Basic information

2001/0186(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Medical devices incorporating stable derivates of human blood or human plasma See also Directive 2000/70/EC 1995/0013B(COD) **Subject** 4.20.04.02 Safety of blood and transfusion 4.60.02 Consumer information, advertising, labelling	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy		

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	2392	2001-12-03

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
22/08/2001	Legislative proposal published	COM(2001)0480	Summary
03/09/2001	Committee referral announced in Parliament, 1st reading		
08/10/2001	Vote in committee, 1st reading		
23/10/2001	Decision by Parliament, 1st reading	T5-0526/2001	Summary
03/12/2001	Act adopted by Council after Parliament's 1st reading		
07/12/2001	Final act signed		
07/12/2001	End of procedure in Parliament		
10/01/2002	Final act published in Official Journal		

Technical information

Procedure reference	2001/0186(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	See also Directive 2000/70/EC 1995/0013B(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095 Rules of Procedure EP 52-p1
Stage reached in procedure	Procedure completed

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Text adopted by Parliament, 1st reading/single reading		T5-0526/2001 OJ C 112 09.05.2002, p. 0026-0094 E	23/10/2001	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2001)0480 OJ C 304 30.10.2001, p. 0334 E	22/08/2001	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1484/2001 OJ C 048 21.02.2002, p. 0069	28/11/2001	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2001/0104
OJ L 006 10.01.2002, p. 0050-0051 Summary

Medical devices incorporating stable derivates of human blood or human plasma

2001/0186(COD) - 07/12/2001 - Final act

PURPOSE : to amend Council directive 93/42/EEC to include medical devices incorporating substances derived from human blood or plasma. COMMUNITY MEASURE : Directive 2001/104/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC concerning medical devices. CONTENT : This directive aims at including in the scope of directive 93/42/EEC only medical devices which incorporate as an integral part, substances derived from human blood or human plasma. Medical devices incorporating other substances derived from human tissues remain excluded from the scope of the Directive. DATE OF APPLICATION : 13 June 2002 ENTRY INTO FORCE : 10 January 2002.

Medical devices incorporating stable derivates of human blood or human plasma

2001/0186(COD) - 22/08/2001 - Legislative proposal

PURPOSE:To propose a new Directive on human blood or human plasma in order to clarify a mis-transcription in the original text. CONTENT: Directive 2000/70/EC regulates devices incorporating stable derivatives of human blood or human products. Following agreement on the Directive, it was brought to the Commission's attention by the Member States that there was a mis-transcription in the wording as agreed by the Council. The existence of the anomaly was confirmed by experts in the European Parliament, the Council and the Commission. It was decided that this situation could lead to confusion should the legislation require interpretation. All parties therefore agree that the simplest solution would be for the Commission to propose the Directive anew whilst at the same time incorporating the agreed, rather than mis-transcribed text. This, it is believed is the quickest way to implement the requirements of the Directive. This proposal effectively gives expression to what had originally been agreed.

Medical devices incorporating stable derivates of human blood or human plasma

2001/0186(COD) - 23/10/2001 - Text adopted by Parliament, 1st reading/single reading

The European Parliament approved this proposal, which amends Directive 93/42/EEC, by extending its scope to devices incorporating stable derivates of human blood or blood products. It was agreed not to table amendments since this would imply the opening of a second reading under the co-operation procedure.