

3.5. *Article 8*

3.5.1. Explicit provision should be made for rigorous respect for the confidentiality of data and the utmost discretion regarding research under way.

3.6. *Article 9*

3.6.1. In cases where a trial is suspended or prohibited, the Member State should inform not only the Commission and the other Member States, but also the sponsor, before taking any decision.

3.7. *Article 10*

3.7.1. For investigational medicinal products, it would seem best to use the provisions on Good Manufacturing Practice (Directive 91/356/EEC) ⁽¹⁾.

3.8. *Article 13*

3.8.1. The Committee recommends that procedures and definitions be made consistent with the ICH text.

⁽¹⁾ OJ L 193, 17.7.1991.

Brussels, 28 January 1998.

*The President
of the Economic and Social Committee*
Tom JENKINS

Opinion of the Economic and Social Committee on the 'Proposal for a Council Regulation (EC) amending Council Regulation (EEC) No 1210/90 of 7 May 1990 on the establishment of the European Environment Agency and the European Environment Observation Network'

(98/C 95/02)

On 18 November 1997 the Council decided to consult the Economic and Social Committee, under Article 130s of the Treaty establishing the European Community, on the above-mentioned proposal.

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 6 January 1998. The rapporteur, working without study group, was Mrs Sánchez Miguel.

At its 351st plenary session (meeting of 28 January 1998), the Economic and Social Committee adopted the following opinion by 109 votes, with three abstentions.

1. Introduction

1.1. In application of the principle of transparency in the budgetary workings of EU bodies, the Commission proposes to amend nine regulations covering the so-called 'second-generation' agencies which, when created, were given different budgetary rules to those in force for the 'first-generation' agencies.

1.2. The first-generation agencies ⁽¹⁾ have a budget management and approval system under which the

European Parliament grants discharge to the Management Board, after consulting the Council. In the second-generation agencies ⁽²⁾, on the other hand, the Management Board grants discharge to the Executive Director, who is responsible for implementing the budget.

1.3. After reviewing the operation of these second-generation agencies, once established in their functions,

⁽¹⁾ Bodies set up in 1975: CEDEFOP (Thessaloniki) and the European Foundation for the Improvement of Living and Working Conditions (Dublin).

⁽²⁾ The European Environment Agency, the European Training Foundation, the European Monitoring Centre for Drugs and Drug Addiction, the European Agency for Safety and Health at Work, the Translation Centre for Bodies of the European Union, the Office for Harmonization in the Internal Market, the European Agency for the Evaluation of Medicinal Products, the Community Plant Variety Rights Office and the European Monitoring Centre on Racism and Xenophobia.

the Commission has concluded that the Regulations should be amended with regard to their budgetary discharge procedure.

2. General comments

2.1. The Commission points out that the Parliament has called for greater budgetary control over the second-generation bodies; the reason for this proposal is not however explained. It may consequently be understood as a measure to harmonize the two systems, with a view to the Parliament gaining the power of discharge.

2.2. The proposed amendments relate to:

2.2.1. The power of discharge, to follow the procedure laid down in Treaty Article 206, under which the Parliament, after consulting the Council, grants discharge to the Management Board.

2.2.1.1. A variant is introduced into the procedure for bodies which are entirely or largely self-financing from their own resources⁽¹⁾, to the effect that the Management Board grants discharge, on the recommendation of the Parliament.

2.2.2. The Commission envisages regulating agencies' own resources by integrating them with the Community's own resources, having noted that some agencies are entirely or largely financed from their own resources.

2.2.2.1. The difficulty lies in the fact that not all agencies with own resources obtain them in the same way: they may come from provision of consultation services, sale of publications or fees, etc. Nevertheless,

⁽¹⁾ The Office for Harmonization in the Internal Market, the European Agency for the Evaluation of Medicinal Products and the Community Plant Variety Rights Office.

as they are not profit-making bodies, they could set up reserves of these resources, provided that they do not exceed certain limits and that the Management Board, with the prior consent and approval of the Parliament, enters them in its accounts as such.

2.2.3. It is proposed that the Commission's Financial Controller should perform the budgetary control function for these agencies, thus complying with the principle of accounting independence and objectivity.

3. Specific comments

3.1. The amendment to Regulation 1210/90 affects Article 13(2) and (4). The current system corresponds to the second-generation agency model, in which the Management Board grants discharge to the Executive Director and appoints the Financial Controller.

3.2. The proposal introduces the system of a single discharge granted by the Parliament to the Executive Director on the recommendation of the Management Board. The ESC endorses the amendment insofar as it increases the objective nature of budgetary control, without the Management Board thereby losing any decision-making powers.

3.3. Paragraph 2 is amended to the effect that the Commission's Financial Controller is to be responsible for the control of the budget and expenditure. It should be pointed out that the European Environment Agency has already been doing this on a voluntary basis: in practice, therefore, there will be no change. The Agency's willingness to submit its annual accounts for external control is thereby confirmed.

3.4. To conclude, the ESC considers that any measure which further improves the current system and enables budgetary controls to be objective will help the proper functioning of Community bodies.

Brussels, 28 January 1998.

The President
of the Economic and Social Committee
Tom JENKINS