Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) 2001/0110(COD) Directive	Procedure completed
Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC) Subject 4.15.15 Health and safety at work, occupational medicine 4.20.05 Health legislation and policy 4.60.04.02 Consumer security	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	DELE EP Delegation to Conciliation Committee		18/12/2002
		PPE-DE NISTICÒ Giuseppe	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		29/05/2001
		PPE-DE NISTICÒ Giuseppe	
	ENVI Environment, Public Health, Consumer Policy		29/05/2001
		PPE-DE NISTICÒ Giuseppe	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2500	08/04/2003
	Economic and Financial Affairs ECOFIN	2480	21/01/2003
	Employment, Social Policy, Health and Consumer Affairs	2431	03/06/2002
	Competitiveness (Internal Market, Industry, Research and Space)	2389	26/11/2001
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events

14/05/2001	Legislative proposal published	COM(2001)0256	Summary
17/05/2001	Committee referral announced in Parliament, 1st reading		
26/11/2001	Debate in Council	2389	
22/01/2002	Vote in committee, 1st reading		Summary
22/01/2002	Committee report tabled for plenary, 1st	A5-0015/2002	

	reading		
05/02/2002	Decision by Parliament, 1st reading	T5-0025/2002	Summary
03/06/2002	Council position published	08328/1/2002	Summary
13/06/2002	Committee referral announced in Parliament, 2nd reading		
10/09/2002	Vote in committee, 2nd reading		Summary
10/09/2002	Committee recommendation tabled for plenary, 2nd reading	A5-0285/2002	
10/10/2002	Debate in Parliament		
10/10/2002	Decision by Parliament, 2nd reading	T5-0460/2002	Summary
21/01/2003	Parliament's amendments rejected by Council		
22/01/2003	Report tabled for plenary, 3rd reading	A5-0064/2003	
18/02/2003	Formal meeting of Conciliation Committee		
18/02/2003	Final decision by Conciliation Committee		Summary
11/03/2003	Joint text approved by Conciliation Committee co-chairs	3606/2003	
26/03/2003	Debate in Parliament		
27/03/2003	Decision by Parliament, 3rd reading	T5-0121/2003	Summary
08/04/2003	Decision by Council, 3rd reading		
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	2001/0110(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	CODE/5/19019

Documentation gateway

Legislative proposal		COM(2001)0256 OJ C 213 31.07.2001, p. 0263 E	14/05/2001	EC	Summary
Economic and Social Committee: opinion, report		CES1113/2001 OJ C 311 07.11.2001, p. 0007	12/09/2001	ESC	
Committee report tabled for plenary, 1st		A5-0015/2002	22/01/2002	EP	

reading/single reading					
Text adopted by Parliament, 1st reading/single reading		T5-0025/2002 OJ C 284 21.11.2002, p. 0022-0088 E	05/02/2002	EP	Summary
Council position		08328/1/2002 OJ C 197 20.08.2002, p. 0001 E	03/06/2002	CSL	Summary
Commission communication on Council's position		SEC(2002)0619	10/06/2002	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0285/2002	10/09/2002	EP	
Text adopted by Parliament, 2nd reading		T5-0460/2002 OJ C 279 20.11.2003, p. 0020-0092 E	10/10/2002	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2002)0768	27/12/2002	EC	Summary
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A5-0064/2003	22/01/2003	EP	
Joint text approved by Conciliation Committee co-chairs		3606/2003	11/03/2003	CSL/EP	
Text adopted by Parliament, 3rd reading		T5-0121/2003 OJ C 062 11.03.2004, p. 0018-0144 E	27/03/2003	EP	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2003/34
OJ L 156 25.06.2003, p. 0014-0016 Summary

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

PURPOSE : to amend for the 23rd time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classifed as carcinogens, mutagens or substances toxic to reproduction - c/m/r). CONTENT : within the framework for action in the field of public health, the European Parliament and the Council have adopted an action plan to combat cancer (Decision 646/96/EC). Due to the fact that use of chemicals by consumers cannot be controlled, safety can only be ensured by prohibiting use by consumers of c/m/r substances and preparations. Following the adoption of the Directive 94/60/EC the Commission is invited to propose measures governing substances newly classified as c/m/r categories 1 or 2. The aim of the proposal is to preserve the Internal Market and at the same time ensure a high level of protection of health of the consumers. When Member States adopt national provisions restricting the marketing and use of c/m/r substances and preparations there will be obstacles to trade because of different development of national legislation. It is therefore necessary to improve the conditions for the functioning of the Internal Market to the benefit of the protection of the health and safety of consumers. The only course of action available is a proposal for an amendment to Directive 76/69/EEC, the 23rd amendment, providing for harmonised rules on the use of substances and preparations classified as category 1 or 2 c/m/r's. The proposed 23rd amendment establishes uniform rules for the circulation of substances and preparations classified as c/m/r. It also guarantees a high level of protection of health and safety of consumers. The proposed 23rd amendment is the only way to meet these goals. The proposed ban will ensure that the carcinogenic and mutagenic substances and substances toxic to reproduction and preparations are not placed on the market for consumer use either now or in the future. The benefit of the proposal is to protect the health of the consumers.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The committee adopted the report by Giuseppe NISTICO' (EPP-ED, I) approving the proposal without amendment under the codecision procedure (1st reading).?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The European Parliament adopted, without debate, the report by Mr Giuseppe NISTICO (EPP-ED, I). ?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The European Parliament adopted 2 amendments, proposing to extend the restrictions to products. The Council has rejected both amendments. The Council cannot agree to an extension of the scope of the application of the Directive without basing it on a 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 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. It has therefore rejected the Parliament's amendments.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The two amendments adopted by the Parliament have been rejected by the Commission. The Commission cannot accept an extension of the ban on substances classified as CMR of category 1 and 2 and preparations to products containing such substances, placed on the market for use by the general public. The approach under the current chemicals regime is to assess substances on a case by case basis with risk management measures being taken where it is established that action should be taken to prevent unacceptable risks. The Commission will continue this practice and if particular risks arising from CMR substances in producers are identified, proposals will be made for restrictions on a case by case basis. To further extend the scope of the Directive to ban CMR substances in products sold to the general public would be an immense undertaking requiring risk assessments for probably hundreds of substances and possibly thousands of uses. Launching such a high number of risk assessments would not be feasible and would be inconsistent with Council Regulation 793/93/EEC and Commission Regulation 2364/2000. As regards the general issue of reduction of risks from dangerous substances, the Commission draws 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 Parliament's proposed amendments.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The committee adopted the report by Giuseppe NISTICO' (EPP-ED, I) tabling one amendment to the Council's common position under the second reading of the codecision procedure. The amendment partially reinstated the two amendments adopted by Parliament at first reading which were not taken up by the Council. It therefore repeated Parliament's call for the Commission to: (1) extend the ban on CMR-classified substances of Category 1 or 2 and preparations to products placed on the market for use by the general public; and (2) submit a proposal to prohibit the use of such substances in products for use by the general public. ?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The European Parliament adopted a resolution drafted by Giuseppe NISTICO (EPP-ED, Italy) which slightly amends the Council's common position. A clause is added to one of the recitals, stating that the Commission should submit a proposal to prohibit the use of products containing c/m/r substances, when there is scientific evidence that they are released from these products leading to exposure of the general public.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The Commission states that it cannot accept the amendment proposed by the European Parliament. 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 issues of reduction of risks from dangerous substances, the Commission draws 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 30000 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.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The Conciliation Committee reached agreement on the directive. The compromise provided for the Commission to submit as soon as possible a legislative proposal aimed at banning the use of products containing CMR substances, where there is scientific evidence that they are released by such products, thereby exposing the general public to risks.?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

The European Parliament adopted a resolution approving the text jointly agreed by the Conciliation Committee. (Please refer to the document dated 17/03/03).?

Dangerous substances: carcinogens, mutagens or toxic to reproduction, c/m/r (23rd amend. Directive 76/769/EEC)

PURPOSE : to amend for the 23rd time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classifed as carcinogens, mutagens or substances toxic to reproduction - c/m/r). COMMUNITY MEASURE : Directive 2003/34/EC of the European Parliament and of the Council 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 - 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 should not be placed on the market for use by the general public. The Parliament and the Council have adopted this Directive which amends for the 23rd time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classifed as carcinogens, mutagens or substances toxic to reproduction - c/m/r). The Directive intends to restrict the marketing and the use of 25 new substances classified as carcinogenic, mutagenic or toxic to reproduction. To recall, Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25th time Council Directive 67/548/EEC, which in particular adapts Annex I thereto, 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 26th time Council Directive 67/548/EEC, which in particular adapts Annex I thereto, 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. ENTRY INTO FORCE : 15/07/2003. TRANSPOSITION : 15/07/2004. Member States shall apply these measures from 15/01/05.?