1st reading/single reading	A5-0181/2002	23/05/2002	EP	
Economic and Social Committee: opinion, report	CES0675/2002 OJ C 221 17.09.2002, p. 0008	29/05/2002	ESC	
Text adopted by Parliament, 1st reading/single reading	T5-0284/2002 OJ C 261 30.10.2003, p. 0027-0086 E	11/06/2002	EP	Summary
Council statement on its position	15299/2/2002	18/12/2002	CSL	
Council position	15703/2/2002 OJ C 064 18.03.2003, p. 0006-0012 E	21/01/2003	CSL	Summary
Commission communication on Council's position	SEC(2003)0130	28/01/2003	EC	Summary
Committee draft report	PE328.755	10/03/2003	EP	
Committee recommendation tabled for plenary, 2nd reading	A5-0099/2003	25/03/2003	EP	
Text adopted by Parliament, 2nd reading	T5-0180/2003 OJ C 064 12.03.2004, p. 0391-0503 E	10/04/2003	EP	Summary

Additional information

European Commission	EUR-Lex
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Final act

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

PURPOSE: To include an updated list of carcinogens, mutagens and substances toxic to reproduction (c/m/r) to Community legislation relating to the marketing and use thereof. CONTENT: Commission Directive 67/548/EEC deals with the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. An Annex attached to this Directive lists all the c/m/r substances banned for use in the EU. It is updated on a regular basis depending on technical progress. It was last amended in 2001 for the twenty-eighth time. Added to the Annex were: - two new 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). Complementing Directive 67/548/EEC is Directive 76/769/EEC on the approximation of the laws regulations and administrative provision of the Member States relating to restriction on the marketing and use of certain dangerous substances and preparations. The aim of this Directive is to establish uniform rules for the circulation of substances and preparations classified as c/m/r. The purpose of the present Commission proposal is to update Directive 76/769/EEC in line with the amendments to Directive 67/548/EEC. In other words incorporating the newly labelled substances outlined above into the Annex of Directive 76/769/EEC. The estimated costs are low due to their limited use by the general public.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

The committee adopted the report by Inger SCHÖRLING (Greens/EFA, S) amending the proposal under the codecision procedure (1st reading). It deleted the derogation excluding cosmetic products from the ban on the sale to the general public of substances and preparations classified as CMR. It pointed out that, although the derogation had originally been introduced to allow specific - and stricter - rules for cosmetics, in fact the opposite was true, as CMR substances were not fully restricted in current legislation on cosmetics. Following the opinion of the Scientific Committee of 25 September 2001, which said that CMR substances should not be intentionally added to cosmetic products, the committee took the view that the derogation needed to be deleted. Another amendment sought to increase the transparency of current chemicals legislation by calling for the Commission to make the annexes of the relevant directives publicly available in consolidated form, to be updated after each modification of the directives.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

Using its procedure without debate, the European Parliament adopted a resolution drafted by Inger SCHORLING (Greens, EFA, Sweden) on substances classified as carcinogens, mutagens or substances toxic to reproduction. (Please refer to the document dated 23/05/02.) The Commission is required to submit a proposal by the end of 2002 to phase out the use of such substances in articles for use by the general public.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

The Council has been examining the proposal since spring 2002. The Council's common position is in substance identical to the Commission's proposal. As concerns amendment 5, 3 and 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 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 exist and that these are contained in an indefinite number of products. A product based approach to CMR substances would this, 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. 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. Finally, 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 amendments proposed by the Parliament. ?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

The common position corresponds with the Commission's proposal and the Council rejects the five amendments adopted by the European Parliament as the Commission has done. The Commission supports the common position, adopted by the Council unanimously.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

The committee adopted the report by Inger SCHÖRLING (Greens/EFA, S) approving the Council's common position without amendment under the 2nd reading of the codecision procedure.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

The European Parliament adopted the resolution by Inger SCHÖRLING (Greens/EFA, S) approving the Council's common position without amendment.?

Dangerous substances: carcinogens, mutagens, toxic to reproduction c/m/r (25th amend. Directive 76/769/EEC)

PURPOSE : to amend for the 25th time the directive on the limited use of certain dangerous substances and preparations. **COMMUNITY MEASURE :** Directive 2003/36/EC of the European Parliament and of the Council amending, for the 25th 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). **CONTENT :** In order to improve health protection and consumer safety, substances classified as carcinogenic, mutagenic or toxic to reproduction, and preparations containing them must not be placed on the market for use by the general public. Council Directive 76/769/EEC lays down restrictions on the marketing and use of certain dangerous substances and preparations. Annex I to Directive 76/769/EEC contains a list containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2. Commission Directive 2001/59/EC which adapted to technical progress for the 28th time Council Directive 67/548/EEC, lists: - two substances newly classified as carcinogenic category 1; - 19 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, - 16 substances newly classified as toxic to reproduction category 2. Those substances are added to the list in the appendix to Annex I to Directive 76/769/EEC. **DATE OF TRANSPOSITION :** 25/06/2004. **DATE APPLICABLE :** 25/12/2004. **ENTRY INTO FORCE :** 25/06/2003.?