



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.02.2005
COM(2005)59 final

Draft

INTERINSTITUTIONAL AGREEMENT

on the operating framework for the European regulatory agencies

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT AND OBJECTIVES

The European agencies have been set up in successive waves in order to meet specific needs on a case-by-case basis. They are typified by their diversity. If these agencies are set up in an uncoordinated manner, without a common framework having been defined, this is likely to result in a situation which is rather untransparent, difficult for the public to understand, and, at all events, detrimental to legal certainty.

In its White Paper on European Governance ⁽¹⁾, the Commission proposed that, in accordance with the principles of good governance a framework should be established setting out the conditions relating to the creation, operation and control of “regulatory” agencies ⁽²⁾, which help to improve the implementation and application of Community legislation.

Coherence: By adopting a horizontal approach, the aim is to ensure compliance with a minimum common core of principles and rules on the creation, operation and control of these agencies. Their involvement in exercising executive powers must be organised in a coherent and balanced way which takes account of the need to preserve the unity and integrity of this function at Community level.

Effectiveness: The credibility of these agencies rests largely on their effectiveness. They must be organised in such a way that they can perform the tasks devolved on them effectively. The principle of effectiveness essentially involves simplifying the decision-making process, cutting costs and giving these agencies a certain degree of organisational, legal and financial autonomy.

Accountability: The independence of these agencies goes hand in hand with an obligation to meet their responsibilities. In order to strengthen the legitimacy of Community action, it is important to establish and delimit the responsibilities of the institutions and agencies. The decision to set up these agencies must be taken prudently on the basis of an impact assessment conducted by the Commission. This impact assessment must be as thorough and rigorous as possible. Moreover, the principle of accountability requires that a clear system of controls be put in place.

Participation and openness: The agencies must also be organised internally in such a way as to guarantee the participation of interested parties and a high level of transparency. The acts establishing these agencies must stipulate that, like the European institutions, they will be subject to the requirements of good administration.

2. CONSULTATION OF THE OTHER INSTITUTIONS AND OTHER INTERESTED PARTIES

In December 2002, the Commission adopted a Communication which, on the basis of these principles, paves the way for a future operating framework for the European regulatory

⁽¹⁾ COM(2001) 428, OJ C 287 of 12.10.2001, p. 1.

⁽²⁾ A framework regulation has already been adopted for “executive” agencies which are responsible for management tasks, i.e. helping the Commission to implement financial programmes (Council Regulation (EC) No 58/2003 of 19.12.2002, OJ L 11 of 16.1.2003).

agencies ⁽³⁾. It was welcomed by the Parliament ⁽⁴⁾ and the Council ⁽⁵⁾. The directors of the existing agencies were also consulted.

3. CHOICE OF LEGAL INSTRUMENT: INTERINSTITUTIONAL AGREEMENT

The Commission has proposed an interinstitutional agreement to ensure that the three institutions are involved from the outset in establishing the basic conditions to be met when acts are subsequently adopted to set up sectoral agencies. Under the case law of the Court of Justice, it will be possible for the interinstitutional agreement to be binding insofar as its content shows that the three institutions intend to enter into a commitment towards each other ⁽⁶⁾. The fact that this type of legal instrument has been chosen does not rule out the possibility of more detailed arrangements subsequently being concluded as part of a framework regulation.

4. SCOPE

Because of the diversity of the tasks and the structures of the existing agencies, the Commission proposed in its Communication that an operating framework should initially be established for those European regulatory agencies which are set up in future under the EC Treaty. It would be difficult, if not impossible, to incorporate both the future agencies and the diverse range of agencies already in place within a common operating framework from the outset. The risk would be that this would considerably slow down the adoption process and would undermine legal certainty, particularly for the agencies set up recently. For the same reasons, the agreement is not meant to apply from the outset to agencies created outside the framework of the EC Treaty.

The Council and the Parliament have given their support to the use of a selective time frame. The Parliament has pointed out that discussions should also be held concerning the existing agencies and the EU agencies and proposals put forward as to how they could be altered.

The interinstitutional agreement therefore also stipulates that, as a second step, the institutions will explore under what arrangements its scope could be extended to existing European regulatory agencies and, where necessary, to other agencies. In the meantime, there is no reason why any future revision of each basic act should not be guided by, or even incorporate, some of the principles, rules and procedures in the operating framework.

5. LEGAL BASE

Given that the European regulatory agency is an instrument for implementing a particular Community policy, its basic act must be built on the provision of the EC Treaty which forms the specific legal basis of the policy in question. This is the approach adopted with respect to the agencies set up most recently.

⁽³⁾ Communication from the Commission of 11.12.02 on the operating framework for the European regulatory agencies (COM(2002)718).

⁽⁴⁾ Resolution of 13.01.04, P5_TA(2004)0015.

⁽⁵⁾ Conclusions of 28.06.04, Doc. 17046/04.

⁽⁶⁾ Judgment of 19.03.96, Commission -v- Council, case C-25/94, ECR I-1469.

However, the agreement also makes provision for Article 308 of the EC Treaty to be used as a legal base in exceptional cases.

6. SEATS OF THE AGENCIES

The Council, while referring in its conclusions to the practical application of the agreement by all the Member States at the level of the Heads of State and Government, acknowledged that the agency's seat should be chosen at the earliest opportunity.

So far, almost all the decisions concerning the seats of the agencies have been taken en bloc, at ten year intervals, by the Heads of State and Government at the occasion of European Council meetings. Negotiations of this kind on "packages" of issues have led to serious delays in the effective establishment of a number of agencies, which have been set up temporarily in Brussels for an *a priori* indefinite period. This approach is at the root of a number of administrative and practical problems which have arisen during the start-up phase: problems concerning the recruitment of staff, additional costs, practical problems with moving to another location, difficulties of access, etc.

Like the Parliament, the Commission also feels that the agency's seat is a constituent element of the basic act and should therefore be included in it.

Without denying the Member States the right to decide the agency's seat at the highest political level, the Commission therefore proposes that this decision be taken in time so that it can be incorporated into the basic act. Failing that, the Commission proposes that a decision be taken within six months at the latest.

7. DEFINITIONS AND TASKS

A number of different factors must be taken into account in order to establish a working definition of regulatory agencies:

7.1 THE "REGULATORY" CONCEPT

A distinction must be made between "regulatory" activities and the adoption of legal rules or binding legal norms which are applicable across the board. Regulatory activities do not necessarily involve the adoption of legal acts. They may also involve measures of a more incentive nature, such as co-regulation, self-regulation, recommendations, referral to the scientific authority, networking and pooling good practice, evaluating the application and implementation of rules, etc. It therefore follows that a European "regulatory" agency does not necessarily have the power to enact binding legal norms.

7.2 TASKS DEVOLVED ON THE AGENCIES

In keeping with the regulatory concept defined above, these agencies may be assigned one or more of the following tasks:

- a. adopting individual decisions which are legally binding on third parties;

- b. providing direct assistance to the Commission and, where necessary, to the Member States in the interests of the Community, in the form of technical or scientific advice and/or inspection reports;
- c. creating a network of national competent authorities and organising cooperation between them in the interests of the Community with a view to gathering, exchanging and comparing information and good practice.

Each European regulatory agency will also be responsible for gathering, analysing and forwarding objective, reliable and easy-to-understand information concerning its area of activity.

7.3 EXECUTIVE RESPONSIBILITIES

By accomplishing these tasks, the agencies will take an active part in exercising executive powers at Community level:

The agencies which adopt individual decisions will be given the power to implement laws. However, this power will be limited to applying the rules of secondary legislation to specific cases, in accordance with the institutional system and the case law of the Court of Justice ⁽⁷⁾.

The other tasks allocated to the agencies must allow them to provide the Commission, in particular, with the experience and expertise it needs so that it can fully meet its responsibilities as the Community executive.

7.4 Structural autonomy

The autonomy of European regulatory agencies is the key to their effectiveness and credibility in the long term. It must allow them to take account of all the information concerning their environment while freeing themselves as far as possible from external influence. Particularly with regard to the technical and scientific assessments they must make, it is important that they be given a significant degree of autonomy in their dealings not only with the EU institutions but also with the Member States and the operators themselves.

7.5 Conclusion

A European regulatory agency may therefore be defined as an independent legal entity created by the legislator in order to help regulate a particular sector at European level and help implement a particular Community policy. By performing its tasks, it helps to improve the way in which the rules are implemented and applied throughout the EU. It thus plays an active role in exercising executive powers at Community level.

8. AUTONOMY AND CONTROLS

The provisions of the interinstitutional agreement are based on a delicate balance between the need for autonomy and the need for controls.

⁽⁷⁾ Judgment of 13.06.58, in case 9/58, Meroni, ECR 1958, p. 11; judgment of 14.05.81, in case 98/80, Romano, ECR 1981, p. 1241.

8.1 Autonomy

The need for autonomy (see point 7.4) takes several forms: granting of legal personality, budgetary autonomy, collective responsibility and own powers of the administrative board (hereinafter referred to as the "AB"), the independence of the director, of the members of the scientific committees and of the boards of appeal, etc.

8.2 Evaluations and controls

The autonomy of these agencies goes hand in hand with an obligation to meet their responsibilities. These agencies which exercise autonomous responsibility in the executive sphere are therefore directly accountable to the institutions, the Member States and European citizens. Thus the principle of accountability demands that these agencies are subject not only to *ex ante* and *ex post* evaluations but also to clear control mechanisms.

Evaluations

The Commission will justify any proposal to set up one of these agencies on the basis of a rigorous impact assessment. All possible alternatives must first be explored: the Commission could take responsibility for the activities envisaged, the tasks of an existing agency could be extended, an office or executive agency could be set up and/or individual tasks could be subcontracted.

Once the agency has been set up, both it and the Commission will carry out regular evaluations of its activities and operations. On this basis, the Commission may propose revising or, where appropriate, repealing the basic act.

Controls

Budgetary control, internal audits, annual reports by the Court of Auditors, the annual discharge for the execution of the Community budget and the investigations conducted by OLAF will make it possible to ensure, in particular, that the resources allocated to the agencies are put to proper use.

Administrative control will ensure that a number of procedural safeguards are put in place so that account is taken of the interests of interested parties and the quality of output.

Political control will be exercised both by the legislative authority and by the Commission.

Judicial control will be exercised by the Court of Justice (after any internal remedies have been exhausted — see point 9.4).

9. STRUCTURE

The structure of the agencies must allow them not only to perform the tasks devolved on them effectively but also to respect the delicate balance between autonomy and control.

9.1 Administrative board

The tasks of the AB will be those which are traditionally assigned to the programming and monitoring body.

It emerged from the discussions with the Parliament and Council on the basis of the Communication that there could not be a single formula for the composition of the ABs. However, it is imperative that the principles of good governance are applied:

1. The principles of accountability and coherence demand that the composition of the AB reflects the agency's position with regard to the distribution of powers between the executives at Community and national levels.
2. The principle of effectiveness and cost reduction calls for an AB with a limited number of members.
3. The principles of participation and openness require the involvement of interested parties.

Parity of executives

The agency's involvement in exercising executive powers at Community level calls for the equal representation of the two branches of the Community executive within the AB. The aim of equal representation is to struck a proper balance between pursuing Community objectives and taking account of national interests.

Representation of the Member States

The tasks devolved on the agency do not, in principle, mean that all the Member States should be represented on the AB. However, this may be justified if the agency, in the interests of the Community, is also involved in the exercise of executive powers by the Member States. The agency will thus enable the Member States to fulfil the obligations arising from Community law in accordance with Article 10 of the EC Treaty

In this case, the Council will designate a representative from each Member State. Each of whom will have one vote. In order to maintain parity of the executives within the AB, the institutions agree to grant an equal number of votes in total to the members designated by the Council and to those designated by the Commission.

Parliament

On the other hand, it is not envisaged that members designated by the Parliament should participate in the AB because this would cast doubt on the Parliament's ability to perform external controls objectively, particular in its capacity as the discharge authority.

Participation of interested parties

In order to guarantee a high level of transparency, the interested parties may be authorised to participate as members, but without the right to vote, in deliberations of the AB.

9.2 Executive board

In order to enhance the agency's effectiveness, an executive board with a limited number of members may be created in cases where the size of the AB does not allow it to perform the tasks devolved on it effectively. In that case, the delegation of tasks to the executive board will be strictly defined in the basic act.

9.3 Director

In order to ensure the effectiveness and independence of the agency in its day-to-day-management and in its activities, the director will assume full responsibility for the operational tasks assigned to the agency and will be the agency's legal representative.

As already mentioned, the composition of the AB will reflect the agency's position with regard to the distribution of powers between the Community and national executives. In this connection, provision may be made for a single procedure for appointing the director, with the AB appointing the director on the basis of a list of candidates proposed by the Commission.

Before being appointed, the candidate selected by the AB may be asked to attend a hearing before the competent committee of the Parliament.

9.4 Other bodies

If the agency is to perform the tasks devolved on it effectively, other bodies, such as a coordinating body or bodies, scientific committee(s) and/or committee(s) of experts and board(s) of appeal, may need to be set up.

Draft

INTERINSTITUTIONAL AGREEMENT

on the operating framework for the European regulatory agencies

THE EUROPEAN PARLIAMENT, THE COUNCIL OF THE EUROPEAN UNION AND
THE COMMISSION OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Community,

Bearing in mind the Commission White Paper of 25 July 2001 on European Governance ⁽⁸⁾
and the Communication from the Commission of 11 December 2002 on the operating
framework for the European Regulatory Agencies ⁽⁹⁾,

Having taken note of the European Parliament's resolution of 13 January 2004 ⁽¹⁰⁾ and the
Council's conclusions of 28 June 2004 ⁽¹¹⁾,

Whereas:

- (1) In accordance with the White Paper on European Governance, the European regulatory agencies help to implement and apply Community law. Their creation, operation and control are therefore of major political and institutional importance.
- (2) Without a common framework, the proliferation of designations, tasks, structures and control arrangements for these agencies has resulted in a situation which is rather untransparent, difficult to understand and detrimental to legal certainty. Greater transparency and coherence are therefore needed in order to prevent the legislative authority from setting up agencies which are increasingly diverse, thereby undermining the unity of the executive function.
- (3) As a first step, the operating framework should apply to future initiatives to set up European regulatory agencies under the EC Treaty and should promote their coherence. As a second step, the institutions will undertake to explore under what arrangements the operating framework could be extended to European regulatory agencies set up beforehand under the EC Treaty and, where necessary, to other agencies.
- (4) The operating framework must comply with the principles of good governance proposed in the White Paper: openness, participation, accountability, effectiveness and coherence. The objectives of openness and participation call for the application of the

⁽⁸⁾ COM(2001) 428, OJ C 287 of 12.10.2001, p. 1.

⁽⁹⁾ COM(2002) 718.

⁽¹⁰⁾ Doc. P5_TA(2004)0015.

⁽¹¹⁾ Doc. 17046/04.

conditions referred to in Article 255 of the EC Treaty for public access to documents held by these agencies and the representation of interested parties within them. The objective of effectiveness makes it necessary, in particular, to simplify the decision-making processes, reduce costs and give these agencies autonomy of action. With such autonomy goes the obligation for them to exercise clearly defined responsibilities, while respecting the unity of the executive function. The objective of accountability therefore calls for a simple and effective system of controls. Coherence depends on a system in which the responsibilities between institutions and agencies, on the one hand, and between the agencies themselves, on the other, are clearly separated in order to guarantee an integrated approach.

- (5) Any proposal for the creation of a European regulatory agency must be the subject of a rigorous impact assessment which not only applies the principles of subsidiarity and proportionality but also includes an *ex ante* evaluation which is as thorough as possible.
- (6) It is important to note that the present agreement lays down a minimum common core of principles, rules and procedures to be adhered to in the legislative act setting up a European regulatory agency, without prejudice to what might have to be added on a case-by-case basis, depending on the objectives, responsibilities and specific tasks assigned to each agency,

HAVE ADOPTED THIS AGREEMENT:

1. PURPOSE

The purpose of this agreement is to establish a horizontal framework for the creation, structure, operation, evaluation and control of European regulatory agencies.

The European Parliament, the Council of the European Union and the Commission of the European Communities agree to respect the principles, rules and procedures set out in this agreement when adopting legislative acts to set up European regulatory agencies (hereinafter referred to as “basic acts”).

2. SCOPE

The three institutions agree that the present agreement will apply to the European regulatory agencies proposed after it enters into force.

The institutions agree that the present agreement is aimed at all the European regulatory agencies which will be set up under the EC Treaty.

The three institutions undertake to explore, as soon as possible after the entry into force of the present agreement, under what arrangements the scope of this agreement could be extended to European regulatory agencies set up beforehand under the EC Treaty and, where necessary, to other agencies, without prejudice to the gradual adaptation of the latter agencies in accordance with the revision procedure provided for in the basic acts.

3. DEFINITION

For the purpose of the present agreement, the term "European regulatory agency" (hereinafter referred to as "agency") shall mean any autonomous legal entity set up by the legislative authority in order to help regulate a particular sector at European level and help implement a Community policy.

The agency shall be invested with a public service role. It shall help to improve the way in which Community legislation is implemented and applied throughout the European Union.

This definition shall not include the so-called "executive" agencies set up by the Commission to carry out, under its control and responsibility, certain tasks relating exclusively to the management of Community programmes. The executive agencies are the subject of Council Regulation (EC) No 58/2003 of 19 December 2002 ⁽¹²⁾, which lays down their statute.

4. TASKS

An agency may be entrusted with one or more of the following tasks:

- a) applying Community standards to specific cases. To this end, the agency shall be given the power to adopt individual decisions which are legally binding on third parties;
- b) providing direct assistance to the Commission and, where necessary, to the Member States in the interests of the Community, in the form of technical or scientific opinions and/or inspection reports;
- c) creating a network of national competent authorities and organising cooperation between them in the interests of the Community with a view to gathering, exchanging and comparing information and good practice.

Each agency shall also be responsible for gathering, analysing and forwarding objective, reliable and easy-to-understand information concerning its specific area of activity. The nature of this information and its recipients shall be specified in the basic act.

5. EXECUTIVE RESPONSIBILITIES

By accomplishing these tasks, the agency shall take an active part in exercising executive powers at Community level.

- (1) For the tasks provided for in point 4(a), the agency shall exercise direct executive responsibility within the scope of the powers conferred on it by secondary legislation and in accordance with the provisions of the EC Treaty.

In particular, when carrying out these tasks, agencies may not:

- a) adopt general regulatory measures;

⁽¹²⁾ OJ L 11 of 16.1.2003, p. 1.

- b) have decision-making powers conferred on them in areas in which they would be required to arbitrate in conflicts between public interests or exercise political discretion;
- c) have responsibilities entrusted to them with respect to which the EC Treaty has conferred direct decision-making powers on the Commission.

Any powers delegated by the legislative authority must be strictly defined and subject to rigorous controls.

- (2) For the tasks provided for in points 4(b) and (c), the agencies shall provide the Commission, in particular, with the expertise it needs in order to meet its responsibilities as the Community executive.

6. LEGAL STATUS

The agency shall have legal personality. In each Member State, it shall exercise the widest possible legal powers accorded to legal persons under national legislation. In particular, it may acquire or dispose of immovable or movable property and be a party to legal proceedings. It shall be represented by its director for this purpose.

I. CREATION

7. IMPACT ASSESSMENT

The Commission undertakes to justify any proposal to set up an agency on the basis of an impact assessment, which will not only apply the principles of subsidiarity and proportionality but also include an *ex ante* evaluation which is as thorough as possible. This impact assessment shall take several factors into account, including the following:

- a) the problem which must be resolved and the need which must be met in the short or long term;
- b) the added value of Community action;
- c) alternatives to the creation of a European regulatory agency, such as responsibility being taken by the Commission for the activities envisaged, extending the tasks of an existing agency, setting up an office or executive agency, and/or subcontracting individual tasks;
- d) the objectives to be met at general, specific and operational levels and the indicators necessary for evaluating them;
- e) any inadvertent repercussions and mutual concessions to be considered;
- f) the tasks to be allocated;
- g) any benefits in terms of expertise, visibility, transparency, flexibility and timeliness, coherence, credibility and effectiveness of public action;
- h) the costs generated by control, coordination and the impact on human resources and other administrative expenditure;
- i) the lessons learned from previous similar exercises;
- j) the system of monitoring and periodic evaluation to be established.

The Commission shall draw the conclusions from its impact assessment in the explanatory memorandum to its proposal.

The European Parliament and the Council undertake to have evaluations carried out before adopting any substantial amendment to the Commission's proposal.

8. LEGAL BASE

The three institutions agree that the basic act shall be based on the provision of the EC Treaty which forms the legal basis of the policy envisaged.

The institutions agree that Article 308 of the EC Treaty will serve as a legal base only in cases where no other provisions of the EC Treaty allow Community competence to be exercised.

9. OBJECTIVES AND MANDATE

The three institutions shall ensure that the objectives and mandate of the agency are clear and precise and are in keeping with the general policy guidelines of the European Union and the strategic objectives of the Commission.

10. SEAT

The three institutions acknowledge that the seat is one of the constituent elements of the agency. In the interests of effectiveness and transparency, the seat should be known when the basic act is adopted. The three institutions agree that a provision concerning the seat will be included in the act. If the seat is not known when the basic act is adopted, a decision in this regard must be taken within six months at the latest.

II. STRUCTURE AND OPERATION

It is particularly important that the involvement of the institutions in the structure and operation of the agency reflects their role in the institutional system of the European Union.

STRUCTURE

11. ADMINISTRATIVE BOARD

11.1. Tasks of the administrative board

The administrative board shall ensure that the agency performs the tasks entrusted to it under the basic act. It shall be the agency's planning and monitoring body. In particular, it shall be responsible for:

- a) appointing and, where necessary, dismissing the director of the agency and the members of certain bodies within the agency, in accordance with the procedures laid down in points 13(2) and 14;
- b) exercising disciplinary authority over the director;

- c) adopting the agency's annual work programme on the basis of a draft submitted by the director and after the Commission has delivered an opinion, in accordance with the conditions laid down in point 20;
- d) drawing up an annual estimate of expenditure and revenue for the agency and sending it to the Commission;
- e) adopting the definitive budget of the agency and the list of posts following completion of the annual budget procedure, in accordance with the conditions laid down in point 28(2);
- f) adopting the agency's annual activity report, in accordance with the conditions laid down in point 21, and sending it to the institutions and the Member States;
- g) adopting the agency's rules of procedure on the basis of a draft submitted by the director and after the Commission has delivered an opinion;
- h) adopting the financial rules applicable to the agency on the basis of a draft submitted by the director after the Commission has delivered an opinion, in accordance with the conditions laid down in point 28(1);
- i) adopting the procedures for applying Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽¹³⁾, in accordance with the conditions laid down in point 16(6).

11.2. Composition and designation of the administrative board

- (1) The three institutions agree that there cannot be a single formula for the composition of the administrative board.

The three institutions undertake, however, to limit the size of the administrative board in such a way as to promote highly effective decision-making and minimise operating costs.

- (2) The institutions acknowledge, moreover, that the agency's involvement in exercising executive powers at Community level calls for the equal representation of the two branches of the Community executive within the administrative board. The Commission and the Council should therefore designate an equal and limited number of members within the administrative board.
- (3) The tasks devolved on the agency shall not mean that each Member State should be given a seat on the administrative board, unless the agency also plays a part, in the interests of the Community, in the Member States exercising executive powers with respect to the policy envisaged. In such cases, the agency shall allow the Member States to ensure that the obligations arising from the EC Treaty or from secondary legislation are fulfilled, in accordance with Article 10 of the EC Treaty.

In this case, the Council shall designate a representative from each Member State. Each of these representatives shall have one vote. In order to maintain parity of the executives within the administrative board, the institutions agree to grant an equal number of votes in total to the members designated by the Council and to those designated by the Commission.

⁽¹³⁾ OJ L 145 of 31.05.2001, p. 43.

- (4) In the interests of transparency, the institutions agree that the Commission will also designate representatives of interested parties as members of the administrative board. These representatives shall sit on the board without having a right to vote. The sectors concerned shall be clearly identified in the basic act.
- (5) All the members of the administrative board shall be appointed on the basis of their experience in the sector concerned. The Commission and the Council shall ensure that men and women are represented equally on the administrative board. The members of the board shall be appointed for a five-year term, renewable once.
- (6) The institutions shall ensure that the composition of the administrative board is reviewed periodically in light of how the agency is operating, its objectives and the development of the powers and tasks attributed to it, in accordance with the review procedure provided for in point 27(2).

12. EXECUTIVE BOARD

Where the size of the administrative board is such that it cannot effectively fulfil the tasks devolved on it, an executive board may be set up. In this case, the administrative board shall meet only once a year, without prejudice to a special supplementary meeting.

The executive board shall be responsible for certain tasks associated with the preparation and follow-up of meetings of the administrative board, without prejudice to the tasks of the director referred to in point 13(1).

The executive board shall be composed of an equal number of representatives of the Council and of the Commission. The representatives of the interested parties designated by the Commission shall also sit on the board without the right to vote. The size of the executive board shall under no circumstances exceed eight members.

13. DIRECTOR

In order to ensure the independence of the agency in its day-to-day management and activities, the director must assume full responsibility for the operational tasks conferred on the agency.

13.1. Tasks of the director

The director's main responsibilities are:

- a) preparing the annual work programme, the draft estimate of expenditure and revenue for the agency, its rules of procedure and those of the administrative board, its financial rules and the meetings of the administrative board;
- b) taking part, without the right to vote, in meetings of the administrative board;
- c) implementing the agency's annual work programme and responding to requests for assistance from the Commission;
- d) performing the duties of authorising officer, in accordance with Articles 33 to 42 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June

2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁴⁾;

- e) implementing the agency's budget;
- f) putting in place an effective monitoring system to allow the regular evaluations referred to in point 27(1) to be carried out and, on this basis, preparing a draft annual report of the agency's activities;
- g) presenting this report to the European Parliament;
- h) managing all staff-related matters, and in particular exercising the powers provided for in point 23(2);
- i) defining the agency's organisational structure and submitting it to the administrative board for approval;
- j) taking any other action necessary to ensuring that the agency operates in accordance with its basic act;
- k) representing the agency before both the European Parliament and the Council, in accordance with the conditions laid down in point 29(1).

13.2. Appointment and dismissal of the director

- (1) The director shall be appointed by the administrative board on the basis of a list of candidates proposed by the Commission. Before being appointed, the candidate selected by the administrative board may be asked to make a declaration before the competent committee(s) of the European Parliament and answer questions from its(their) members.
- (2) The director shall be appointed on the basis of merit, administrative and management skills and expertise and experience in the field concerned. The director shall be appointed in principle for a five-year term. At the proposal of the Commission and following an evaluation, the director's tenure may be extended once for a period not exceeding the duration of his first term of office.

In its evaluation, the Commission shall take account of the following points in particular:

- a) the results obtained during the first term of office and the way in which they were obtained;
 - b) the objectives and requirements of the agency over the next few years.
- (3) The administrative board may remove the director from his duties before his term of office has expired, on the basis of a proposal from the Commission.

14. OTHER BODIES

14.1. Coordinating bodies between national competent authorities

The agencies responsible for coordinating and creating a network of national competent authorities (task referred to in point 4(c)) must be provided with one or more coordination bodies composed of representatives of these entities.

⁽¹⁴⁾ OJ L 357 of 31.12.2002, p. 72.

14.2. Scientific committees and/or committees of experts

The agencies which provide technical and scientific advice to the Commission and, where necessary, to the Member States (task referred to in point 4(b)) must be provided with one or more scientific committees and/or committees of experts.

The members of the scientific committees must be independent scientists appointed by the administrative board on the basis of an open invitation to tender. The members of the committees of experts shall be appointed by the administrative board on the basis of a clear and transparent procedure laid down in the basic act.

14.3. Boards of appeal

The agencies which adopt individual decisions which could give rise to complaints from third parties (task referred to in point 4(a)) must be provided with one or more boards of appeal whose role will be to check that the agency has applied the implementing rules correctly, within the scope of the tasks devolved on it and the responsibilities assigned to it.

The members of the boards of appeal shall be appointed by the administrative board for a period of five years on the basis of a list of candidates proposed by the Commission.

OPERATION

15. PUBLIC INTERESTS AND INDEPENDENCE

The members of the administrative board, the director, the members of the coordinating bodies between the competent national authorities, the members of the scientific committees and of the boards of appeal shall undertake to act in the public interest.

The director, the members of the scientific committees and of the boards of appeal shall also undertake to act independently of any external influence. To this end, they shall make a written declaration of commitment and a written declaration of interests every year.

16. TRANSPARENCY

- (1) The agency shall ensure that its activities are conducted with a high level of transparency and, in particular, that they comply with the following provisions.
- (2) It shall make public without delay:
 - a) its own rules of procedure and those of the administrative board;
 - b) its annual activity report.
- (3) The administrative board may, at the proposal of the director, authorise representatives of the interested parties, in appropriate cases, to attend meetings of the agency's bodies in the capacity of observers.
- (4) Without prejudice to paragraph 6, the agency shall not divulge to third parties confidential information it has received for which confidential treatment has been

requested and is justified.

The members of the administrative board, the director, the members of the coordinating body between the national competent authorities, the members of the scientific committees and of the boards of appeal shall be subject to the confidentiality requirement referred to in Article 287 of the EC Treaty.

- (5) The information gathered by the agency in accordance with its basic act shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ⁽¹⁵⁾.
- (6) Regulation (EC) No 1049/2001 shall apply to the documents held by the agency.

The administrative board shall adopt the practical arrangements for applying Regulation (EC) No 1049/2001 no later than six months after the agency has been set up.

17. LANGUAGE RULES

The administrative board shall establish the internal language rules for the agency.

The provisions of Regulation No 1 of 15 April 1958 determining the languages to be used by the European Atomic Energy Community ⁽¹⁶⁾ shall apply to the external language rules.

Translation work required for the operation of the agency shall be carried out by the Translation Centre for the Bodies of the European Union.

18. OBLIGATIONS REGARDING GOOD ADMINISTRATION

The basic act must guarantee that the agency upholds the principles and rules of good public administration, such as the right of the operators concerned to be heard and consulted, the obligation to justify any acts, language rules, access to documents, the protection of personal data and of business confidentiality, rules on sound financial management, action to combat fraud and the protection of the Communities' financial interests.

19. REVENUES OF THE AGENCY

The agency may be financed through:

- a) a subsidy from the general budget of the European Communities (hereinafter referred to as "Community subsidy"), and/or
- b) payment and fees for services provided to operators. The basic act shall specify the services concerned.

⁽¹⁵⁾ OJ L 8 of 12.01.2001, p. 1.

⁽¹⁶⁾ OJ 17 of 06.10.1958, p. 385.

In certain cases in which the agency assists the Member States directly, a contribution from them may also be considered. Similarly, the basic act may make provision for a contribution from non-Community countries taking part in the agency's work, in accordance with the conditions laid down in point 24. These contributions shall supplement the revenue referred to in points (a) and/or (b).

The term "self-financed" agency shall be understood to mean any agency not in receipt of a Community subsidy.

20. ANNUAL WORK PROGRAMME

- (1) The annual work programme must comply with the objectives, mandate and tasks of the agency as defined in the basic act.

The institutions recommend that the presentation of the annual work programme be based on the methodology developed by the Commission as part of Activity-Based Management (ABM).

- (2) The annual work programme shall be adopted by the administrative board on the basis of a draft submitted by the director and after the Commission has delivered an opinion.

The institutions agree that the legal scope of the Commission's opinion on the annual work programme must reflect the agency's contribution to exercising executive responsibility.

With respect to the agencies which assist the Commission directly, the Commission must be able to ascertain that the annual work programme is consistent with its executive responsibility. Where the Commission expresses its disagreement with the annual work programme, the administrative board shall re-examine and adopt it, with amendments where necessary, by an enhanced majority to be determined in the basic act.

21. ANNUAL ACTIVITY REPORT

The annual activity report shall describe the way in which the agency has implemented its annual work programme.

The report shall outline the activities conducted by the agency and evaluate the results with respect to the objectives and timetable set, the risks associated with the activities carried out, the use of resources and the general operation of the agency.

The report shall be prepared by the director of the agency and adopted by the administrative board.

22. PRIVILEGES AND IMMUNITIES

The Protocol on Privileges and Immunities of the European Communities of 8 April 1965 ⁽¹⁷⁾ shall apply to the agency's staff.

23. STAFF

- (1) The Staff Regulations of officials of the European Communities, the Conditions of employment of other servants of the European Communities and the rules adopted jointly by the European Community institutions for the purpose of applying these staff regulations and conditions of employment shall apply to the staff of the agency. The administrative board, in agreement with the Commission, shall adopt the necessary implementing measures, in accordance with the arrangements provided for in Article 110 of the Staff Regulations of officials of the European Communities and of the Conditions of employment of other servants of the European Communities. The administrative board may adopt provisions to allow national experts from other Member States to be employed on secondment at the agency.
- (2) The agency shall exercise, with regard to its staff, the powers which are devolved on the appointing authority.

24. PARTICIPATION OF THIRD COUNTRIES

The agency shall be open to the participation of third countries which have concluded agreements with the European Community which provide for the adoption and application by these countries of Community law in the area covered by the basic act. Under these agreements, arrangements shall be made specifying, in particular, the nature and the manner in which these countries will participate in the agency's work, including provisions on participation in certain internal bodies, financial contributions and employment of staff. These agreements may not, however, make provision for these countries to be represented on the administrative board with the right to vote and must, at all events, be in accordance with the Staff Regulations of officials of the European Communities and the Conditions of employment of other servants of the European Communities.

25. COOPERATION WITH OTHER AGENCIES

Under the working agreements concluded with other agencies, the agency may cooperate with them in the areas governed by the basic act, in order to avoid any duplication of work and create synergies.

26. INTERNATIONAL ACTIVITIES

- (1) Where the tasks conferred on the agency call for it to operate at international level, the basic act may make provision (with respect to all or certain tasks) for the agency

⁽¹⁷⁾ Protocol annexed to the Treaties establishing a Single Council and a Single Commission of the European Communities, OJ 152 of 13.07.1967, p. 13.

to cooperate with the competent authorities of non-Community countries and with international organisations which have similar tasks, on the basis of working arrangements concluded with the aforementioned authorities and organisations.

- (2) These working arrangements must comply with Community law and shall be adopted by the administrative board on the basis of a draft submitted by the director and after the Commission has delivered an opinion. Where the Commission expresses its disagreement with these arrangements, the administrative board shall re-examine and adopt them, with amendments where necessary, by an enhanced majority to be determined in the basic act.

III. EVALUATIONS AND CONTROLS

27. EVALUATIONS AND REVISION

27.1. Evaluation by the agency

In accordance with Article 25(4) of Financial Regulation (EC, Euratom) No 2343/2002, the agency shall regularly carry out *ex ante* and *ex post* evaluations of its programmes or activities when these necessitate significant expenditure. The administrative board shall be notified of the results of these evaluations.

The agency shall take all appropriate steps to remedy any problems which may come to light.

27.2. Evaluation by the Commission and revision

The Commission undertakes to carry out periodic evaluations of the implementation of the basic act, of the results obtained by the agency and of its working methods, in line with the objectives, mandate and tasks defined in the basic act and the indicators established by the *ex ante* evaluation and set out in the agency's annual work programme.

Following this evaluation, the Commission shall present, where necessary, a proposal for the revision of the provisions of the basic act. If the Commission feels that the very existence of the agency is no longer justified with regard to the objectives assigned to it, it may propose that the act in question is repealed.

The European Parliament and the Council shall use the Commission's proposal as a basis for examining whether the basic act should be amended or repealed.

28. BUDGET CONTROLS, FINANCIAL CONTROLS, AUDITS AND ACTION TO COMBAT FRAUD

28.1. Financial rules

Each agency must adopt its financial rules.

If the agency is in receipt of a Community subsidy, Article 185(1) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the

general budget of the European Communities ⁽¹⁸⁾, shall apply. The agency's financial rules must, in this case, comply with Financial Regulation (EC, Euratom) No 2343/2002. They may not depart from this Regulation unless their specific operating requirements so demand and the Commission has given its prior consent.

If the agency is self-financed, its financial rules shall be based on the aforementioned Financial Regulations, while respecting the specific nature of the agency.

28.2. Budget

In the case of agencies which are in receipt of a Community subsidy, a list of posts for staff covered by the Staff Regulations shall be drawn up each year by the budgetary authority as part of the budgetary process, pursuant to Article 46(3)(d) of Financial Regulation (EC, Euratom) No 1605/2002. The budgetary authority shall also authorise appropriations for the subsidy to be granted to the agency.

In the case of each agency, the administrative board shall adopt the definitive budget and the list of staff every year.

28.3. Accounting rules

By virtue of Article 185(4) of Financial Regulation (EC, Euratom) No 1605/2002, the agency shall apply the accounting rules adopted by the Commission's accounting officer, in accordance with the procedure set out in Article 133 of the said Regulation, so that its accounts can be consolidated with those of the Commission.

28.4. Audits

By virtue of Article 185(3) of Financial Regulation (EC, Euratom) No 1605/2002, the Commission's internal auditor shall exercise the same powers over the agency in receipt of a Community subsidy as he does in respect of the Commission.

28.5. External audit and discharge

In accordance with Article 248 of the EC Treaty, the Court of Auditors shall examine the accounts of all agencies in receipt of a Community subsidy.

By virtue of Article 185(2) of Financial Regulation (EC, Euratom) No 1605/2002, discharge for the implementation of the agency's budgets shall be given each year by the European Parliament on the recommendation of the Council.

If the agency is self-financed, discharge shall be given to the director by the agency's administrative board. The administrative board shall then inform the European Parliament, the Council, the Commission and the Court of Auditors of its decision giving discharge.

The director shall take all appropriate steps to act on the observations accompanying the decision giving discharge.

⁽¹⁸⁾ OJ L 248 of 16.09.2002, p.1.

28.6. Action to combat fraud and protect the Communities' financial interests

With a view to combating fraud, corruption and other illegal acts, Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) ⁽¹⁹⁾ shall apply to the agency in its entirety.

The basic act shall stipulate that, upon its establishment, the agency will accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF) ⁽²⁰⁾. The administrative board shall formalise this accession and adopt the necessary measures to help OLAF carry out internal investigations.

29. POLITICAL CONTROLS

29.1. European Parliament and Council

Without prejudice to the controls referred to above and, in particular, the budgetary and discharge procedures, the European Parliament or the Council may ask at any time, and, in particular, upon publication of the agency's annual activity report, for a hearing with the director on a subject relating to the agency's activities.

29.2. Commission

The Commission shall exercise control using its prerogatives:

- (1) In accordance with point 27(2), the Commission shall exercise its power of initiative by proposing, where necessary, that the basic act be revised or repealed.

By virtue of point 11(1)(d), the Commission shall also propose to the budgetary authority each year the amount of the subsidy for the agency and the number of staff it considers the agency needs, on the basis of the estimate of expenditure and revenue drawn up by the administrative board.

- (2) The Commission shall exercise its executive responsibility:
 - a) through its representatives on the administrative board;
 - b) by drawing up a list of candidates for appointing the director and the members of the boards of appeal, in accordance with points 13(2)(1) and 14(3);
 - c) by proposing to extend the mandate of the director depending on his evaluation in accordance with point 13(2)(2);
 - d) by delivering opinions on the annual work programme in accordance with point 20(2), on the rules of procedure in accordance with point 11(1)(g) and on any working arrangements concluded with the competent authorities of non-Community countries and/or international organisations with similar tasks, in accordance with point 26(2).

⁽¹⁹⁾ OJ L 136 of 31.05.1999, p. 1.

⁽²⁰⁾ OJ L 136 of 31.05.1999, p. 15.

30. ADMINISTRATIVE CONTROLS

In accordance with Article 43 of the Charter of Fundamental Rights of the European Union, the institutions agree that the agency will be subject to the administrative control of the European Ombudsman, pursuant to the conditions set out in Article 195 of the EC Treaty.

31. JUDICIAL CONTROLS

Actions may be brought before the Court of Justice for the annulment of acts carried out by an agency which are legally binding on third parties, for failure to act and for damages caused by any agency in the course of its activities.

Actions for the annulment of acts adopted in connection with the tasks laid down in point 4(a) may be brought before the Court of Justice only after all the appeal procedures within these agencies, provided for in point 14(3), have been exhausted.

IV. ENTRY INTO FORCE, IMPLEMENTATION AND MONITORING OF THE AGREEMENT

32. ENTRY INTO FORCE

The present agreement shall enter into force on the day following its publication in the *Official Journal of the European Union*.

Upon its entry into force, it shall apply to all proposals to set up a European regulatory agency.

33. IMPLEMENTATION AND MONITORING

The three institutions agree to take all the necessary steps to ensure coordination and due regard of the present agreement by their respective departments.

The implementation of the present agreement shall be monitored by the *High Level Technical Group for Interinstitutional Cooperation*.

For the European Parliament *For the Council*

For the Commission

The President

The President

The President