

THE FRAMEWORK FOR EUROPEAN REGULATORY AGENCIES: A BALANCE BETWEEN ACCOUNTABILITY AND AUTONOMY

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INTRODUCTION

The number of European agencies has almost doubled over the past three years. Overall, more than 25 agencies have thus been set up at the European level in fields as diverse as vocational training, safety and health at work, the fight against drugs and drug addiction, racism and xenophobia, control and prevention of communicable disease, protection of the environment, trademarks, plants variety, medicinal products, food safety, aviation safety, maritime safety, railway safety and interoperability, satellite radio-navigation, network and information security, border control, police cooperation, judicial cooperation and defence capabilities. These agencies have been dispatched over the whole EU territory (see annex I). They currently employ more than 2,700 statutory staff and receive a total EU subsidy of almost €300 million per year. The establishment of agencies at the European level bears considerable political, legal, budgetary and administrative repercussion on EU regulatory policy.

In its 2001 White Paper on European Governance ⁽¹⁾, the Commission proposed that a framework should be established setting out the conditions relating to the creation, operation and supervision of European regulatory agencies, in accordance with the principles of good governance. Further to a Commission Communication adopted in December 2002 ⁽²⁾ and discussed in the course of 2003 and 2004 with the European Parliament and the Council, the Commission issued a draft interinstitutional agreement for a framework on European regulatory agencies on 25 February 2005 ⁽³⁾.

This article will briefly recall the context and content of this European Commission's policy initiative, with a focus on the intertwined issues of 'accountability' and 'autonomy'. This paper is by no means exhaustive in its content and scope. Many other issues related to the framework (choice of an interinstitutional agreement as the legal instrument, scope of the framework, legal basis, seats of agencies, etc.) could be dealt with in the course of panel 4 discussions.

¹ COM(2001)428, 25.07.2001

² COM(2002)718, 11.12.2002

³ COM(2005)59, 25.02.2005

DEFINITION OF A EUROPEAN REGULATORY AGENCY

“Regulation” is a concept in the making. The framework’s definition of a “regulatory” agency is primarily based on the useful semantic distinction that can be made in French or German between “règlementation / Regelung” (adoption of legally binding rules applicable across the board) and “régulation / Regulierung” (wide-ranging concept, encompassing “règlementation”). “Regulatory” activities do not, therefore, only involve the adoption of legally binding instruments. They may also cover measures of a more incentive nature, such as networking and pooling of good practices, use of / reliance on scientific authority, co- and self-regulation, evaluation of the application and implementation of rules etc. A regulatory agency is not, therefore, necessarily endowed with decision-making or enforcement powers. Its tasks may cover a wide range of other “regulatory” activities, ranging from decision-making to networking (regulation through coordination) and the provision of scientific or technical expertise (regulation through information).

The following tasks may in particular be assigned to European regulatory agencies:

- adoption of *individual decisions* which are legally binding on third parties.

In terms of delegation of decision-making powers to these agencies, the Commission and the other EU institution have so far opted for a cautious approach. In accordance with the case-law⁴ and the institutional system, a body which is not foreseen in the EC Treaty cannot be endowed with discretionary powers implying a large margin of political appreciation. According to the underlying principle of institutional balance, the competences attributed to the institutions by the Treaty must be preserved. In particular, agencies are not entitled to: adopt rules of general application; arbitrate in conflicts between public interests or exercise political appraisal; have responsibilities entrusted to them with respect to which the EC Treaty has conferred direct decision-making powers on the Commission (for example in the fields of competition or, *mutatis mutandis*, in infringement proceedings under Article 226 to 228 of the EC Treaty). When given decision-making powers, these must be strictly limited to applying clearly defined rules of secondary legislation to individual cases (eg. EC trademark granted to commercial products by the Office for Harmonisation of the Internal Market - OHIM, protection to new varieties of plants granted by the Community Plant Variety Office - CPVO, airworthiness certificates to specific products and equipment issued by the Air Safety Agency - EASA)

- provision of *direct assistance* to the Commission and, when necessary, to the Member States in the interest of the Community (in the form of technical and/or scientific advice and/or inspection reports).

Agencies thus provide the European Commission and, possibly, the Member States with the independent specialised technical and scientific expertise needed to allow it/them to assume their Community obligations in highly specialised technical areas. As opposed to a generalist institution like the Commission, agencies allow for the speedy mobilisation of specialised scientific and technical expertise.

⁴ Judgment of 13.06.1958, in case 9/58, Meroni, ECR, 1958, p.11; judgment of 14.05.1981, in case 98/80, Romano, ECR 1981, p.1241.

- *creation of a (or various) network(s) of national competent authorities and cooperation between them in the interest of the Community with a view to gathering, exchanging and comparing information and good administrative practice.*

Administrative/operational decentralisation for implementation of EU rules at the level of the Member States has resulted in some shortcomings: unequal transposition of directives, variable monitoring of their implementation, different regulatory cultures, difficulties in the coordination of crisis management, etc. To overcome the regulatory gap between the European level of rule-making and the national (and infra national) level of implementation, a certain “europeanisation” of cooperation between national regulators is thereby warranted.

Most of the existing European agencies have been assigned at least two of the above-mentioned tasks, which means that any classification based on these tasks alone would tend to be artificial. Moreover, all European regulatory agencies will be responsible for gathering, analysing and forwarding objective, reliable and comprehensible information concerning its area of activity.

The tasks allocated to agencies have two direct corollaries:

1. the agencies structure must permit them to perform their function correctly. To provide the Commission and possibly the Member States with much needed specialised independent expertise, agencies must in particular be given a significant degree of structural autonomy in their dealings with public authorities and economic operators alike (see below section on ‘autonomy’)
2. as instruments for implementing a given EU policy, regulatory agencies should be held accountable to the institutions, operators and the public at large (see below section on ‘accountability’).

SOME BENEFITS INVOLVED IN THE CREATION OF REGULATORY AGENCIES

The prime advantages of setting up decentralised entities at EU level lie in the provision of impartial and highly specialised *expertise* to a generalist institution like the Commission. As mentioned above, regulatory agencies provide the Commission with the expertise it needs to exercise its competences as policy initiator, Community’s executive and/or as guardian of the Treaties.

In addition, European agencies can reinforce the *transparency* and *visibility* of EU decision-making, allowing economic operators and the public to identify more easily who within the EU machinery is fulfilling a given responsibility. From this stance, the geographical decentralisation of agencies’ seats plays an important role. A particular issue is thus increasingly associated with a precise agent and location (⁵).

Finally, thanks to their relatively small and highly specialised structures, agencies can respond to emerging crises in a *flexible* and *speedy* manner (⁶).

⁵ Eg. one would refer to the “London” agency for the evaluation of medicinal products or the “Copenhagen” agency for environmental issues.

⁶ Eg. European Food Safety Authority (EFSA) opinions on GMOs or BSE.

This rather schematic list of benefits must not overshadow the costs possibly involved in creating agencies, related not only to administrative / human resource expenditure but also to the loss of control and/or the need for enhanced coordination. In view of the costs incurred, the institutions may also need to contemplate other alternatives to the creation of a 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 an executive agency⁽⁷⁾ and/or subcontracting individual tasks.

THE NEED FOR A FRAMEWORK

The decision to create each agency is motivated by the need to respond to the particular circumstances of the moment. Each regulatory agency's constituent act is the result of particular sectoral negotiations, following procedure foreseen in the EC/EU Treaty for the policy in question. Interstate and inter-institutional bargaining under codecision procedure⁽⁸⁾ have played an important role in this piecemeal approach. As a result, European agencies are in many regards typified by their diversity. Differences in terms of denomination ("foundation", "centre", "authority", "agency", etc.), structure, relations with the EU institutions, responsibilities and powers do not necessarily reflect the reality of the tasks allocated to each agency. Moreover, interinstitutional politics and sectoral/particularistic considerations have at times prevailed at the expense of good governance⁽⁹⁾.

The framework therefore represents a minimum core of good governance principles⁽¹⁰⁾ to be applied in the creation, the functioning and the supervision of these agencies. As mentioned above, agencies must act in an autonomous way. Their functioning must not be dependent on any hierarchical structure. For instance, there can be no direct legal supervision of the Commission over the activities of the agency: the Commission cannot give instructions to the agencies or oblige them to withdraw certain decisions. Quite the contrary, they are given considerable legal, budgetary and operational autonomy. Precisely because of this autonomy, agencies must be held responsible directly for their actions, notably in view of their active contribution to the European regulatory area. The direct corollary of an agency's autonomy is thus the need to develop mechanisms of accountability. A coherent framework for European agencies aims to combine their autonomy with the Commission's ultimate responsibility within the Community system. For the sake of clarity, the two interrelated issues of 'autonomy' and 'accountability' are presented separately in the headings below.

AUTONOMY

As mentioned above, regulatory agencies should be organised in a way that they can perform the tasks devoted on them effectively. Agencies must be able in particular to gather and exploit the highest standards of scientific and technical expertise in their corresponding field. They should be equipped to react smoothly to issues arising in their particular sector. The

⁷ Executive agencies operate under the control and responsibility of the Commission to implement certain management tasks related to Community programmes.

⁸ Consultation procedure has become the exception.

⁹ eg. plethora of management boards for relatively small agencies; periodic external evaluation of and/or review clause not foreseen in all constituent acts; apparently unjustified diversity of appointment procedure / judicial control procedures.

¹⁰ As set out in the 2001 White Paper on European Governance : 'accountability', 'effectiveness', 'coherence', 'participation' and 'openness'.

autonomy of regulatory agencies is key to their effectiveness. Particularly with regard to the technical and scientific assessment that they must make, it is important that these agencies 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. These agencies should thus not be placed under the control of any particular entity, but rather at the centre of a constellation of multiple interests that could lead them to pursue the objectives laid down in their mandate in the most efficient manner. The principle of effectiveness notably involves granting these agencies with a certain degree of organisational, legal and financial autonomy.

Organisational autonomy

All existing agencies are based on a dual executive structure: a management board and an executive director placed under the former's responsibility.

Management board

Management boards are the programming and supervisory bodies of agencies. They are vested with their own decision-making (adoption of the agency's work programme, annual report, rules of procedure, budget etc.) and nomination (notably that of the director and the members of the agency's bodies) powers. So as to ensure organisational autonomy, management boards should not be placed under the authority or control of any given actor/institutions.

However, the composition of existing management boards departs greatly from this rule: except in the case of the European Food Safety Authority (EFSA¹¹), all management boards are made up of at least one representative per Member State. Following the last enlargement, the representation of Member States has thus become clearly over-proportionate and rather plethoric. The problem is particularly acute in small-to-medium size agencies (¹²). The minority role reserved to the Commission, sometimes without voting rights (¹³), does not allow the agencies to make the most of their potential as instruments intended to contribute to the European regulatory area.

The framework thus proposes a more balanced composition of the management board as the expression of the Community executives (European Commission and Council), together with stakeholders' participation. The proposed limited and equal representation (or weighting votes) of members appointed by the Commission and members appointed by the Council aims notably at ensuring a proper balance between pursuing Community objectives and taking account of national interests.

Executive director

The director assumes full responsibility for the operational tasks assigned to the agency and is the agency's legal representative. He or she is directly responsible for the execution of the agency's own budget. If the agency receives a Community subsidy as part of its yearly budget, the director is responsible for its execution directly before the European Parliament. If

¹¹ The EFSA management board includes one Commission representative plus 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission.

¹² The number of members of some agencies' management boards (eg. GNSS Supervisory Authority – GALILEO - or the Agency for Security and Health at Work – EU-OSHA) actually exceeds their number of staff.

¹³ Eg. the Commission has no voting rights in the Office for Harmonisation in the Internal Market (OHIM).

not ⁽¹⁴⁾, he or she is responsible before the management board. The director is also the agencies appointing officer (recruitment and promotion of personnel).

Therefore, the director of an agency must be able to run the agencies' daily business, insulated from any political or other interference. He should neither solicit nor accept any instructions from any government (or other) body.

In most cases ⁽¹⁵⁾, appointment of the director is made by the management board, acting as a collegial body. Before being appointed, the candidate selected by the management board may be asked to attend a hearing before the competent committee of the Parliament.

Other entities

Independent expert bodies (expert/scientific groups when agencies issue scientific/technical opinions, boards of appeal when agencies adopt legally binding decisions) are also established within some agencies to gather the independent expertise needed. The members of these structures are nominated by the management board on the basis of their expertise and their capacity to perform their tasks independently.

Legal autonomy

Each regulatory agency is granted its own independent legal personality. In each Member State, they can exercise the widest possible legal powers accorded to legal persons under national legislation. In particular, they may acquire or dispose of immovable or movable property and be a party to legal proceedings. They are represented by their director for this purpose.

Budgetary/Financial autonomy

Agencies adopt their own budget. In nearly all cases ⁽¹⁶⁾, this budget is in part or fully subsidised by the Community.

Income

The agency's budget may consist of a subsidy from the general budget of the Communities, Member States (and other participating countries) contributions and revenues from fees for services rendered to interested operators ⁽¹⁷⁾. To ensure that the agency remain impartial and is not unduly influenced by those operators, mechanisms are needed to keep the agencies financially independent of such revenues. Fees amount and structure are often set out in Community's implementing measures ⁽¹⁸⁾.

¹⁴ OHIM and the Community Plant Variety Office (CPVO) are currently 'self-financed'.

¹⁵ There are a few exceptions to this rule: OHIM and CPVO directors are appointed by the Council of Ministers; the European Foundation for the Improvement of Living and Working Conditions (EUROFOUND) and the European Centre for the Development of Vocational Training (CEDEFOP) have their directors appointed by the Commission.

¹⁶ See supra n.14 for exceptions.

¹⁷ Eg. fees paid to the European Medicines Agency (EMA) by pharmaceutical companies for evaluation of authorisation files.

¹⁸ A Commission and/or Council act.

Implementation of the budget

The agency's director is solely responsible for the execution of the agency's budget. This has important consequences in terms of accountability vis-à-vis the budgetary control/discharge authority that will be examined below.

ACCOUNTABILITY

The autonomy of regulatory agencies goes hand in hand with an obligation for accountability. As instruments for the implementation of EU policy, these agencies bear responsibilities vis-à-vis EU institutions, Member States, operators concerned and more generally the public. Similarly, the responsibilities of the Commission and other institutions vis-à-vis these agencies need to be clearly defined.

Generally speaking, agencies are directly responsible within the framework of their mandate, for the actions they take. They must be able to justify a particular course (or lack) of action to the general public.

Democratic accountability

It is the Community legislator – not the Commission – that will ultimately decide on the creation, review and possibly the closing down of an agency. Furthermore the European Parliament may request to hear the agency's director at any time, and in particular before his appointment and upon publication of the annual report on the agency's activity and/or within the framework of the discharge procedure (see below).

Budgetary and financial accountability

Almost all agencies receive a subsidy from the Community budget (¹⁹). The Community's financial regulations (²⁰) ensure that 'subsidised' agencies include appropriate arrangements for budgetary and financial accountability. Under the financial regulations:

Community subsidies are determined directly by the budgetary authority. The European Parliament, as the budgetary branch responsible for non-compulsory expenditure, decides on this allocation.

Similarly, the European Parliament is the recognised authorised authority for granting discharge in respect of the agency budget, whenever it receives an EU subsidy. In the course of the discharge procedure each agency's director will be heard by the European Parliament (Budget control committee) on the budgetary exercise in question. Before the discharge procedure starts, the implementation of the agency's budget is controlled by the European Court of Auditors.

Finally, the European Anti-Fraud Office (OLAF) can carry out its investigations directly on agencies with a view to combat fraud and protect the Communities' financial interests.

¹⁹ See supra n.14 for exceptions.

²⁰ Council Regulation 1605/2002 of 25.06.2002 applicable to the general budget of the European Communities, Art. 185; Commission Regulation 2343/2002 of 23.12.2002 for the bodies referred to in Art. 185 of Council Regulation 1605/2002.

Judicial accountability

Agencies are responsible before the Court of Justice of the European Communities for the decisions they take. More specifically, when agencies adopt legally binding decisions, the institutions, Member States and interested third parties can appeal to the Court of Justice (Court of First Instance for the latter) to request the annulment of such decisions (after possible review by the internal board of appeal).

Third parties concerned should also be able to bring an action for 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, provisions must be made for compensation by them for any damages caused by such acts, where appropriate after judicial confirmation of their liability.

These recourses should be clearly set out in a transparent framework and applied to all agencies.

Procedural accountability

Input legitimacy

Regulatory agencies would also need to act in a transparent manner so that the various players concerned can effectively participate in and monitor their operations. The implication of interested parties in management boards ⁽²¹⁾ allows for their points of view to be considered in fixing the agency's orientations. In addition, all agencies would need to comply with some basic requirements in terms of good administration, including stakeholders' rights to be heard / consulted in good time and provided with detailed feedback, the obligation of the agency to justify instruments, to call on relevant expertise in an impartial and transparent manner, to apply Community provisions on transparency, access to documents, personal data protection and business confidentiality and to respect the Community linguistic regime. Finally, agencies constituent acts should foresee the administrative supervision of the European Ombudsman.

Output legitimacy

Regulatory agencies will also be judged on the performance and outcomes delivered in light of their objectives. The framework therefore foresees that an evaluation should be carried out periodically by the Commission to assess the results obtained by each agency and working methods. This evaluation will allow the Commission to decide whether a proposal is needed to review the agency's constituent act or even to repeal it if it feels that the very existence of the agency is no longer justified. Ultimately, it will be up to the European Parliament and the Council (or the Council alone if the constituent act is adopted under consultation) to decide on the modification or abrogation of such basic act.

²¹ Stakeholders' representatives are present without voting rights in several management boards, including the European Maritime Safety Agency (EMSA), the European Network and Information Security Agency (ENISA) and the European Railway Agency (ERA).

CONCLUSION: THE NON-HIERARCHICAL RELATIONSHIP BETWEEN REGULATORY AGENCIES AND THE EUROPEAN COMMISSION

European regulatory agencies allow the Commission to:

- better prepare draft implementing measures and, possibly, legislative proposals (eg. agencies drawing up opinions/studies/report)
- better fulfil its role as the “guardian” of Community law (eg. agencies preparing inspection reports or organising networks of national regulators)
- refocus on its core functions (eg. agencies dealing with highly specialised technical authorisation to individual operators)

Regulatory agencies thus bear considerable responsibility in enabling the Commission *inter alia* to exercise its own competences correctly. Therefore, the Community’s executive must be able to take steps to ensure that its overall responsibility for implementation of EU policy is not put at risk by the actions taken by the agency. However, as mentioned above, there is no hierarchical relationship between the Commission and the Agency. Quite the contrary, the relationship is one of partnership, where reciprocal responsibilities need to be clearly defined and mutual trust /cooperation has to develop.

(All views expressed are those of the author only and should not be attributed to the European Commission.*

Annex I

LIST OF EC AND EU AGENCIES (NON EXECUTIVE/REGULATORY) – AS AT 01.07.05

Existing Agencies (1 st pillar)	Seats	Establishing Legal Acts
European Centre for the Development of Vocational Training (CEDEFOP)	Thessaloniki/GR	Regulation (EEC) No 337/75 of 10 February 1975
European Foundation for the Improvement of Living and Working Conditions (EUROFOUND)	Dublin/IE	Regulation (EEC) No 1365/75 of 26 May 1975
European Environment Agency (EEA)	Copenhagen/DK	Regulation (EEC) No 1210/90 of 7 May 1990
European Training Foundation (ETF)	Turin/IT	Regulation (EEC) No 1360/90 of 7 May 1990
European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	Lisbon/PT	Regulation (EEC) No 302/93 of 8 February 1993
European Medicines Agency (EMA)	London/UK	Regulation (EC) No 726/2004 of 31 March 2004 (repealing Regulation (EEC) No 2309/93 of 22 July 1993)
Office for Harmonisation in the Internal Market (OHIM)	Alicante/ES	Regulation (EC) No 40/94 of 20 December 1993
European Agency for Safety and Health at Work (EU-OSHA)	Bilbao/ES	Regulation (EC) No 2062/94 of 18 July 1994
Community Plant Variety Office (CPVO)	Angers/FR	Regulation (EC) No 2100/94 of 27 July 1994
Translation Centre for the bodies of the EU (CDT)	Luxembourg/LU	Regulation (EC) No 2965/94 of 28 November 1994
European Monitoring Centre on Racism and Xenophobia (EUMC)	Vienna/AT	Regulation (EC) No 1035/97 of 2 June 1997
European Agency for Reconstruction (EAR)	Thessaloniki/GR	Regulation (EC) No 2454/99 of 15 November 1999
European Food Safety Authority (EFSA)	Parma/IT	Regulation (EC) No 178/2002 of 28 January 2002
European Maritime Safety Agency (EMSA)	Lisbon/PT	Regulation (EC) No 1406/2002 of 27 June 2002
European Aviation Safety Agency (EASA)	Köln/DE	Regulation (EC) No 1592/2002 of 15 July 2002
European Network and Information Security Agency (ENISA)	Heraklion/GR	Regulation (EC) No 460/2004 of 10 March 2004
European Centre for Disease Prevention and Control (ECDC)	Stockholm/SE	Regulation (EC) No 851/2004 of 30 March 2004
European Railway Agency (ERA)	Lille-Valenciennes/FR	Regulation (EC) No 881/2004 of 29 April 2004
European GNSS Supervisory Authority (GALILEO)	Not decided	Regulation (EC) No 1321/2004 of 12 July 2004
European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the EU (FRONTEX)	Warsaw/PL	Regulation (EC) No 2007/2004 of 26 October 2004
Community Fisheries Control Agency (CFCA)	Vigo/ES	Regulation (EC) N°768/2005 of 26 April 2005

Proposed Agencies or under inter-institutional negotiation	Seats	Commission Proposal
European Chemicals Agency (ECA)	Helsinki/FI	COM(2003)644 of 29 October 2003
European Institute for Gender Equality	Not decided	COM(2005)81 of 8 March 2005
Fundamental Rights Agency	Vienna/AT	The Member States meeting at the level of Heads of State or Government agreed in their 13 December 2003 Conclusions to build upon the Existing Monitoring Centre on Racism and Xenophobia. COM(2005)280 of 30 June 2005

EU Agencies of the 2nd and the 3rd Pillar	Seats	Establishing Legal Act
European Police Office (EUROPOL)	The Hague/NL	Council Act of 26 July 1995 (Europol Convention)
European Police College (CEPOL)	Bramshill/UK	Council Decision (JHA) 2000/820 of 22 December 2000
European Institute for Security Studies (ISS)	Paris/FR	Council Joint Action (CFSP) 2001/554 of 20 July 2001
European Union Satellite Centre (EUSC)	Torrejón de Ardoz/ES	Council Joint Action (CFSP) 2001/555 of 20 July 2001
European Body for the Enhancement of Judicial Co-operation (EUROJUST)	The Hague/NL	Council Decision (JHA) 2002/187 of 28 February 2002
European Defence Agency (EDA)	Brussels	Council Joint Action (CFSP) 2004/551 of 12 July 2004