COMMISSION OF THE EUROPEAN COMMUNITIES



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COMMUNICATION FROM THE COMMISSION

The operating framework for the European Regulatory Agencies

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INTRODUCTION

In the White Paper on European Governance¹, the Commission affirmed that one possibility envisaged for improving the way rules and policy are applied across the Union was to use regulatory agencies. With this in view, criteria were needed for the creation, operation and supervision of such agencies under the current legal and institutional system.

In its Communication on "better lawmaking"², the Commission placed the use of regulatory agencies in the broader context of the exercise of the executive function and definition of the responsibilities of the institutions.

What is needed, if European Community action is to be more effective, coherent, legitimate and transparent, is for the institutions to be able to assume their responsibilities fully. To achieve this, their respective roles must be clearly determined and current practices changed where necessary.

In particular, the Commission sees a need to refocus on its core functions, with an emphasis on its executive responsibilities under the EC Treaty, when it comes to adopting the implementing measures for certain legislation at Community level. Obviously, these responsibilities must be performed within the limits defined by the legislation and subject to the appropriate control and monitoring arrangements put in place for the purpose. Furthermore, the legitimacy, effectiveness and credibility of the Community depend on preserving, even reinforcing the unity and integrity of the Community executive function and ensuring that it continues to be vested in the chief of the Commission, if the latter is to have the required responsibility vis-à-vis Europe's citizens, the Member States and the other institutions.

It is essential to keep this requirement in mind when considering the European regulatory agencies. By virtue of their nature and the tasks assigned to them, these agencies share in the executive function at Community level. Their participation must be organised in a way which is consistent and in balance with the unity and integrity of the executive function and the Commission's ensuing responsibilities.

To this end, the Commission would like to begin work with the European Parliament and the Council on defining the framework criteria for recourse to the agencies in question in the light of this fundamental requirement and the considerations set out below.

1. CONCEPT – REGULATORY AGENCY

Within the European Union's legal system, there are various decentralised organisations which can be grouped together under the general umbrella of European agencies. These

¹ COM (2001) 428, 25.07.2001.

² COM (2002) 275, 05.06.2002.

include 15 agencies created under the EC Treaty³, one under the Euratom Treaty⁴ and four under the second and third pillars of the European Union⁵. Two proposals for regulations creating further agencies are currently pending⁶.

These agencies have certain formal characteristics in common: they were created by regulation in order to perform tasks clearly specified in their constituent Acts, all have legal personality and all have a certain degree of organisational and financial autonomy.

However, their differences – in terms of internal structure, their relations with the institutions, responsibilities and powers - far outweigh their similarities. These differences arise from the fact that the agencies were created at different points in the past to meet specific requirements identified at the time. In other words, there is no single model for a European agency; there are several.

In view of these great differences, some specialists have suggested that existing agencies be classified by various criteria, such as the institutional and legislative frame of reference, the tasks they have been delegated and the executive powers they have been given, etc. Each classification envisaged is made up of several categories of agencies.

More pragmatic discussions conducted by the Commission have identified the profiles of two types of agencies: executive and regulatory ones.

Executive agencies are responsible for purely managerial tasks, i.e. assisting the Commission in implementing the Community's financial support programmes and are subject to strict supervision by it. The Commission has presented a proposal for a regulation to establish their general status in order to make it easier to set up an agency of this type whenever it is deemed to be suitable for implementing a specific programme. This proposal for a framework regulation is already at an advanced stage of examination by the Council after having elicited a favourable opinion from the European Parliament.

³ European Centre for the Development of Vocational Training (Regulation (EEC) No 337/73 of 10.02.75); European Foundation for the Improvement of Living and Working Conditions (Regulation (EEC) No 1365/75 of 26.05.75); European Environment Agency (Regulation (EEC) No 1210/90 of 07.05.90); European Training Foundation (Regulation (EEC) No 1360/90 of 07.05.90); European Monitoring Centre for Drugs and Drug Addiction (Regulation (EEC) No 302/93 of 08.02.93); European Agency for the Evaluation of Medicinal Products (Regulation (EEC) No 302/93 of 22.07.93); Office for Harmonisation in the Internal Market (Regulation (EC) No 40/94 of 20.12.93); European Agency for Safety and Health at Work (Regulation (EC) No 2062/94 of 18.07.94); Community Plant Variety Office (Regulation (EC) No 2100/94 of 27.07.94); Translation Centre for bodies of the European Union (Regulation (EC) No 1035/97 of 02.06.97); European Agency for Reconstruction (Regulation (EC) No 2454/1999 of 15.11.99); European Food Safety Authority (Regulation (EC) No 178/2002 of 28.01.02); European Maritime Safety Agency (Regulation (EC) No 1406/2002 of 27.06.02); European Aviation Safety Agency (Regulation (EC) No 1592/2002 of 15.07.02).

⁴ Euratom Supply Agency, Article 52 ff of the Euratom Treaty (see also the Statutes of the Agency, published in OJEC No 534, 06.12.58).

⁵ European Union Institute for Security Studies (Joint Action of 20.07.2001, OJEC No L 200, 25.07.01); European Union Satellite Centre (Joint Action of 20.07.2001, OJEC No L 200, 25.07.01). European Police Office-Europol (Convention of 26.07.95, OJEC No C 316, 27.11.95); Eurojust (Decision of 28.02.02, OJEC No L 63, 06.03.02).

⁶ Proposal for a Council Regulation laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes, COM (2000) 788, December 2000; proposal for a Regulation establishing a European Railway Agency, COM (2002) 23, 23.01.2002.

By contrast, regulatory agencies are required to be actively involved in the executive function by enacting instruments which help to regulate a specific sector. The majority of them are intended to make such regulation more consistent and effective by combining and networking at Community level activities which are initially a matter for the Member States. They are examined in detail in the White Paper on European Governance.

It should be stressed that some of the existing agencies in the Union — that also play an important part in the European system — do not fall into either of the above categories.

The concept of European Regulatory Agency designates agencies required to be actively involved in exercising the executive function by enacting instruments which contribute to regulating a specific sector.

2. **REASONS FOR THE FRAMEWORK**

The White Paper on European Governance proposes setting out a framework of conditions for the use of agencies, focusing on the regulatory agencies under the EC Treaty.

There are many factors in favour of this proposal.

Firstly, it is not possible to draw up a single framework covering all the prospective agencies, in view of the major differences between them. Nor is there any point in devising several different frameworks for the various categories of agencies. It is best therefore to concentrate on the above two types of agencies which are likely to play an important part at Community level in the immediate future in coping with the shortcomings the system is known to have. As mentioned above, a proposal for a regulation has accordingly been presented for the executive agencies but nothing of this nature is in the pipeline for the regulatory agencies as yet.

Secondly, the conditions for the creation, operation and supervision of the regulatory agencies need to be more coherent and transparent than they are at present. At the moment, even within this fairly restricted category, there are differences in the internal structures, such as the composition and method of appointing the governing bodies; in their relations with the institutions, for example the role played by the Commission; and, especially, in their responsibilities and powers. In the case of the latter, looking only at the existing agencies under the EC Treaty, a distinction can be made between:

- those whose function is primarily to provide assistance in the form of opinions and recommendations, which provide the technical and scientific basis for the Commission's decisions (cf. European Agency for the Evaluation of Medicinal Products and the European Food Safety Authority);
- those primarily providing assistance in the form of inspection reports, intended to enable the Commission to meet its responsibilities as "guardian" of Community law (cf. the European Maritime Safety Agency);
- those empowered to adopt individual decisions which are legally binding on third parties (cf. Office for Harmonisation in the Internal Market, Community Plant Variety Office and the European Aviation Safety Agency).

Thirdly, criteria should be defined once and for all which guarantee greater effectiveness of the agencies' activities while ensuring that the agencies themselves fit in fully with the general scheme of the Treaty and its fundamental principles.

In other words, an appropriate framework will make for a coherent approach to creating future regulatory agencies, by providing for an internal organisation which is up to the tasks the agency will be called upon to perform. It will also facilitate the decision-making process involved in the creation of each individual agency, by guaranteeing that its sound organisation and operation are not prejudiced by tactical considerations connected with particular sectors or interests. And, finally, use of agencies as an executive instrument will be governed by greater transparency vis-à-vis Europe's citizens.

With regard to the above, it should be stressed that the framework in question is not intended to apply directly to agencies which do not come under the heading of regulatory agencies or any agencies which might be set up outwith the institutional framework of the EC Treaty.

3. BASIS OF THE OPERATING FRAMEWORK

Although, generally speaking, executive responsibility for Community policies is delegated to the Member States and their internal administrative bodies, in certain cases the Treaties or Community legislative acts require executive tasks to be implemented centrally at European level to ensure coherence and proper functioning of the policies concerned or to maintain fair competition, in order to increase confidence among the operators concerned and the public in general.

In such cases, it is up to the Commission, as the institution normally responsible for the executive function, to ensure that these tasks are accomplished correctly and effectively. This does not necessarily mean, however, that it must always act alone, particularly in view of its limited resources, the upcoming enlargement and the future reforms of the Union's institutional system.

In certain cases, therefore, the Community legislator may consider it better to delegate certain clearly defined tasks to European regulatory agencies with the competence needed to achieve the aims pursued by the legislation in question. In particular, this would make the executive more effective at European level in highly specialised technical areas requiring advanced expertise and continuity, credibility and visibility of public action.

Clearly, these agencies fulfil a very important public service function. Their structure must permit them to perform that function correctly. It is particularly important that they should have genuine autonomy in their internal organisation and functioning if their contribution is to be effective and credible. The independence of their technical and/or scientific assessments is, in fact, their real raison d'être. The main advantage of using the agencies is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations.

Given this autonomy, the regulatory agencies must also be accountable to the institutions, operators concerned and more generally the public. This also means that the agencies' activities need to be fully transparent so that the various players concerned can effectively monitor their operations.

However, as stated in the introduction, use of the regulatory agencies must be in accordance with the basic principles on which the system of the Union is founded. This means respecting

the balance of powers between the institutions under the Community method. In particular, the unity and integrity of the executive function at European level must be preserved, as must the Commission's capacity to assume responsibility for the satisfactory general exercise of that function. This affects the scope of the responsibilities and powers which can be delegated to the regulatory agencies, and the relations between these agencies and the Commission.

Whether a regulatory agency should be used in a specific case will always be up the legislator, on the Commission's initiative, to decide, via the adoption of a specific legislative instrument governing the organisation and functioning of the agency and its relations with the institution and with the operators concerned.

Nevertheless, for the reasons given above, it is essential for the European Parliament, the Council and the Commission — as their respective roles in the legislative process demand — to commit themselves to respecting certain criteria and conditions when creating individual new regulatory agencies, in order to contribute to improving the European Union's system of governance. The framework conditions for the use of regulatory agencies will be defined with these considerations in mind, via an appropriate legal instrument.

The Commission must ensure that the unity and integrity of the executive function at Community level is safeguarded.

For certain, clearly specified tasks, legislative provision may be made for the regulatory agencies to participate in exercising this executive function.

In discharging their public service responsibilities, the agencies must have a certain degree of organisational and functional autonomy and be accountable for the action they take. Their activities must be transparent.

The agencies' role and activities must form a coherent part of the Community's institutional system. Their autonomy must be compatible with the unity and integrity of the executive function, to ensure that the Commission is able to assume its general overall responsibility.

4. CONTENT OF THE FRAMEWORK

The criteria governing the regulatory agencies must be based, on the one hand, on the need to foster their independence, competence and credibility whilst ensuring that they are accountable and transparent; and, on the other, on the need to reconcile this with the Commission's overall responsibility, which must include the possibility of intervention by the latter in the event of serious dysfunction which could prejudice the integrity of the European executive function.

The various elements to be incorporated into this framework are set out below. Many of the observations are based on experience with the current regulatory agencies.

4.1. Creation of the agencies

Legislative act — As emphasised above, the creation of individual regulatory agencies must be at the explicit choice of the legislator, whose responsibility it is to determine the conditions for implementation at European level of certain specific instruments.

Legal basis — Since the regulatory agency is an instrument of implementation of a specific Community policy, it follows that the legal instrument creating it must be based on the provision of the Treaty which constitutes the specific legal basis for that policy. This was the approach adopted when creating the most recent regulatory agencies in the fields of food safety and transport, which represented a break with the previous system of automatically using Article 308 of the EC Treaty as the legal basis. Of course, in the current institutional framework, when the legal basis for a specific action is Article 308 itself, the instrument setting up the agency must also be based on this provision⁷.

Legal personality — Each regulatory agency must have legal personality as is currently the case with all the existing agencies. This both strengthens the agencies' independence and gives them a higher profile in the Community legal system.

Location — The constituent Acts of most of the existing agencies did not make any specific provision concerning the location of their headquarters. In these cases, the decision was taken by the Heads of State and Government, applying by analogy Article 289 of the EC Treaty concerning the seat of the institutions of the Community.

This practice is not without its disadvantages, as illustrated by the failure to reach a decision on the headquarters of certain agencies at the Laeken European Council in December 2001. It has also caused certain administrative and practical problems, particularly at the delicate startup stage of the agencies' activities: problem of selecting a provisional location, problem of recruiting staff when the final location of the headquarters is not known, additional cost and practical difficulties in switching activities to the definitive location.

Given these problems and the fact that, in the final analysis, determining the seat of an agency is part and parcel of its creation, it would seem reasonable to include such provision in the instrument establishing each agency.

Each regulatory agency must be created by a specific legislative instrument, on a proposal from the Commission.

The legal basis for that instrument shall be the provision of the EC Treaty which constitutes the specific legal basis for the policy the agency in question will be called upon to implement.

Each agency must have legal personality.

The seat of each agency must be specified in the instrument of establishment.

4.2. Functioning of the agencies

Powers — Experience has shown that, within the category of European regulatory agencies, their responsibilities and powers can differ⁸.

Generally speaking, these agencies may be given tasks which involve only assistance, such as drawing up opinions or studies so that the Commission can prepare legislative proposals or take specific decisions, carrying out or coordinating checks and inspections at certain operators so that the Commission can fulfil its role as the "guardian" of Community law, and

⁷ See examples of regulations on Community industrial property rights.

⁸ See examples of the existing Community agencies given in section II above.

any other tasks to assist the institutions which may be necessary to carry forward various Community policies. Such assistance may also involve external aspects of certain policies, whereby these agencies take part in international cooperation activities without encroaching on the Commission's exclusive responsibility in that area.

Under certain conditions, granting regulatory agencies their own decision-making powers might also be envisaged. However, it is essential to stress that the principles governing the current Community legal order impose constraints on the scope of such powers. These agencies may, for example, be empowered to adopt individual decisions in a clearly specified area of Community legislation but not legislative measures of general application, although their decision-making practices might result in codifying certain standards⁹.

In practice, each regulatory agency would normally be responsible for a variety of tasks which means that any classification based on them would tend to be artificial. For the purposes of the framework in question, a distinction can be made between the decision-making agencies, i.e. those empowered, inter alia, to enact legal instruments binding on third parties, and executive agencies, i.e. those which have no independent power of decision vis-à-vis third parties but perform all other regulatory tasks, including the organisation and coordination of activities which, in part, fall within the remit of national authorities in order to enable the Commission to discharge its duties.

In view of this distinction, it may be appropriate to provide for operating and control criteria specific to each of these two types.

Scope – As stated above, particularly appropriate areas for intervention by regulatory agencies are those of high technical specialisation which, on the one hand, require specialised skills and expertise which are not available in an administration like the Commission and, on the other, must allow the agencies the margin of autonomy needed for their technical and scientific appraisals.

In view of considerations in connection with both the purely technical nature of the agencies and, more generally, the principles on which the Community legal order is based, the White Paper on European Governance placed further restrictions on the decision-making agencies' scope for action, authorising them to intervene only in areas where a single public interest predominates and in areas where the agencies are not called upon to arbitrate on conflicting public interests, exercise any powers of political appraisal or conduct any complex economic assessments. Neither can they be delegated responsibilities for which the EC Treaty has conferred direct power of decision on the Commission (for example in the field of competition or, *mutatis mutandis*, in infringement proceedings under Articles 226 to 228 of the EC Treaty).

Administrative board – The regulatory agency's administrative board must have responsibility for defining the agency's general operating guidelines within the legal framework established by the legislator and the regulatory measures adopted by the Commission. In particular, it should be responsible for adopting the agency's work programme and rules of procedure, and play a central role in the adoption of its budget. In the case of the executive agencies, given that the Commission must have a guarantee that the work programme will enable it to discharge its own responsibilities correctly, these procedures must be subject to the Commission's prior agreement.

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See the tasks attributed to the European Agency for Aviation Safety.

The administrative board must also deal with the agency's internal administrative matters; for example, it must be involved in the appointment of the Director and the members of the agency's other bodies.

The existing agencies have taken differing approaches to the composition of the administrative board¹⁰, but their experience is not necessarily of value where it is a question of preserving the unity and integrity of the executive function at European level, essentially because they fail to take sufficient account of the Community dimension. This consideration, and the need for the agencies to function effectively with the upcoming enlargement, argues in favour of a smaller administrative board which reflects the executive at Community level, while taking account of the expertise of the Member State executives. It would also be of benefit to include representatives of the interested parties, so that the views of both the economic players in the sector in question and the persons affected by the agency's activities could be taken into account, provided that this does not give rise to any conflicts of interest and is not likely to undermine proper management of the agency. This would ensure greater transparency and might enhance public confidence.

On this basis, a 15-member administrative board could be envisaged, including six representatives appointed by the Commission and six by the Council — representing the national executives — and three, with no voting rights, representing the interested parties.

Appointment of members by the European Parliament, on the other hand, would seem inappropriate in view of the nature of the regulatory agencies' work and the fact that the Parliament must be free to exercise external political supervision over their activities, without feeling tied by its membership of the administrative board.

<u>*Director*</u> – The Director must have overall charge of the agencies' operational tasks and is hence responsible for adopting individual decisions in the case of the decision-making agencies and, depending on the legal framework, preparing or organising opinions, studies and other contributions in the case of the executive agencies.

The Director would have to be given technical and scientific assistance to discharge these responsibilities. In certain cases he would be assisted by the agency's staff and in others it would be necessary to provide for specific advisory bodies set up within the agency, which might take the form of a restricted executive board and an advisory committee. The advisory committee would be made up of independent experts appointed by the administrative board in accordance with predetermined and transparent criteria and would be responsible for drawing up technical and scientific opinions within a legal framework which would duly safeguard its powers of independent judgement. The restricted executive board would be made up of the chairman of the Advisory Committee and several senior officials of the agency and would be responsible for giving the director an opinion in specific cases, such as on highly sensitive subjects or if major differences of opinions arose in the Advisory Committee.

The Director must also be responsible for preparing discussions within the administrative board and for representing the agency. In the latter role, it is up to him to maintain suitable

¹⁰ While, in most cases, the administrative board is composed of one (or two) representative(s) of each Member State and of the Commission, some include members appointed by the European Parliament or the social partners. The administrative board of the European Food Safety Authority is a special case, being composed of one Commission representative and 14 members appointed by the Council, in consultation with the Parliament, on the basis of a list drawn up by the Commission, four of whom must have experience of working within consumer organisations and other operators concerned.

relations with the bodies that the agency has dealings with and especially the Community institutions.

The procedure for appointment/dismissal of the Director should differ according to the type of agency. In the case of the executive agencies, appointment should be by the administrative board on the basis of a list of candidates put forward by the Commission. For the decision-making agencies, however, appointment — and dismissal, if necessary, on the basis of a transparent procedure specifying the grounds — should be by the Commission on the basis of a list of candidates put forward by the administrative board. Making the Commission the basis of a list of candidates put forward by the administrative board. Making the Commission the appointing authority in the latter case — which, to an extent, marks a departure from the existing situation¹¹ — is necessary if it is to assume its responsibility for the executive function at European level effectively while respecting the autonomy of the decision-making agency. The agency Director would thereby retain the entire margin of discretion in decision-making recognised under the applicable legislative and regulatory framework. He must, however, as a general principle, be capable of gaining and maintaining the confidence of the administrative board and, especially, of the Commission, as the authority ultimately in charge of implementation.

At all events, in order to consolidate the agency's authority, it is appropriate to make formal appointment of candidates for the post of Director dependent on a hearing before the European Parliament.

Boards of appeal – Provision should be made in decision-making agencies' internal organisation for boards of appeal to deal with any complaints by third parties arising from decisions they adopt, as is already the case with the Office for Harmonisation in the Internal Market, the Community Plant Variety Office and the European Aviation Safety Agency. These appeal boards would act as an initial internal control, independent of the decisions taken by the agency director, prior to any referral to the Court of First Instance.

The specific rules governing the composition and procedure of these boards should be defined by the legislator, and possibly supplemented by implementing measures adopted by the Commission. The basic requirement is that they can make an independent judgement. The criteria for selection and appointment of their members must ensure that this requirement is met.

Financial and budgetary aspects – The new Community Financial Regulation applicable to the European Communities' general budget¹² provides for specific rules applying to agencies. Specifically, Article 185 of the Regulation contains provisions which are directly applicable to discharge of the agencies' budgets, their audits and their accounting rules. The Article also requires the Commission to adopt a framework Financial Regulation which, in principle, applies to all the Community agencies that receive subsidies from the European Communities' budget. Obviously, the provisions contained in these texts must be taken into account in the framework in question; in particular, financial regulation of a regulatory agency must comply with the above framework Regulation unless the specific requirements of this agency dictate otherwise and the Commission has given prior approval.

¹¹ The Director is appointed by the Commission only at the European Centre for the Development of Vocational Training and the European Foundation for the Improvement of Living and Working Conditions, both created in 1975, which cannot be considered as regulatory agencies in the sense described above.

¹² Regulation (EC, EURATOM) No 1605/2002 of 25.6.02.

Furthermore, it is particularly important to provide for a straightforward procedure for drawing up the regulatory agencies' budgets, according to which the Director prepares the draft budget, which is then examined and approved by the administrative board, after ensuring that it has the Commission's approval, in the light of the decisions taken in connection with the Communities' general budget. Discharge must be given by the European Parliament at the Council's recommendation.

Concerning the agencies' revenue, the – at least partial – subsidy element from the general budget should be generalised in view of the importance of the regulatory agencies' public service mission. Self-financing of agencies, through fees paid for services rendered to the operators concerned, would also be justified, following the example of some existing regulatory agencies. However, to ensure that they remain impartial and are not unduly influenced by operators, mechanisms are needed to keep the agencies financially independent of such revenue. Finally, in certain cases, contributions from the Member States might also be envisaged.

Other administrative aspects – The EC Treaty and certain acts of secondary legislation impose a number of obligations on the institutions, which generally relate to principles of sound administration. These include, for example, principles in respect of operators' right to be heard and to present counter-arguments prior to the adoption of any decisions detrimental to their interests, the obligation to justify instruments, provisions on transparency and access to documents, rules on personal data protection and business confidentiality, on protection of the Community's financial interests, on combating fraud, corruption and any other illegal activity which is harmful to the interests of the Community.

Given that the regulatory agencies participate actively in the executive function, the public and the Member States can legitimately expect them to be equally subject to the Community's principles and rules on sound administration, including those on the use of languages. Provision is therefore needed imposing similar obligations on these agencies relating to all their activities.

For the purposes of this framework, the regulatory agencies can be divided into decision-making agencies empowered, inter alia, to enact instruments binding on third parties, and executive agencies responsible for performing various executive tasks to assist the Commission in the discharge of its responsibilities but without any real decision-making powers.

The decision-making agencies may adopt individual decisions but not legislative measures of general application.

The use of regulatory agencies is appropriate in areas of high technical specialisation.

Use of decision-making agencies is restricted to areas where a single public interest predominates and where they do not have to arbitrate on conflicting public interests, exercise powers of political judgement or make complex economic assessments. These agencies may not be granted responsibilities for which the EC Treaty confers decision-making power directly on the Commission.

The agency's administrative board should be responsible for defining its general operating guidelines (work programme, rules of procedure, budget, appointment of the Director and the members of the agency's other bodies). Its composition must reflect the agency's position in the Community executive, while taking account of the expertise of the national executives and, under certain conditions, the point of view of interested parties.

The agency's Director should have responsibility for operational tasks (adopting individual decisions, preparing opinions and studies, representing the agency and relations with Community institutions). In discharging his duties, he may be assisted, as appropriate, by agency staff, a restricted executive board or an advisory committee, which may be required to prepare independent technical and scientific opinions.

Appointment of the Director should be by the administrative board or by the Commission, as appropriate. To reinforce the agency's authority, the European Parliament should be involved in the appointment procedure.

The internal organisation of the decision-making agencies should include boards of appeal to provide an initial internal control function while remaining independent of decisions.

Article 185 of the new general Financial Regulation contains provisions directly applicable to the agencies' financial and budgetary aspects. The framework Financial Regulation for the agencies drafted by the Commission must also be taken into account. Moreover, a straightforward procedure is needed for drawing up the agency's budget. This budget should be supplemented by a subsidy from the general budget of the European Communities and, where appropriate, by revenue from fees for services rendered to interested operators, whilst ensuring that the agencies are not unduly dependent on such revenue. In certain cases, contributions from the Member States might be envisaged.

Certain principles and rules of sound administration (operators' rights to a hearing and to present counter-arguments, obligation to justify instruments, access to documents, protection of personal data and business confidentiality, protection of the Communities' financial interests, combating fraud and corruption and language rules) must be made applicable to the agencies.

4.3. Controls

As emphasised above, the autonomy conferred on the regulatory agencies also requires them to assume clear responsibilities. It is therefore essential that they should be subject to an appropriate control system.

Relations with the Commission – Firstly, for the reasons given above, provision needs to be made for special relations with the Commission.

Obviously, this is not a question of giving the Commission powers of legal supervision; i.e. empowering it to issue instructions to the regulatory agencies or quash or oblige them to withdraw certain individual decisions.

It is a question rather of establishing a coherent framework for relations which reconciles the agencies' autonomy with the Commission's ultimate responsibility within the Community system. Reference has already been made to the role the Commission must have in appointing the agency's Director; in adopting the work programme and the budget; and, indirectly, in the

other affairs of the agency's administrative board, through the members it appoints. Article 185 of the general Financial Regulation has already been mentioned, which provides that audits of the agencies must be performed by the Commission's internal auditor.

To this should be added, on the one hand, a mention of the Commission's obligation to act as the "guardian" of Community law, which requires that it must able to take action to ensure that the agencies comply with the provisions under this law as regards, say, application of the staff regulations of Community officials to agency personnel. On the other hand, the Commission must be able to take steps to ensure that its overall responsibility for implementation of the European Communities' general budget, as laid down in Article 274 of the EC Treaty, is not encroached upon by any action taken by the agencies.

Administrative supervision – In accordance with Article 43 of the Charter of Fundamental Rights of the European Union, provision should be made subjecting the regulatory agency to administrative supervision by the European Ombudsman, in accordance with the conditions set out in Article 195 of the EC Treaty.

Political supervision – The European Parliament and the Council should have certain powers of political supervision over the regulatory agencies. There could, for example, be a requirement for hearings of the agency Directors by these institutions and for the agencies to draw up regular reports on their own operation.

Financial supervision – Implementation of the regulatory agencies' budget must be subject to control initially by the Court of Auditors, pursuant to Article 248 of the EC Treaty, and subsequently by the European Parliament under the discharge procedure for the agency's budget.

The regulations on the investigative powers of the European Anti-Fraud Office (OLAF) should also be made applicable, without restrictions, to these agencies.

Judicial supervision – Guarantees are needed ensuring that the regulatory agencies respect the principles of the institutional system of which they form a part, and the specific regulations applicable to them. Provision must therefore be made for appeal by the Member States or the institutions to the Court of Justice for confirmation of any breach of these principles and rules by the agencies and annulment of any acts vitiated by such breaches.

More specifically, in the case of the decision-making agencies, compliance with the general legality principle includes the requirement to provide for appeal by interested third parties to the Court of First Instance or, in the future, to a specialised tribunal, to request the annulment of decisions taken by the agency – possibly reviewed by the internal boards of appeal – in respect of those third parties, or for a declaration of failure to act, in the event of unjustified absence of a decision.

Finally, the regulatory agencies must assume legal responsibility for acts attributable to them. Consequently, provision must be made for compensation by them for any damages caused by such acts, where appropriate after judicial confirmation of their liability.

To ensure that the activities of the regulatory agencies are consistent with the Community executive function, provision must be made for special relations between them and the Commission: in addition to the existing proposals (direct participation in the appointment of the Director and in the adoption of certain acts of major importance, participation on the administrative board, performance of audits), provision must be made ensuring that the Commission can exercise its role as the guardian of Community law and its overall responsibility for implementation of the Community budget.

The agencies should be subject to the administrative supervision of the European Ombudsman.

They should be subject to political supervision by the European Parliament and the Council (hearings of the Director, activity reports).

They should also be subject to financial supervision by the Court of Auditors and the European Parliament. The regulations on the investigative powers of OLAF must be made applicable to the agencies without restrictions.

Any binding acts adopted by the agencies must be subject to judicial supervision, by providing for the Member States, the institutions and the third parties concerned to appeal for annulment. The latter must also be able to bring a failure to act action against the agencies, and action for damages arising from acts attributable to the agencies.