

Procedure file

Basic information		
CNS - Consultation procedure Regulation	2002/0170(CNS)	Procedure completed
Agency for the Evaluation of Medicinal Products: budget and finances, access to documents (amend. Regulation (EEC) No 2309/93)		
Subject		
1.20.05 Public access to information and documents, administrative practice		
8.40.08 Agencies and bodies of the EU		
8.70.02 Financial regulations		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	BUDG Budgets		28/08/2002
		NI DELL'ALBA Gianfranco	
	Committee for opinion	Rapporteur for opinion	Appointed
	CONT Budgetary Control		02/09/2002
		PSE VAN HULTEN Michiel	
	LIBE Citizens' Freedoms and Rights, Justice and Home Affairs		12/09/2002
		PPE-DE HERNÁNDEZ MOLLAR Jorge Salvador	
	AFCO Constitutional Affairs	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2516	18/06/2003
European Commission	Commission DG	Commissioner	
	Budget		

Key events			
17/07/2002	Legislative proposal published	COM(2002)0406	Summary
23/09/2002	Committee referral announced in Parliament		
02/10/2002	Vote in committee		Summary
02/10/2002	Committee report tabled for plenary, 1st reading/single reading	A5-0336/2002	
22/10/2002	Decision by Parliament	T5-0479/2002	Summary
27/03/2003	Decision by Parliament	T5-0110/2003	Summary
18/06/2003	Act adopted by Council after consultation of Parliament		
18/06/2003	End of procedure in Parliament		
29/09/2003	Final act published in Official Journal		

Technical information	
Procedure reference	2002/0170(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 308
Stage reached in procedure	Procedure completed

Documentation gateway					
Legislative proposal		COM(2002)0406	17/07/2002	EC	Summary
Committee draft report		PE318.749	30/09/2002	EP	
Committee opinion	CONT	PE315.796/DEF	01/10/2002	EP	
Committee report tabled for plenary, 1st reading/single reading		A5-0336/2002	02/10/2002	EP	
Committee opinion	LIBE	PE319.235/DEF	07/10/2002	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		T5-0479/2002 OJ C 300 11.12.2003, p. 0022-0091 E	22/10/2002	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T5-0110/2003 OJ C 062 11.03.2004, p. 0018-0133 E	27/03/2003	EP	Summary

Additional information	
European Commission	EUR-Lex

Final act
Regulation 2003/1647 OJ L 245 29.09.2003, p. 0019-0021 Summary

Agency for the Evaluation of Medicinal Products: budget and finances, access to documents (amend. Regulation (EEC) No 2309/93)

PURPOSE : to present a proposal for amendment of the constituent acts of Community bodies following the adoption of the new financial regulation. **CONTENT** : the new Financial Regulation applicable to the general budget of the EC will enter into force on 1 January 2003 (see CNS/2000/0203). It presents a new approach concerning the budgetary and financial status of the decentralised Community Agencies. The most important novelties concerning Community Agencies are as follows: - Article 185: the Commission adopts a framework Financial Regulation applicable to the bodies set up by the Communities, having legal personality and which actually receive grants from the general budget (see CNS/2002/0902). The financial rules of these bodies may not depart from the framework Regulation unless specifically required for their operation and with the Commission's prior consent; discharge for the implementation of the budgets of the bodies is to be given by the European Parliament, acting on a recommendation by the Council; the Commission's internal auditor exercises the same powers over these bodies as over Commission departments; the above-mentioned bodies must apply the accounting rules established by the Commission's accounting officer so that their accounts can be consolidated with the Commission's accounts; - Article 46(3)(d) : the establishment plans of the bodies are to be decided by the general budgetary authority. These novelties require corresponding amendments to the legal acts establishing the Agencies concerned in order to implement the new system. These changes are the subject of the present proposals. In these proposals the Commission also tackles two further questions concerning the decentralised Community bodies. The first is connected with the current general reform process, viz. the question of transparency and public access to documents. The second question concerns the procedure for appointing the Directors of the Community bodies. Taking into account the above-mentioned development of the general recasting process, it is assumed that the new arrangements (Articles 185 and 46(3)(d)) will apply to the thirteen existing Community Agencies, namely: - the European Centre for the Development of Vocational Training (Thessaloniki); - the European Foundation for the Improvement of Living and Working Conditions (Dublin); - the European Environment Agency (Copenhagen); - the European Training Foundation (Turin); - the European Monitoring Centre for Drugs and Drug Addiction (Lisbon); - the European Agency for the Evaluation of Medicinal Products

(London); _ the European Agency for Safety and Health at Work (Bilbao); _ the Translation Centre for the Bodies of the EU (Luxembourg); _ the European Monitoring Centre on Racism and Xenophobia (Vienna); _ the European Agency for Reconstruction (Thessaloniki); _ the European Food Safety Authority; _ the European Aviation Safety Agency; _ the European Maritime Safety Agency; as well as to one body established under the Third Pillar, but treated as a traditional Community body in budgetary and financial terms, Eurojust. There are two decentralised Community bodies which do not receive grants from the general budget, namely the Office for Harmonisation in the Internal Market (Alicante) and the Community Plant Variety Office (Angers). They therefore do not fall within the definition of Article 185. However, they are affected by the proposals to bring their internal control mechanisms into line with the new Financial Regulation.?

Agency for the Evaluation of Medicinal Products: budget and finances, access to documents (amend. Regulation (EEC) No 2309/93)

By adopting the report by Mr Gianfranco DELL'ALBA (Ind, It), the European Parliament approved the proposal subject to amendments adopted by the committee responsible (please refer to the previous text). The vote on the draft legislative resolution was postponed pursuant to Rule 69. ?

Agency for the Evaluation of Medicinal Products: budget and finances, access to documents (amend. Regulation (EEC) No 2309/93)

The European Parliament adopted a resolution approving the Commission's proposal as amended during the sitting of 22/10/02. (Please refer to the document of that date).?

Agency for the Evaluation of Medicinal Products: budget and finances, access to documents (amend. Regulation (EEC) No 2309/93)

PURPOSE : to bring the constituent instruments of the European Communities decentralised bodies into line with the New Financial Regulation of June 2002 as well as with the Regulation relating to the access to public documents of May 2001. **LEGISLATIVE ACT** : Council Regulation 1647/2003/EC amending Regulation 2309/93/EEC laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of Medicinal Products. **CONTENT** : this Regulation aims to amend Regulation 2309/93/EC as regards the budgetary and financial rules applicable to the Agency, in order to bring it into line with the new general Financial Regulation that entered into force on 1 January 2003, and also as regards access to the Agency's documents, with a view to implementing within the Agency Regulation 1049/2001/EC of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council and Commission documents. **ENTRY INTO FORCE** : 01/10/2003.?