Procedure file

3.50.01.05 Research specific areas

4.20.04 Pharmaceutical products and industry

Basic information COD - Ordinary legislative procedure (ex-codecision 2002/0231(COD) Procedure completed Procedure completed Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification Subject 3.40.01 Chemical industry, fertilizers, plastics 3.40.12 Luxury products industry, cosmetics

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	JURI Legal Affairs and Internal Market		19/02/2003
		PPE-DE GARGANI Giuseppe	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health, Consumer Policy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	2557	20/01/2004
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	<u> </u>	

Key events			
26/09/2002	Legislative proposal published	COM(2002)0530	Summary
09/10/2002	Committee referral announced in Parliament, 1st reading		
10/06/2003	Vote in committee, 1st reading		Summary
10/06/2003	Committee report tabled for plenary, 1st reading	A5-0206/2003	
01/07/2003	Decision by Parliament, 1st reading	T5-0302/2003	Summary
20/01/2004	Act adopted by Council after Parliament's 1st reading		
11/02/2004	End of procedure in Parliament		
12/02/2004	Final act signed		
	Final act published in Official Journal		

Technical information	
Procedure reference	2002/0231(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Codification
Legislative instrument	Regulation

Procedure completed

Rules of Procedure EP 52-p1; EC Treaty (after Amsterdam) EC 095

Documentation gateway					
Legislative proposal	COM(2002)0530	26/09/2002	EC	Summary	
Economic and Social Committee: opinion, report	CES0075/2003 OJ C 085 08.04.2003, p. 0138-0139	22/01/2003	ESC		
Committee report tabled for plenary, 1st reading/single reading	A5-0206/2003	10/06/2003	EP		
Text adopted by Parliament, 1st reading/single reading	T5-0302/2003 OJ C 074 24.03.2004, p. 0021-0044 E	01/07/2003	EP	Summary	

Additional information

20/02/2004

Legal basis

Stage reached in procedure

European Commission EUR-Lex

Final act

Directive 2004/10

OJ L 050 20.02.2004, p. 0044-0059 Summary

Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification

PURPOSE: to present a proposal for a Directive on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (Codification). CONTENT: Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. In the context of the people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen. This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain shattered, so that they must be sought partly in the original instrument and partly later amending ones.

Considerable research work, comparing many different instruments, is thus needed to identify current rules. For this reason a codification of rules that have frequently been amended is also essential if Community law is to be clear and transparent. The purpose of this proposal is to undertake the codification of Council Directive 87/18/EEC of 18 December 1986, on the harmonisation of laws, regulations and administrative provisions relating to the principles of good laboratory practice and the verification of their applications for tests on chemical substances. The new Directive will supersede the various Directives incorporated in it; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.

Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification

The committee adopted the report presented by its chairman, Giuseppe GARGANI (EPP-ED, I) (under the simplified procedure), approving the proposal without amendment (codecision procedure, 1st reading).?

Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification

The European Parliament adopted a resolution drafted by Giuseppe GARGANI (EPP-ED, Italy) and approved the Commission's proposal.?

Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification

PURPOSE: the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (Codification). LEGISLATIVE ACT: Directive 2004/10/EC of the European Parliament and of the Council on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version). CONTENT: The European Parliament and the Council adopted Directive 2004/10/EC concerning the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version). ENTRY INTO FORCE: 11/03/2004.?