

Doctoral Dissertation

**Delegation and Responsibility: the Role of the Agency Model in the  
Communitarian Setting**

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## **Part 1**

### **Theoretical outline, agency model's description and comparative analysis**

#### **1. Introduction: towards a framework for the analysis**

The overall rationale of this dissertation is to reveal the basic features of the agencification process occurring inside the European Union and to account theoretically and empirically for this administrative change of the communitarian system. In the first chapter, after the definition of the aim of the thesis, the theoretical background and the analytical approach and the elements of innovativeness of the research will be briefly described in the first three chapters. In chapter 1.4, the research questions are laid out. A synthetic overview of the study is introduced in chapter 1.5.

In this research it will be faced the challenge to analyze in depth the delegation issue inside the communitarian setting, taking as a starting point the already existing works done in the European studies' literature but trying to go further and applying the tools of public management studies to this topic usually biased by too much "political" *criteria* of examination. Taken as a starting point the wide debate occurring inside the public management realm about the concepts of "delegation" and "responsibility" it will be tried to deepen the knowledge of the agencification *phenomenon* as occurring in the communitarian setting, having in mind, as privileged audience of the research the management scholars, as it will be clearer when the literature references and the investigation tools will be further clarified. Being this dissertation organized as a set of integrated modules, it should be considered as a monographic research where the different modules constitute a unit, sharing them several theoretical and methodological properties. This introductory chapter provides an exhaustive framework for understanding the different modules of the dissertation and for showing how the findings of the research, if taken together contribute for an enrichment of the understanding of the role of the European agencies in the communitarian context.

##### **1.1 Delegation and responsibility: a preliminary assessment**

As one of the most interesting processes of institutional change occurring inside the communitarian system, "delegation" might be considered one of the most important answers to the recent concerns about the problematic management of EU's policies. Before going into details about the concepts of "delegation" and "agency" and their practical application inside the EU system, which will be extensively done in the chapter 1.2, it is useful to give some insights about the motivations behind the delegation of power or more generally delegation of functions to delegated bodies, given by agency theory. Olson (1965) contends that collective action becomes more difficult as the group to be mobilized becomes larger: larger groups inherently have greater transaction costs in collective action. In addition small groups permit coercion, either social or political, because "free riders" cannot remain invisible. Agency theory has been used by scholars in economics (e.g., Spence & Zeckhauser,

1971); political science (e.g., Mitnick, 1986); organizational behaviour (e.g., Eisenhardt, 1988) and sociology (e.g., White, 1985). The main question is about what agency theory contributes to management research and in particular to public management research as applied to EU's issues. Agency relations are created when one party, the "principal", enters into a contractual agreement with a second party, the "agent", and delegates to the latter responsibility for carrying out a function or set of tasks on the principal's behalf (Kassim & Menon, 2003). Difficulties arise because of the asymmetric distribution of information in favour of the agent (Holmstrom, 1979), including adverse selection and moral hazard: the challenge is to avoid an opportunistic behaviour by the agent, ensuring adequate compliance.

#### *Transaction costs' theory*

Transaction costs are associated with asset specificity, uncertainty and frequency of transactions and they determine the optimal level and shape of the organizations<sup>1</sup>. Williamson (1981) analyzed three dimensions of transactions: "uncertainty", "frequency" and "transaction-specific" investments required.

Transaction uncertainty can be defined with reference to the dimension of "metering": it means the difficulty in monitoring and measuring the application of the contract. Transaction costs are economized by assigning different transactions to different governance structures in a discriminating way (Williamson, 1985). The decision to delegate is usually motivated by the will to minimize transaction costs and by other aims: for instance, to overcome problems of collective action, where actors might anticipate long-term cooperation benefits and want to minimize the amount of transaction costs in comparison to the benefits of the agreement (Shepsle, 1979); to improve the quality of policy in technical areas by delegating responsibilities to a specialist agent (Egan, 1998); to deal with the problem of "incomplete contracting" which can arise when the interaction is based on a long term agreement, where the bargain is complex and the negotiation process difficult (Williamson, 1985). In those cases the parties prefer an "incomplete contract"<sup>2</sup> in which general goals are stated and *criteria* for decision-making in unforeseen circumstances are established (Milgrom & Roberts, 1992); to displace responsibility for unpopular decisions (Epstein & O'Halloran, 1999); to resolve the problem of policy-making instability (Pollack, 1997).

Some public management scholars underline the difficulty of applying agency and transaction costs' theory to the public realm: in Stein research (1990) it is confirmed that the asset specificity is fundamental to understand how a public service is provided but his conclusions are partially in contrast to the Williamson's ones and more than efficiency issues he considers fundamental the characteristics of the services provided and ethic or equity evaluations of the services. A study by Rehnberg (1990) on the health care system in Sweden demonstrated that the asset

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<sup>1</sup> Transaction cost is, in Dixit's words, "anything that impedes the specification, monitoring, or enforcement of an economic transaction" (1996).

<sup>2</sup> When significant transaction costs exist, and individuals are bounded rational, contracts will be in general incomplete, that is missing provisions and ambiguous clauses: this incompleteness is caused by factors as, for instance negotiation costs and writing or enforcements costs (Epstein & O'Halloran, 1998).

specificity and the degree of uncertainty of the transactions were poor predictors of the degree of externalization and Arnold (1991), studying the American health care system, discovered that the motivations behind institutional changes in the public sector had to be found in the political more than in the efficiency realm.

#### *The concepts of efficiency and effectiveness*

The main focus of private management is usually concentrated on “management within an organization” or on the way managers should deal with the external environment in which the company they work for is embedded. Borgonovi (1984) defines economical efficiency as a mix of technical-operative and purely economical efficiency: the former referring to the productivity level of the different processes (quantity of input resources *per* output produced) and the latter referring to performance indicators as for instance costs and revenues (in general terms the relation cost/value in the productive processes). Efficiency has been defined in at least two different ways (or better to say, efficiency-oriented search processes): “static efficiency”, which involves continuous search for improvements within a fixed set of initial conditions, and “dynamic efficiency”, which involves continuous reconsideration of the initial conditions (Ghemawat & Ricart, 1993). Klein (1984) defines static efficiency as “fine-tuning whose objective is to make the best use of existing information” and dynamic efficiency as “changing production in profitable directions”. Klein goes further differentiating between flexibility associated with anticipated uncertainty and flexibility associated with unanticipated uncertainty. Carlsson (1989) classifies efficiency into its operational, tactical and strategic aspects. Klein’s classification is based on the “type of uncertainty”; Carlsson’s classification is based on the “time horizon”. A third way of defining efficiency, which emphasises more the organizational choices instead of largely exogenous environmental attributes, refers to the processes of “organizational learning” (e.g., March & Olsen, 1976). Argyris and Schon’s (1974) distinction between single- and double-loop learning is also important. “Single-loop learning” involves the adaptation of actions in response to discrepancies between intentions and outcomes within a framework of beliefs; “double-loop learning” involves also the reconsideration of those beliefs.

Effectiveness can be defined as how well the service outputs achieve the agreed objectives: it can be measured by means of four effectiveness indicators: “overall outcomes” – short- or long- term – measures the impact or consequence of a service in relation to policy objectives; “access” and “equity” indicators measure timelines, affordability and services to designated groups; “quality” indicators measure “conformance to standards” and/or “fitness for intended purpose”: by means of these indicators it may be possible to compare “performances” and judge efficiency and effectiveness of the actions of different institutions (McGuire, 2004).

The efficiency and effectiveness issues at the EU’s level, if referred to policy management are based on the responsibility of many organizations, in some ways interconnected between them. In this sense, the performance of the system depends also on the degree of coordination of these organizations and not solely on their individual performances. Addressing the management issue, Metcalfe (2000; 1992) is interested in the Commission’s missing strategic capabilities for managing EU’s

networks in “turbulent organisational environments”. This contribution suggests that the European Commission should react in a proactive way to the challenges coming from its (turbulent) environment: a static behaviour cannot be efficient. It follows that European Commission reform cannot be a “static” reform but it should be necessary for the Commission to become a “learning organization” in which the mechanisms of reaction to new problems would bring to flexible and immediate solutions. For the development of a new and more effective “management regime” are required structural and cultural changes: consequently a stronger coordination among the institutions belonging to the European policy networks is needed.

#### *Delegation and New Public Management*

European Commission reform might have been significantly influenced by New Public Management (NPM) approach which has pushed many national Governments to use “semi-detached” bodies, instead of national ministries or centralized institutions, in order to perform a wide variety of functions (Pollitt & Bouckaert, 2000). Some scholars on the contrary (e.g., Metcalfe 1996; Stevens & Stevens, 1997) argue that European Commission reform has been immune from this *phenomenon*. Over the past two decades, reform of public administration systems have largely been synonymous of NPM, that is an embracement by public organizations of private sector management norms and values going from focus on customers and fragmentation of public services’ delivery to decentralization of the organizational structures (Dunleavy, 1994; Hood, 1991; Pollitt 1993). To make an example, the American administrative reform started by President Clinton in 1992 reveals many points of contacts with the book by Osborne & Gaebler (1992) in which one of the most important principle was “steering rather than rowing”<sup>3</sup>.

On the other hand, if the characteristics of EU’s management are explicitly taken into consideration, it seems clearly understandable that EU’s policies create highly complex management problems that hamper the direct imitation of business management practices or public reforms as they have been developed at the national and local level. Metcalfe and Richards (1990) argue that agencification involves a move away from a hierarchical organization structure to one which they describe as a “core-periphery” model. During the last decade a lot of literature, firstly emerged in the economics’ realm and then migrated to business management and public administration challenged the once-dominant view that tightly integrated and controlled organizations were more efficient than fragmented, self-operated units. The arguments against integrated organizations can be summarized as follows: hierarchical, centrally-controlled organizations lack initiative, are slow to adapt to changing conditions and are not adequately responsive to the interest of those they serve (PUMA, 2002). In the framework of the NPM approach two are the core principles: “let managers manage” by deregulating the use of operating resources and “make managers manage” by specifying what is expected from them and

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<sup>3</sup> Recent reform efforts in US public management have been characterized by five key themes: a critical role for information and technology (Swiss, 1992); passion for customer satisfaction (Denhardt, 1993); increased authority for public managers over budgeting, purchasing and personnel matters (Caiden, 1994); flatter organizations peopled by “empowered” workers (Pindur *et al.*, 1993); value of competition in improving government’s services (Osborne & Gaebler, 1992).



measuring their performance against these expectations. The bargaining process – giving managers discretion in exchange for strict accountability – should be made of interdependent phases: this point should need a deep analysis; now it is important to underline that it is much easier to divest administrative controls than to enforce strong accountability so that it is very likely to forget about the accountability part of the bargain. As Talbot *et al.* (2000) underlined, agencification has been seen as a tool for “unbundling the bureaucracy” and creating more flexible and responsive public organizations, and to gather efficiency improvements.

To better focus the analysis, it is important to address the agencification topic in the context of the European public management: the Commission seems to lack the capacities for managing out-sourcing. Facing the make-buy decisions – what to do “in house” and what to “contract out” – the Commission didn’t show a clear view of what were core functions that cannot be out-sourced and an adequate recognition that out-sourcing requires specialized internal capacities for contract and project management. Weaknesses in the systems of control, audit and accountability directly related to this lack of expertise have been frequently reported (Metcalf, 2000). European public management introduces additional elements of complexity because of the need to manage a “network” of coordinated organizations spread across the European, the national and the sub-national levels. In this sense, if NPM precepts are individuated as concerning the efficiency of individual organizations they cannot provide a complete and exhaustive model for developing a new EU’s structure with better managerial performances. In addition, the concept of “delegation” cannot be considered always a feature of NPM-type reforms and decentralized patterns of governance cannot be seen as an exclusive to NPM (Levy, 2002).

Pollitt *et al.* (1998) differentiated between three different types of delegation: political and administrative; competitive and non-competitive; internal decentralization and devolution. The first pair refers to the allocation of empowerment between diverse levels of government: this differentiation says nothing about the internal management of the functions transferred. On the contrary, competitive, non-competitive and internal decentralization specify the implications for internal service management. To make an example, allocation of functions by means of competitive delegation means a contractual relationship shaped on the principal-agent model, while non-competitive delegation might be an expansion of responsibilities already held by delegated agencies; internal decentralization refers to delegation of responsibilities to staff other than the one actually holding them.

Considering the management rules inside European Commission and its policy-making and policy implementation competences, the delegation process might assume different elements coming from NPM approach but also other more traditional approaches can be easily individuated. This theme will be widely analyzed in this dissertation: at the moment it is performed a brief analysis of the delegation issue as it stands in the last modernization attempts in Europe and Italy, and later into the EU system (i.e., the “White Paper”).

#### *Administrative reforms and delegated bodies*

When discussing public management reforms, it is important to distinguish between countries with high administrative stability, followed by quick changes (i.e. France,

Belgium and also UK) and countries where it has been witnessed a gradual change of the public administration (i.e., Germany). It is also possible to speak of two other tendencies: "escaping" from the State and "rediscovering" the State (Cassese & Franchini, 1989). To summarize, in the first case there is a change towards a "higher" level (the communitarian system), a "lower" level (i.e., the creation of an intermediate administrative level in France and Italy), or the private area (e.g. in France and UK). In UK, on the other hand, the rediscovering of the "State" (in terms of a central authority) is a recent *phenomenon*: this is not contradictory with the first tendency because without a "strong" central administration it would be impossible to deal with an extensive and quick privatization of the public administration.

It would be more appropriate to interpret changes in the United Kingdom as a part of an Anglo-Saxon tradition rather than as part of an emerging European pattern (Kickert, 1997a): at the same time it is important to be careful when assuming the existence of a single European pattern of administrative reform. Netherlands seems to be adopting the English agency model (borrowed from the Scandinavian countries) but this model is only partially used in the other European countries. Pollitt and Bouckaert (1995) put in evidence that the "quality movement" as implemented across Europe is not so evident in the Scandinavian countries, where on the contrary have been implanted successful personnel management reforms as "pay for performance" (Lægneid, 1994). About Germany, for instance it could be said that it has been relatively uninterested in major administrative changes (Klöti, 1996).

The problem with reforming (or "reinventing") public administration is that it is not entirely clear what this term means: deregulation of the public service in the US by eliminating *ex-ante* controls on managers wouldn't be acceptable in, for instance German administrative tradition and even in Canada this concept hasn't been easily transmitted. The American deregulating movement differs from the use of market models in Europe because of the absence of clear substitutes for rules and hierarchy: in many European reforms, instruments such as internal markets have been implemented to substitute hierarchical control (Kickert, 1997a).

Looking to the European reforms<sup>4</sup>, one of the most important structural changes has been the creation of "agencies" or semi-autonomous organizations responsible for the implementation of public programs. The "next step" program in UK has been the most relevant example but analogous programs have been implemented in the Netherlands and Denmark (Kickert, 1997b). Former use of these bodies has been done in Scandinavian countries, and it has been in some ways a basis for the English "Next Step" program (Kemp, 1990). Not considering the experience in US, where agencies have been introduced in the administrative structure many decades ago, it should be pointed out that the Canadian government has been experimenting "special operating agencies" similar to the British executive agencies (Clark, 1991).

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<sup>4</sup> In general terms, the administrative functional model might be modeled for areas of competence or for objectives (goal attainment): in the former case the unit of reference is a Minister (i.e., in France, Italy and Germany), in the latter case this unit of reference is the aim of the organization (i.e., in Sweden). In other countries, as in US and UK, there is a co-existence of traditional functional institutions (Departments) and various "goal attainment" organizations.

Also in countries not engaged in an agency-oriented “revolution” of the national public administration, there has been an appreciable movement towards the use of more autonomous organizations. For instance, the Italian unitary ministerial structure has been modified in some sectors (i.e., education) by the creation of autonomous organizations (Trosa, 1995).

#### *Administrative reforms and delegated bodies – The Italian case*

Italian public administration has been always characterized, at the national and local level, by the co-existence of French tradition elements (i.e., the predominance of the ministerial structures) and of Anglo-Saxon elements (i.e., the presence of independent bodies). In the last decades, also because of the communitarian pressure, the Italian public administration has witnessed the creation of a set of delegated bodies, even if some scholars (e.g., Spagna Musso, 1971) saw in the article 91 of the Constitution, dealing with the necessity for the public bodies to conduct their activities in an “impartial” way, an impediment to the creation of “independent” bodies, in some cases functioning in the framework of the private law.

Even if the communitarian law doesn't directly intervene on the decision of the member States to build up independent authority, it stimulates them by means of directives and regulations (Picozza, 1997): reorganization of the Italian ministries and development of “independent” structures with a consistent degree of autonomy was also result of NPM-inspired reforms occurring in the Italian public administration. In 1999, nineteen “agencies” were created or completely reorganized. Concerning the so-called “Administrative Independent Authorities” (independent institutions with regulatory, inspection and safeguarding powers), their existence in the Italian public administration goes back to the early 70s: however, the larger share was initiated during the 1990s. Capano (2003) summarized the Italian administrative paradigm as characterized by:

- the perception of law as expression of administrative action;
- the separation of political decision-making from administrative implementation;
- the importance of legality, impartiality and neutrality principles;
- the formal rules as instruments of administrative action;
- the attention for organizational structures more than for policies;
- the control of legitimacy.

Changes occurring in the Italian public administration during the last twenty years should be interpreted paying great attention to this point. Re-elaboration of the Italian hegemonic paradigm has involved a partial shift from the principle of conformity to law to conformity to NPM ideas. The creation of most of the Italian agencies was a direct consequence of this wave of reforms: the concept of “independent” institutions refers to legal provisions for autonomy in organizational, financial, accounting and personnel policies. In the Italian public administration this juridical transition occurred for instance with the Antitrust Authority, now recognized by a considerable autonomy from political and economic pressures. In general, it is possible to divide the “independent institutions” existing in the Italian

public administration into two categories: the “authorities” and the “administrative agencies”. Authorities are characterized by a considerable degree of autonomy: not subjected to governmental directives, they are organizationally as well as financially autonomous. A distinguishing feature in terms of autonomy can be found in the election of directors; usually the Authorities’ directors are chosen by Parliament or by the President of the Italian Republic rather than the Government. Government usually does not have any power of deliberation or control over how an authority exerts its duties. All in all, there are more than twenty “administrative agencies”, dealing with different sectors from environment to health care.

Some of the distinctive features of Italian administrative agencies are the following:

- they operate under the ministerial jurisdiction, with policy implementation as their main function;
- their roles and objectives are stated by law;
- they enjoy managerial as well as financial autonomy, though within the constraints of a prefixed budget;
- they have flexible hiring rules;
- they are obliged to give periodic reports on their activities to the Government;
- their budget is subjected to control by the Supreme Audit Institution.

As argued by Capano (2003), the creation of agencies did not represent a “revolution” in the real sense; its extension has been quite limited compared with administrative reforms in countries such as UK and New Zealand. Continuity is related to the fact that the organizational format of Italian agencies draws on models already arranged in the past, especially in the 1980s. Moreover, the managerial approach that is manifest in agencies corresponds surprisingly with traditional bureaucratic-ministerial style in Italy.

#### *The oversight mechanisms*

When delegation of functions is applied, in order to ensure favourable outcomes, *ex-ante* and *ex-post* oversight mechanisms are usually designed (Doleys, 2000): *ex-ante* controls typically take the form of administrative procedures, projected to limit the scope of agency’s activity, the legal instruments available to the agency, and the procedures the agency must follow (Pollack, 1997). *Ex-post* mechanisms of control have been categorized as imposition of sanctions and monitoring. Another typical issue is the “effectiveness” of delegation: in this case the choice is either minimizing the risk of losing control over the agency’s activities or allowing the agent the independence to carry out its responsibility efficiently (Moe, 1987).

Romzek & Dubnik (1994) classify accountability tools according whether the source of control is internal or external, and whether the degree of control is tight or loose. They distinguish between four different accountability systems<sup>5</sup>:

- bureaucratic;
- legal;
- political;

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<sup>5</sup> For further details about this classification of accountability systems see Kickert, 1997a: 239-40.

- professional.

Their analysis reflects the difference between an “organizational” and an “institutional” level; internal controls refer to control mechanisms that are operative within the organization. Bureaucratic and professional control systems are ways of managing the behaviour of employees inside the agency. The external controls (legal or political) are about the ways external stakeholders keep a measure of control over the administration of the organization. Another element to be considered is the difference between being held responsible for results (goal attainment) or being held responsible for process (means used to obtain a goal). For instance, there is a “tight accountability for results” when an agency is given a clearly-specified target and when failure to achieve it brings unfavourable consequences. On the other hand, there is “tight accountability for process” when an agency is required to use particular means to achieve its mission.

Majone (1994) argues that, in the case of the EU’s agencies, agency independence and public accountability can be complementary and mutually reinforcing. In order to reconcile them, more flexible forms of control than the traditional one should be used: for instance, professionalism, expertise, monitoring by interest groups. Inter-agency rivalry can also be associated to more “traditional” forms of control as statutory objectives and procedural requirements. Scrutiny of the regulations governing the existing agencies and their actual operations reveals that the Community has subjected the agencies to specific rules on transparency and accountability. For instance, the most part of the EU’s agencies make public the majority of their documents, also on internet; the appointment procedures of their Management Boards and the budgeting rules facilitate the control of the agencies’ operations by the other European institutions. Accountability of agencies and legitimacy of their operations might be also fostered by their inclusion in networks (Vos, 2000). In the end, many specific institutions have been created in the communitarian system as instruments of control: for instance, the Court of First Instance, the Court of Auditors, the European Ombudsman, and the European Anti-fraud Office.

#### *Towards a definition of “agency”?*

To give an unambiguous definition of what an “agency” is, it has always been a problematic issue for the public management studies. Being difficult to define a clear concept of “autonomy”, as a consequence, it has always been problematic to find a fully satisfactory definition of “autonomous organization” (Peters & Bouckaert, 2004). From a “comparative” perspective, the coexistence of profoundly different national legal systems and the difficulty to give a standard functional classification of the relationships between the “central” organizations, i.e., the Ministries, and the delegated bodies because of the variety of the national legal and institutional frameworks, has made problematic to compare “agencies” located in different administrative contexts.

In general terms some degrees of “disaggregation” and “autonomy” are requested to an “organization” to be defined an “agency”. With the concept of disaggregation it is meant a structural separation from the “core” organization; autonomy refers to the possibility to have a certain degree of freedom in the use of finance, personnel or

organization (Pollitt *et al.*, 2004). More than an unequivocal definition of agency, it might be appropriate to state the characteristics an “agency” should have, in order to properly assume that label. Pollitt *et al.* (2004), referring to public national and sub-national agencies, define an agency as an organization which:

- has its status defined in public law;
- is functionally disaggregated from the core of its ministry or department;
- enjoys some degree of autonomy, not enjoyed by the ministry or department;
- ministers/secretaries of State are allowed to alter its budget or main operational goals;
- is not fully independent of its ministry/department of State;
- is not a commercial corporation.

Following these *criteria*, some organizations, apparently considered as “agency” might be not. What about the communitarian agencies? In the next chapter, this topic will be specifically addressed. At the moment, it is enough to underline the controversial solutions found in public management to give a proper definition of “agency”.

## 1.2 Agency model and the European Union

The concept of agencification cannot be defined a truly new *phenomenon* in the institutional framework of the European Union but the increasing push to the creation of delegated bodies since the 1990s reveals that it should be considered one of the key factors of the recent European Union process of reform. The two main background factors pushing for the increasing creation of agencies in the communitarian system might be individuated in the rapid growth of EU’s policy management responsibilities and the increased loads this fact places on the European Commission (Metcalf, 1999a) and, on the other side in the complexity for the Commission to run its internal management processes.

In the “White Paper on European Governance” (European Commission, 2001a), the Commission stated that one possibility for improving its managerial performance, in particular with reference to the way rules and policies are applied across the Union, was to delegate specific functions to regulatory agencies because it was supposed that the “independence” of their technical and scientific assessments should be based on the purely technical evaluations they provide, which should be not influenced by political or contingent considerations. This is one of the most controversial points of debate about the delegation process occurring into the communitarian system: it will be showed further in the text that an unequivocal solution to this controversy is still unfounded.

From a “political” point of view indeed, when implemented, the agency model has profound implications for the role and authority of the Ministers (at the State level) or more generally the central authorities (at the communitarian level: the European Commission), and on their capacity to make, enforce or deliberate policy. Inevitably, therefore, political factors have to be heavily taken into account when the creation of agencies is to be explained in scientific terms. Agencification has been traditionally seen as a way of rationalizing the choice of goals and means of policy delivery and, in general to “depoliticize”, that is to prevent some activities from the political

influence. In the communitarian context, explaining the creation of the agencies as an answer to the increased "politicization" of the Commission or, on the contrary, as an answer to the improved influence of the member States on the European Commission's policy management independence is a widely debated issue and it will specifically addressed in the next chapter.

#### *The European Commission's reforms*

White Paper has been presented as a package of highly innovatory reforms, even if some previous attempts of European Commission reform had pretty similar purposes (Levy, 2002). It is interesting to underline how the principles of "good governance" the White Paper aims to be applied to the European Commission's management rules are quite common in any "traditional" public management reform. For instance, they are the independence of the Commission; the responsibility of allocation within the Commission; the accountability of and within the Commission; the efficient delivery of the Communitarian services and the transparency within the Commission. These principles refer to three main areas of application: priority setting, human resources and financial management. The White Paper takes in high consideration the delegation issue of the Commission's activities, which is defined as the "delegation of all or part of its tasks or activities" and should include "testing a new type of implementing body headed by Commission's staff" (Commission of the European Communities, 2001a: 6-7). With reference to the classification of different types of delegation processes addressed above in the text, it is interesting to note that the White Paper defines them using various, and sometimes contradictory terms (for instance, devolution, decentralization and outsourcing) without defining them properly or contextualizing them in a clear field of application among the different activities of the Commission (Commission of the European Communities, 2001a: 17). One of the most remarkable points is the short and not clearly defined reference to the potential delegation of functions to member States' agencies, possibly revealing a first departure from the centralist traditional organizational mode traditionally preferred in the Communitarian approach, in which no issues are delegated to autonomous bodies of non-communitarian nature outside the direct control of the Commission.

For instance, when addressing the issue of structural funds' management reform, the Commission aims to ensure a clearer division of responsibilities where the European Commission should supervise compliance with the strategic priorities and the programme management should be more decentralized (Commission of the European Communities, 1999: 15). Again, in this peculiar case, the delegation process appears to be counteracted by another "centripetal" process, with the centralization of functions and powers occurring inside the national context, as traditionally happened at the communitarian level with the centralization towards the Commission. A first assessment of this model reveals that it is clearly based on the principal-agent theory more than on the network approach: this impression can be drawn because this model separates policy-making from management and it doesn't assign any role to the agencies in the decision-making process. The agency model existent in the EU system, in particular after the establishment of ten new agencies in 1993, seems on the contrary to be different and nearer to the "network" model,

with an appreciable involvement of national institutions, where the communitarian bodies enjoy maximum authority and flexibility in day to day management of specific community programmes and the network is based on the concept of collaboration of complementary institutions (Commission of the European Communities, 2000). This topic will be widely addressed in the dissertation and it is out of the aim of this introduction to give a fully explicative answer to this controversial issue but this short analysis should be enough to clarify the degree of importance the concept of delegation inside the Communitarian system has reached both between the practitioners and inside the scientific arena.

In the wider context of the modernization of the communitarian institutions it should be underlined that in the last years the few attempts put in essence present also some influences coming from the legalistic and bureaucratic tradition: some scholars (e.g., Levy, 2002) even argue that the externalization process occurring inside the European Commission is not really a radical departure from the centralist model but just another way of trying to achieve it. Stated against this general background it should be clear as the creation of these delegated bodies, have place in the emergent governmental scheme of European Union even if it is still unclear which tasks these bodies could most properly undertake. In the attempt to give an answer to this inquiry, the structural characteristics of these bodies should be assessed in order to find a balance between the crucial general concepts of power and public accountability and specific communitarian principles such as for instance the one of "balancing of powers" (Everson, 1995).

Is it rather difficult to define univocally what an agency, and in particular a "European" agency is and some scholars try to define it by exclusion. In general terms, an "agency" shouldn't be considered as a technical term but as a label to describe many types of organizations. A common definition of agency doesn't exist: instead the character of such bodies differs depending on the nature of the tasks and powers assigned them. One of the most widely accepted definition of agency is provided by the US Administrative Procedure Act (APA) in which an agency is defined as a part of the Government, which is generally independent in the exercise of its functions and that by law has the authority to take a final and binding action: in this definition, what characterizes an agency is not its organizational form but the possession of the legal authority to take final and binding actions (always subjected to legal requirements and judicial review) affecting the rights and obligations of individuals, particularly by the characteristic procedures of rule-making and adjudication<sup>6</sup>. Following this approach, the agency status doesn't require that an agency exercises its power with complete independence, either vertically (in terms of administrative review commitment) or horizontally (in terms of compulsory co-ordination with other organizations). In the case an organization is in complete charge of a programme, it is an agency with reference to that programme, despite its subordinate position in other respects (Everson *et al.*, 1999).

As it should be clear now, the term agency includes a large variety of activities, objectives and institutional designs. It has also to be underlined that agencies

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<sup>6</sup> Source: [www.oalj.dol.gov/libapa.htm](http://www.oalj.dol.gov/libapa.htm) (last access, March 2005)



shouldn't be considered as something new, distinctive or constant because of the fact that the label of agency is now widely accepted for defining public sector organizations introduced by the latest and most important agencification movements as for instance the Next Steps' programme in UK (e.g., Greer, 1994) or the contractualisation of ministries in New Zealand (Boston & Martin, 1986).

For the scope of this dissertation, the definition given by Bergström & Rotkirch (2003: 7) will be used: they refer to decentralized agencies, in the EU's framework, as "bodies with legal personality of their own which have been established in order to accomplish specific technical, scientific or managerial tasks having fundamental similarities but being differentiated by their legal basis, legal personality, organizational features, funding and financial control".

*Behind agencification: the parliamentarization issue*

Over the first years of the agencification *phenomenon* spreading, there was very little empirical work done on its impact and much of the literature was speculative or anticipatory (e. g., see O'Toole & Jordan, 1995; Rhodes, 1997) but recently a lot of comparative work has been done in this field. There might be many reasons behind the delegation of power to an agency: for instance, new activities may not match the already existing duties of the public "central" organizations; in other cases some functions could be better managed as the central interest of a "specialized" agency more than the peripheral matter of a "general" organization. In the specific case of a regulatory agency, delegation of rule-making powers may be needed when constant fine-tuning of standards or quick adaptation to technical progress is needed. To create an agency might be also interpreted as a preferred mechanism for co-opting certain groups into the decision-making process (Everson *et al.*, 1999).

Referring in particular to the EU's setting, one of the reasons pushing for an increased agencification of the communitarian structure can be individuated first in the "parliamentarization" of the European Commission and in the role and capacities owned by the same Commission (Flinders, 2004a). With reference to the "parliamentarization" issue, the dramatic increase of the discretionary tasks for which the Commission has become responsible and the increased power of the European Parliament push, from an institutional point of view, for the necessity to "insulate" some tasks from the "political" sphere. Placing a function "at arms" length might be seen as a step towards lessening political influence over activities which it is wanted to "depoliticise" (Talbot *et al.*, 2000). This argument will be specifically addressed further in the dissertation when assessing the "political" reasons behind the creation of EU's agencies and the definition of their management rules.

The process of European enlargement and the lack of financial, administrative and political capacities of the Commission to devise and implement a new regulatory structure stay at the base of the creation of the set of new European agencies. In this sense, the reasons behind the adoption of the agency model in the communitarian and national or local level differ. In general administrative terms, as assumed in the national public system's reforms occurred in the last twenty years, delegation is seen as a tool for delivering technical efficiency improvements for instance in terms of flexibility, performance orientation and customer closeness. At the European level

the most part of the scholars argue (Flinders, 2004a) that the creations of agencies, in particular in the 1990s, has been grounded in the will to ease the co-operation between member States in specific sectors, trying by this way also to solve the problem to increase the allocation of additional powers to the Commission.

#### *The agency model inside EU*

The creation of agencies inside EU, as briefly addressed above, shouldn't be considered as a truly new *phenomenon*: a detailed empirical analysis of the communitarian agencies features will be performed further in the next. At this point it should be enough to give some introductory insights about the use of the agency model inside EU. The establishment of EU's agencies starts in the mid-1970s and it dramatically increases in the 1990s. New agencies have been set up in 2004 but exhaustive details about their management characteristics and their degree of power and the delegated functions assigned them are still unclear. Up to 2004, the organizations gathered under the definition of "European agency" include twenty agencies (using the European terminology: "satellite bodies") created under the European Community Treaty, one under the Euratom Treaty, and four under the second and third pillars of the EU.

The creation of an independent European agency is subjected to the adoption of a specific legislative instrument by the European Parliament, on Commission initiative: the most fundamental feature of the existing decentralized agencies is the fact that they have all been set up in regulations adopted by the Council. Formally, each agency is a body of the European Union, in principle beyond control of the member State in which it is located. Except for the agencies of most recent creation (and also in the case of the European Environment Agency), all agencies have their legal basis in the article 308 of the European Commission Treaty. European agencies have legal personality and formally they don't belong to the Commission or to the Council. As said above, the creation of agencies is not explicitly mentioned in the Treaty and its legal basis - article 308 - is intended as a residual competence, in the sense that this article is used when an action is necessary but the European Commission Treaty doesn't provide any more specific power. In fact, because of a restrictive interpretation of Article 4 of the Rome Treaty, for a long time it had been decided for a general prohibition on the establishment of additional organs others than organs already established by the Treaty, without a Treaty revision. After the introduction of the so called "Meroni doctrine"<sup>7</sup> by the European Court of Justice, this interpretation was eased but with the still existing limitation that the Commission may only dispose of those powers which itself possesses. For this reason it might happen that these delegated bodies don't own discretionary powers, suffering of a limitation that if, on one hand doesn't fright the "balance of powers" principle, on the other one might create strategic and operative problems. From the organisational point of view, all agencies have a director (executive director or president), and a supervisory board (management, administrative or governing body, or an administrative council). The director represents the agency from the legal point of view and should, as a main duty, work for the preparation and implementation of decisions and programmes adopted by the supervisory board. The director is usually

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<sup>7</sup> Case 9/56 Meroni & Co. S.p.A. vs. High Authority of the ECSC [1957-58]; ECR 133.

appointed by the same supervisory board and is accountable to it. Regarding the composition of the supervisory board, usually the member States are widely represented. A more limited presence is assigned to representatives of European Commission and European Parliament. What mostly differentiates from the organisational point of view the different agencies is the presence of additional representation in the supervisory board. This additional representation might be made of interest groups' representatives, professional experts or others. Advisory units and boards of appeal are frequently part of the agency structure. Regarding the funding issue, it is EU to be financially responsible for the agencies: the expenditures for them are part of the general budget. Again, this theme is one the most differentiating the diverse agencies: sometimes the fees paid for the agencies' services are aimed to give the agencies a partial self-financing independence. About the financial control, different internal control modes exist: sometimes a financial controller is appointed by the Commission; in other cases by the agency itself. The European Court of Auditors is always responsible for the external budgetary control of all the agencies.

#### *Classification of EU's agencies*

In general terms, defining and classifying properly the European agencies involves a deep analysis of their relationships with the other communitarian actors but also with the member States: the organizational processes, the personnel policies and the funding and financial rules will be specifically addressed in the next chapters of the dissertation and a complete classification of the agencies will be provided. At the moment it is more interesting to provide a more general picture of the agency model as applied to the European context: it is not possible, as for instance in the American system, to clearly distinguish between independent executive agencies and independent regulatory agencies (e.g., see Shapiro, 1997).

Kreher (1997) distinguishes between:

- "information function" agencies;
- "executive" agencies.

Everson (1995) individuates four different types of EU's agencies:

- "regulatory";
- "independent information collecting";
- "adjudicational";
- "charged with the pursuit of distinct 'Constitutional-type' normative goals".

In general terms, it is fundamental to distinguish the "agencies" from three other types of European bodies. In the Kreher's classification (1997) for instance:

- first, a distinction should be done between independent agencies and internal bodies or departments of the European Commission: to make an example are included in this category bodies such as the Statistical Office of the European Union (Eurostat), which is independent within the Commission but is still considered a service (in the organizational sense) within the same Commission. One main point distinguishing European agencies from this

type of bodies is the fact that agency's staff is not mentioned in the European Commission's general employment plan;

- second, European agencies are not included in the list of institutions already explicitly listed in the European Commission Treaty: one of these institutions is the European Central Bank. On the contrary, Everson (1995) refers to this institution as one of the organizations charged with the pursuit of distinct "Constitutional-type" normative goals in the sense that it exists in order to maintain the price stability, which is considered as one of the objectives of the European Union Treaty, regarded as a "quasi-constitutional" text;
- third, European agencies should be distinguished from those institutions created on an intergovernmental basis, that is outside the European Commission's legal framework. One example of this third category of institutions is the European University Institute (EUI) in Florence.

In this dissertation, having taken as the accepted definition of agency the one stated by Bergström & Rotkirch (2003) and having underlined here the differences between the "independent agencies" and the other three types of European bodies, the following functional classification of agencies will be used. Excluding from the analysis the agencies constituted under the second and third pillars of EU and the one created under the Euratom Treaty because of their peculiar scopes and characteristics, three different types of European agencies currently in operation within the fields of application of the EC treaty are considered:

- "administration" agencies dealing with matters of internal administration;
- "authorization" agencies responsible for granting permissions;
- "co-ordination/information" agencies collecting, analysing and re-distributing information.

### **1.3 Theoretical and analytical approach**

This chapter has the purpose to present the state of the debate about European issues, in particular from a "systemic" point of view, leaving for the next chapters of the dissertation a deeper and more punctual assessment of the agency management mode, which will be focused in particular on its "managerial" peculiarities.

Theoretical generalizations on the EU's nature have been challenged, and still are, by the complexity and heterogeneity of this institution: generalizations usually have been linked to theoretical interpretations of the EU system which emphasize some of its general characteristics (Andersen, 2003): for instance as an inter-state system (Moravcsik, 1998); a governance system (Kohler-Koch, 1996a); an organizational sphere in which individual States are integrated (Olsen, 1998). On the contrary, the principle of governance in the EU has been always interpreted as the so called "community method" in which the European level institutions shape and decide on policies and programs, and where implementation is regarded as domain of national administrations (Kadelbach, 2002; Olsen, 1997a).

#### *The neo-functionalism*

Research on the communitarian institutions has evolved since the date of their creation: in the 1950s and 1960s there was a strong dominance of the neo-functional

theory, in which the initial delegation of authority to supranational institutions leads to a progressive strengthening of integrationist forces, by ways of spill-over and unintended consequences (Haas, 1958). From a neo-functional perspective, the EU level of governance and the domestic level of governance are linked in several ways (Wessels, 1998) and the logic of territoriality is bypassed for as a central cue for decision-making behaviour: the constant interaction between national officials at the European level brings to a "fusion" of national administrations in a process of so-called "*post national socialization*" (Hussein, 2003). In this sense neo-functionalists tend to undervalue the role of domestic politics and institutions and to present a rather static view of European Union system evolution (Trondal, 2001). Some scholars claim (Moravcsik, 1993) that strong supranational institutions are perfectly compatible within an intergovernmental logic, as they are the results of calculations by member States to strike a balance between greater efficiency and domestic influence, on one hand, and acceptable levels of political risks, on the other. On the contrary Majone (2002a) argues that the increasing delegation of EU's policy enforcement moves contrary to neo-functional expectations, because of the increased dependency of the European Commission on the national administrative systems.

#### *The intergovernmentalism*

The intergovernmentalist approach, dominant in the 1970s, emphasises the centrality of national States and the separateness of European and national levels of governance: European institutions and decision processes are seen as aggregate effects of "national interests" pursued by the member States. Again, preferences and identities are seen as highly static and the institutional variables are perceived at best as intervening variables and not as independent variables (Aspinwall & Schneider, 2001). The European level in this sense is not perceived as a governance system in its own right and hence not as a distinct level of governance as such. Decision processes are seen as products of exogenously defined preferences and strategies (March & Olsen, 1995), decisions and organizational structures resemble "negotiated orders" and the institutional arrangements are seen as arenas for giving and taking between rational actors. Two are the main approaches inside the intergovernmentalist "school": the liberal intergovernmentalism and the institutional intergovernmentalism. Liberal intergovernmentalism explains the creation of the EU's "strong supranational institutions" in terms of interests of the States, which, under conditions of economic interdependence recognize the benefits of entering into long-term co-operation, but they need to overcome problems of collective action (Moravcsik, 1993). A fundamental dilemma of this approach concerns the functional theory of delegation (no empirical evidence demonstrating that member States engage in a cost-benefit analysis exists) and the possibility for the national administrations to monitor the supranational institutions' decision processes (Kassim & Menon, 2003). Institutional intergovernmentalism, a more sophisticated approach than the liberal one, recognizes the influence of the Commission in the decision-making process but underlines the fact that it ultimately depends on the member States and on the Council's influence as "last mover" (Garrett, 1995). The potential

problems arisen from principal-agent relationship affect also the institutional approach.

### *The institutionalism*

In the 1990s, the analysis of the European Union saw the emergence of other two theoretical approaches: new institutionalism and multi-level governance (MLG). Starting from the assumption that the influence of member States over the EU's rules of functioning are limited, historical and rational choice institutionalism consider the supranational institutions as key factors in restricting the ability of member States to shape EU's development (Thelen & Steinmo, 1992). The central claim of historical institutionalism is that intergovernmentalism is flawed because "the current functioning of institutions cannot be derived from the aspirations of the original designers" (Pierson, 1996: 127). According to historical institutionalism, the tendency over time is that member States lose control over the supranational institutions so that they can act autonomously on the basis of preferences possibly diverging from the member States' ones. European context can generate unintended consequences as "overload" and "spillover" which might produce "interaction effects" leading to unanticipated outcomes. In the rational choice institutionalism perspective, member States seek to control the autonomy of the supranational institutions to which they delegate autonomy. Functional theory of delegation (Pollack, 1997) could explain the functions delegated: the tools used by member States to "control" the outcome of the delegation process are monitoring compliance and enforcing treaty provision; solving problems of incomplete contracting; independent regulation and agenda-setting. Applying principal-agent theory to the relationship between member States and supranational agents, it might happen that the latter are able to assume functions that were not originally anticipated by their "creators".

### *Multi-Level Governance*

Multi-Level Governance (MLG) is a highly descriptive conceptual model useful for explaining the EU's new governmental architecture (Carmichael, 2002): EU's policy is produced by a complex web of interconnected institutions at the supranational, national and sub-national levels of government (Marks *et al.*, 1996). In this approach, the role of the European agencies is considered fundamental: European governance is defined as system of multi-level, non-hierarchical, deliberative and apolitical governance, via a complex web of public/private networks and quasi-autonomous executive agencies, primarily concerned with deregulation and re-regulation of the market (Hix, 1998). The creation of agencies at the European level is parallel to a trend towards the development of administrative structures in which national and European-level institutions create closer cooperative arrangements. These structures aim to provide EU with an administrative infrastructure without delegating direct administrative responsibilities to Community institutions, because of the member States' resistance (Kreher, 1997; Egeberg, 2004b). Some scholars even argue (e.g., Egeberg, 2004a) that this trend might lead to the creation of a "networked-administrative system" in which autonomous national agencies prepare and enforce EU's policies at the national level, in a closer cooperative arrangements between national and European-level institutions and so doing "bypassing" the

national ministries. By means of this networked-administrative system, EU might be provided with an administrative structure without delegating direct administrative responsibilities to Community institutions, which could be inconceivable because of the member State' resistance (Dehousse, 2002). Christiansen (2001) interprets the creation of communitarian specialized agencies as a sensible outsourcing of specialised knowledge so that the Commission can concentrate on its core tasks; other scholars (e.g., Kassim & Menon, 2004) see this process as a further evidence of the marginalisation of the Commission. Commission officials seem to have attempted to restrict the effective authority of the European agencies (Majone, 2003). Two can be the first answers to this attitude of the Commission: the desire not to delegate real authority to a potential competitor and the understanding that the agencies could be instrumental tools in the hands of the member States<sup>8</sup>.

### *The networks<sup>9</sup>*

EU's agencies operate in a complex and differentiated institutional environment and have to interface with diverse administrative national systems, with other European institutions and with various stakeholders. In this sense they are embedded in co-operative networks connecting European, national and sub-national organisations. Metcalfe (1999a) defines networks as processes of management characterised by fluid and flexible links among individuals and groups within an organisation enabling it to respond rapidly to new opportunities and adapt easily to change. The concept of network has been introduced for the first time in the field of organizational theory (e.g., Evan, 1966; Ouchi 1980) but it has been widely used also in the strategy realm (e.g., Gulati, 1998; Thorelli, 1986). A network organisation is seen as flexible, informal, adaptive, and entrepreneurial. Two of the main features characterizing the network organizational form are the concepts of "learning" and "trust": networks, to be effective, need the participants to share a common background and to be able to manage innovation or, as in the case of supranational public institutions like the European Commission, to face new problems coming from a turbulent environment, being necessary for an organization

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<sup>8</sup> A slightly different approach is the one proposed by Chiti (2003): it presents an interesting combination of decentralisation and integration processes which has been defined "decentralised integration". By definition, decentralized integration is a very complex administrative structure because it involves different actors in a joint action: decentralized integration approach states that the Community administrative functions to be effectively performed need the involvement of a plurality of administrations (i.e. Commission, national and sub-national institutions) so that the so called "pluralisation" is in this case an essential feature of the administrative framework (Chiti, 2000). The joint exercise of the Community functions in this case requires a structure which is at the same time decentralised, through the establishment of a supranational body which excludes or restrains the administrative powers of the Commission, and integrated, through the provision by Community law of organisational and procedural tools for co-operation among the plurality of competent public bodies. This community administration would be really effective only when it could operate in conditions of full autonomy, being it the case where the Commission could rely on its own agencies at the national level or, by means of a direct relation, independent from any external pressure, on member States' agencies, which is, at the moment, not realistic.

<sup>9</sup> The classification of the "institutional", "organizational" and "social" networks is not addressed in details here: for the scope of this research it is useful to refer to the concept of network as defined by Kickert (1993).

to be part of a "community-level" system (Powell *et al.*, 1996). Network forms of organization are particularly effective in circumstances where there is need of efficient and reliable information, and they can be sustained in the long term only when relations of reciprocity and trust exist among their members (Powell, 1990).

Referring to the public environment governance, networks should be identified by means of three aspects: context (the environment), complexity (number and variety of system's elements and their relationships), and governance: management and organization cannot be isolated from their context and the diverse actors in a public environment are not entirely independent (Kickert, 1993). In the European framework, the Commission cannot dominate and hierarchically dictate, but at the same time it is not horizontally equivalent to the other actors. Kickert (1997b) individuated three perspectives of investigation to be applied to public management networks: instrumental (how one actor can influence the other actors, given the network context); interactive (how the actors mutually adjust their strategies in order to enable collective action and common outcomes); institutional (how the network as a whole, in its "structural" and "cultural" elements, is managed). When addressing the analysis of European agencies it is essential to refer to the patterns of organizational networks in which the agencies are embedded. The constraints and opportunities of different organisational environments change: significant constraints on the focal organisation – the agency – can generate strong pressures on for consistency in the way the agency performs; on the contrary few constraints may diminish the external pressures but also the possibilities of outside supports<sup>10</sup>.

### *The policy networks*

Policy networks can be defined as clusters or complexes of organisations connected to each other by resource dependencies and distinguished from other clusters or complexes by breaks in the structure of resource dependencies (Benson, 1982). The emerging interest in policy networks in the studies on the European system of governance might be understood as a reaction to the critique to the multi-level governance approach, which predominantly focuses the attention on the "multi-

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<sup>10</sup> For what concerns strategic alliances, some researches have shown that once the investigation moves away from purely market and economic models of perfect information and frictionless exchange, it becomes clear that decisions on alliances' performance are predicated on imperfect competition and co-operation based on cultural and/or social institutional factors, as well as relationships at a national or international level (Burt, 1992; Coleman, 1990; Putnam, 1988). In contrast to the transaction cost- and economics- oriented scholars, institutional and social science researchers believe that cooperative exchange may not necessarily need to be driven solely by opportunistic motives (Burt, 1992; Choi, 1994; Ouchi, 1980). Researches in international relations, politics and psychology on collective action (Olson, 1965) and co-operation all indicate the importance of non-market driven *criteria* when an agent is to establish a cooperative relationship with others. First, trust among alliance members is a critical determinant of the alliance success (Bleeke & Ernst, 1993; Buckley, 1992). Trust can increase cooperation and collaboration, improve relationship flexibility, increase quality, lower the costs of co-coordinating activities (Smith, Carroll & Ashford, 1995) and improve alliance productivity and efficiency (Sitkin & Roth 1993). Trust also breeds mutual commitment and effective collaboration, both of which are indispensable for a strategic alliance to operate successfully in an uncertain and turbulent environment. There is relatively little consensus in the vast "trust" literature on the meaning of the term despite some much focused attempts at clarification (e.g, Barber 1983; Seligman 1997). There is even less consideration about how to identify when it exists or how to measure it.



level” aspects (relationships between the territorial levels of government) of multi-level governance, thereby partially neglecting the relationships between the non-territorial levels of government – governance components – that is the public and private actors (Börzel, 1997). In this sense, policy networks are perceived to offer a way to “put governance back into multi-level governance” (Smith, 1996): the European Union can be conceptualised as a multi-level system of governance, where private and public actors at the supranational, national, and sub-national levels cooperate within complex networks to produce policy outcomes.

The distinct institutional setting of the European Union contributes to advance this particular mode of governance: the Commission can be considered as an “ideational entrepreneur” of the network. Evolving the European system of governance towards an organizational network mode rather than a hierarchy and not having the Commission the resources to play the role of a central executive authority (Metcalf, 2000), the Commission should act as the hub of networks of European actors rather than the top of hierarchies. Some scholars argued (e.g., Scharpf, 1997) that EU is a negotiating system geared towards problem solving strategy, a network governance which thrives on co-ordinating a multitude of actors and approximating diverse interests (Kohler-Koch, 2002). The organisation set of a focal point such as an agency is the network of organisations in which it is located: the network is defined by mapping the organisations and the relationships among them. Agencies in this sense might be considered not only as the organisations managing decentralised functions that could be performed within the Commission but as organisations possibly playing a fundamental role in improving the coordination of the organisational networks by which the European policies are managed. An agency should be considered as an agent of integration, an agent of change (Metcalf, 1999b). Policy networks in which the European agencies operate as “hub” organisations should be managed depending on multilateral negotiations with the stakeholders involved in the networks, in order to develop non-hierarchical modes of management<sup>11</sup>.

The basic assumption of the communitarian policy networks’ existence is that their “organizational” features influence the policy outcomes (Börzel, 1997). Networks, as argued above, are predominantly characterised by informal interactions between public (and private) supranational, national and sub-national actors with distinctive but interdependent interests, organized by non-hierarchical modes of co-ordination. Scholars as Scharpf (1993) identify in the “communication” and “trust” concepts the characteristics distinguishing policy networks from other forms of non-hierarchical co-ordination. If EU is defined as a system of “governance” without “government”

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<sup>11</sup> The concept of “collaborative advantage”, defined as “a form of economic advantage which stems not from natural or historical endowment but from various elements of the local economic system working together more effectively than their counterparts” (Huxham & Macdonald, 1992) is essential in order to assess the performances of these networks. Achieving collaborative advantage means meeting an objective which no individual organization could have met alone and achieving the objectives of each collaborating organization better than it could be done alone. Carefully designed partnerships contribute to collaborative advantage by clarifying the organizational division of labour and institutionalizing shared responsibility for performance: this is fundamental in order to transform – possibly incoherent – policy networks in effective regimes (Metcalf, 2000).

(Christiansen, 1994) it should be clear that EU proceeds by means of negotiations in policy networks linking public and private actors of different levels and dimensions. The constitution of these policy networks should solve the problems of efficiency and legitimacy typical of complex public environments as the communitarian one, providing an arena for strategic, informal and communicative activities overcoming the problem of collective action. To give some introductory insights, the environmental policy network is loosely knit, fluid in composition and underdeveloped; on the contrary the pharmaceutical network is well established, tightly knit and there are clearly defined organizational divisions of labours (Metcalf, 2000).

#### **1.4 Research questions**

As assumed before, in order to assess in a proper way the agencification *phenomenon* occurring inside the communitarian setting, a complete analysis has to be performed starting from the assumption that macro factors (for instance, the institutional and political setting) might influence the agencies' performances. If first it is introduced a brief assessment of the macro-level of analysis, it is possible to avoid missing important factors, possibly influencing the micro-level of analysis, and giving important insights, taken for granted the necessity to not insulate the unit of analysis – the agency – from the peculiar politico-administrative setting in which it operates, in many aspects different from any other public or private environment. Being this research addressed to deal with the empirical analysis of the managerial processes occurring in the EU's delegated bodies and the consequences, on the organizational and, more generally, managerial level, of the communitarian institutional change caused by the introduction of those delegated bodies in the communitarian structure, the attention will be focussed on the agencies as public management "organizations". In any case it is not possible to start this investigation without taking into considerations the "networks" of relationships with their stakeholders in which those agencies are involved.

Considering the fact that most part of the European agencies operate as focal points ("hubs") of networks, the analysis will first be focussed on the design of the relationships with their stakeholders, concentrating the attention on the tools used in order to strategically play a significant role when negotiating the relations with them (i.e., informative duties). On one side the structural (institutional) and administrative elements characterising these networks will be analyzed; on the other side the crucial relationship with the Commission has to be detected. It is fundamental that, in a framework of relative "freedom" of action of the agencies, the Commission should be able to define a proper accountability system in order to "control" the agencies' activities: the design of the relationships Commission-agencies will be assessed, at the light of the main suggestions coming from public management literature, with a significant empirical focus. When possible the assessment of "informal" elements at the base of the success of networks' management as "trust" will be compared with factors as "proceduralization" or "information duties" in order to weight their respective importance.

*RQ 1. What are the main structural and administrative features of the networked institutional environment in which the communitarian agencies operate? (descriptive question)*

When carefully designed, partnerships can contribute to enhance the collaborative advantage's promotion, because they might clarify the organizational division of labour and institutionalize shared responsibility for performance (Metcalf, 2000: 830) but in the end it is co-ordination that bonds the actors of the network together. Being in the European setting diverse organizations involved in EU's policy-making and being policy implementation embedded in different national contexts, this means that many problems exist against a proper development of collaborative relationships between them. Agencies might play in order to enhance the possibilities of assuring a collaborative relationship between the different actors of the communitarian networks: it will be analyzed in general terms the role of the agencies in assuring this "entrepreneurial" function in order to guarantee a proper functioning mechanisms to these partnerships. Again, even in this case of "macro" analysis, the "testable" elements of the relationship will be taken into considerations (i.e., type and frequency of contacts) instead of trying to give a "normative" explanation which would drive the analysis too far from the scientific focus of this dissertation.

To give a first example, European agencies ensure that national experts meet within the agency on a regular basis and in some fields (, the environmental one) member States are obliged to establish national focal points which coordinate the preparation and transmission to the respective EU's agencies of the information needed (Kreher, 1997). Being the national experts involved on a periodical basis in meetings within the European agencies, a sort of "Europeanization" of these experts might occur, by which they are "forced" to behave in a "European" more than "national" oriented way. Instead of trying to test this attitude<sup>12</sup> it is pointed out that in order to promote mutual information exchange and to create elements of confidence-building among national administrations (Majone, 1995) and to go further in the direction taken with the comitology web inside the Commission, and given the fact that the meeting of national officials cannot truly create a "community of views", the agencies might respond to these functional needs (Dehousse, 1997). The creation of permanent technical and administrative secretariats and the development of a shared understanding and vision about the issues the agencies deal with, might be dramatically helpful in order to foster the elements of trust, streams of information and proceduralization at the base of the good functioning of the networks in which they are involved. Being the role of many agencies an "informative" one<sup>13</sup>, because

<sup>12</sup> The impact of the organisational design on performance (Dalton *et al.*, 1980), also in the context of the social network studies (Pearce & David, 1983), has been assessed in order to check the mediating effect of group level characteristics between organisations' design and organisations' performance. Some scholars (i.e., Trondal, 2001) showed a partial empirical evidence of the "Europeanization" process affecting communitarian functionaries' attitude but further studies, focused on the agencies' staff would be very insightful.

<sup>13</sup> In general terms, European agencies might be identified as following an approach of "regulation by information" (Majone, 1996) or as "hubs" of networks of administrations in different policy areas (Ladour, 1996).

of the lack of power they usually have in relation with the Commission concerning the possibility of autonomously activating a communitarian decision-making process, only by means of this process the agencies might get a crucial role and actually influence the Commission decisions. For these reasons, the formal (or eventually informal) mechanisms of involvement of national seconded experts, national representatives, and in general of the agencies' stakeholders will be analyzed in order to check if this process can be considered as a case of co-optation, possibly responding to a strategic planning of the same agency's management.

*RQ 1a. What is the role the communitarian agencies might play to foster the collaboration between its stakeholders? (descriptive sub-question)*

Taken for granted the existence of different organizational modes of EU's agencies, and assumed that an agency form of organization is not a sufficient condition for getting formal authority from the Commission, it is worthwhile to try to understand if, and to what extent European agencies are autonomous and, if they are autonomous, how the organisational design chosen can give rise to a credible independent agency that produces relevant outputs. Considering the "depoliticization" issue, in a pure form it should be "impossible" (Flinders & Buller, 2004) and, more generally it should be subjected to a wide public and political debate. But at the EU's level, it should be detected if an empirical evidence of the gain coming from a "depoliticization" of some policy-making processes occurring because of agencification exists. It has to be noted that at the European level, many officials tried to downgrade the importance of the agencies referring to them as pure information-gathering actors. Interest groups' and national regulatory bodies' initiatives to influence agencies' decisions should be also addressed. The purely "technical" and "un-political" nature of the EU's agencies has been often underlined by many communitarian and national actors: in this sense, not considering, if not from a "normative" point of view, the concept of "political" independence, the "operational" aspects of this issue will be addressed, considering the instruments developed in the communitarian framework to deal with this problematic aspect intrinsically included in the process of creation of any delegated body.

Strictly connected to this point is the need to assure a degree of co-ordination and uniformity to the agencies' activities, taking into consideration the increase of the communitarian institutional fragmentation. It has been suggested that the intergovernmental board of each agency, which is usually constituted also of representatives of each member State might assure co-ordination to the agencies' activities. Some agencies apply formal mechanisms of co-ordination and in particular of multi-level, non hierarchical co-ordination. It will be briefly addressed the problem of balance between modalities of co-ordination, hierarchy and networking in order to define the best mode of co-ordination and test if a unique solution exists or every agency should be designed with reference to the matter it deals with and to its stakeholders' interests.

*RQ 2. What are the main "co-ordination" tools developed in the communitarian system to assure a satisfactory degree of uniformity to the activities of the EU's agencies? (descriptive question).*

The transfer and location of power to European agencies is widely biased by the fact that the existing framework for agencies' activities seems to be consequence of a complicated power struggle more than of a rational organisational designing process. This fact influences the possibility to assess scientifically for which kind of reasons these delegated bodies have been created. The inter-institutional relationships between the European actors and the member States should have played the main role in the decision to create and design the agencies. Some scholars refer to the agencification process as an "overloading" reduction of the Commission activities, especially at the light of the 2004 enlargement, having also had the consequence of taking away some topics from the "obscure" comitology process of the Commission (Dehousse, 1997). Some others (e.g., Wincott, 2001), underline the fact that the Commission has in practice attempted to restrict the effective authority of the agencies and how they should be deployed. The institutional developments within European Union enhanced member States' control and limited Commission influence (Kassim & Menon, 2004). For all these reasons it is very difficult, by means of empirical data and using a "managerial" approach to assess whether the creation of the European agencies had as a consequence the diminution of power of the member States or of the Commission or a zero sum game result. It is true that the member States succeeded in "packing" the supervisory boards of the agencies (see for instance the European Environmental Agencies) with their own representatives and so doing they might influence the policy making processes of the agencies and empower the States' capacity (Holliday, 2000) but it is out of the aim of this dissertation to give an answer to this question. On the other way, as said above the co-optation issue should be taken into consideration in the more general level of analysis concerning the relationship of the delegated bodies with their stakeholders.

*RQ 3. What are the main reasons pushing for the creation of the communitarian agencies and which have been the consequence of this settlement on the "power" of the member States? (main "policy" research question)*

The concepts of independence, credibility, and quality are at the base of the debate about the creation of the EU's agencies and their organisational designing process. Equally important is to refer to the funding regulations of the EU's agencies. To answer to these questions aims to make clear whether the communitarian delegated bodies have or should have further place within the governmental scheme of the European Union. In order to assess the role of the European agencies in the communitarian context it is fundamental to understand which tasks these agencies should most properly undertake. Reminding to their organizational designs, it should be defined by which way they could embody general principles as the ones of power and public accountability and communitarian specific principles as the one of "balancing of powers". In this sense, the first issue to take into consideration is the balance between the functional responsibilities of the agencies and the growing load of EU's policies to be implemented. The continued growth in the number and role of autonomous bodies at the public national and local levels (Flinders, 2004a) is perceptible also at the European level. European agencies exhibit a wide range of autonomy from the other EU's institutions and from the member States and a different degree of autonomy in terms of task execution. As a consequence, growing

the number and role of European agencies, it becomes fundamental to apply and eventually modify the schemes of analysis of delegated bodies' management used at the national and sub-national level and to define a type of classification scheme to be applied to the respective internal and external governance requirements of each agency in order to give an empirically reliable definition of "agency" inside EU and of its general and agency-specific procedural and organizational feature.

*RQ 4. What kind of schemes of analysis should be properly used to assess the performance of the EU's agencies? (methodological question)*

Augmenting the number of EU's "independent" institutions, the traditional models of accountability might be undermined or new modes of accountability should be designed: as said before, agencies fall under the "non-compulsory" part of the European Commission budget and as a consequence the European Parliament can impose strict accountability requirements on them. Despite this fact, the need for a clarification of the accountability schemes as applied to the EU's agencies is needed, in particular with reference to their relationship with the European Parliament and with the European Commission. After having analyzed the already existing communitarian accountability schemes, it should be detected, first which are the differences existing among the different agencies and then if this system might be considered effective taking into consideration the communitarian tools designed for this issue.

On the other side, the equation "agencies=better performance" is still empirically little supported (Pollitt, 2000; Talbot, 1996) especially at the European level. To try to "measure" the effectiveness of the management processes of those delegated bodies, it is fundamental to introduce instruments to operationalize the research. The concepts of "structural disaggregation" and "performance contracting" are now reintroduced in the analysis. In Talbot *et al.*'s categorization (2000), the first one is described as a "purchaser-provider" split or as a "policy/operations" or "policy/implementation" division of labour, that is a form of functional specialisation. The second one refers to the relationship established between the "purchaser/provider" and the "policy/operations" structures: a sort of "contract" should define what the agency should do, in return for receiving a stated amount of resources. "Disaggregation" should tend to raise expertise, quality and efficiency; to increase transparency and to develop high quality management. The "contractual relation" form should embed a result-oriented focus in which results are specified in terms of outputs or outcomes and not inputs or processes.

*RQ 5. What are the main features and what has been the evolution and the consequences of the structural disaggregation and performance contracting in the communitarian agencies? (descriptive question)*

Taken for granted the already considered "political" aspects of analysis, being the role of the agencies primarily focused on the management of policy-making and implementation processes or only on the support of European Commission by means of technical advice or information providing, when not just based on a purely administrative role, the two categories of analysis above mentioned should be

carefully assessed before to be used: for instance, not all indicators designed to specify those dimensions can be referred to communitarian agencies.

Structural disaggregation will be analyzed in terms of:

- tasks specification;
- tasks specialisation;
- unit accountability rules;
- financial, personnel and organisational flexibility (the degree of autonomy of the agencies in relation to the Commission and in the global framework of the communitarian rules).

Performance contracting will be analyzed in terms of:

- resource dependency;
- performance reporting (i.e., performance accountability and audit);
- level of output;
- performance budgeting and performance management (i.e., strategic and policy-making processes).

These data will be used to assess in empirical terms the role of the agencies at the “institutional”, “organizational” and “managerial” level.

Defined the “macro” level of analysis as the framework staying behind the managerial analysis, and having underlined how it might be problematic an investigation of those topics in a “public management” research, the main arguments touched will be:

- inter-institutional relationships (i.e., networks’ management);
- stakeholders’ relationships (i.e., co-optation mechanisms);
- balance of power.

*RQ 6. Which conditions influence the functioning of the agencies in a politico-administrative setting like the communitarian one and why? (first main research question)*

The core of the analysis is represented by the empirical assessment of the managerial performances of the communitarian delegated bodies. To provide a consistent scientific picture of this issue, the processes taken into account are, for instance:

- accountability, internal and external audit;
- financial and budgetary processes (i.e., resource dependency);
- personnel and organisational flexibility;
- performance management (i.e., strategic and policy-making processes).

For the most significative organizations it is provided a scheme of analysis containing the essential elements of their managerial-organizational processes, synthesising their institutional objectives, the structure and competencies of their directive and management boards, the configuration of the accounting and control system, the planning and audit processes, the personnel management policies.

*RQ 7. Is it possible to speak of a communitarian agency model and how may it work for improving EU’s administrative management? (second main research question)*

As a final result of this analysis it is expected also to provide an insightful scheme of classification of the communitarian delegated bodies, having assessed their "managerial" performances once defined the peculiarities of the institutional setting and of the stakeholders' relationships which might inhibit the application of traditional public management *criteria* of analysis, as developed in a national and sub-national framework of study<sup>14</sup>.

### 1.5 Overview of the study

Here below, some insights about the contents of the different chapters of the dissertation are provided.

#### *Chapter 2*

This chapter of the dissertation starts from the assumption of the concept of differentiated integration as an initial point of investigation about EU's agencies, in order to answer the question whether to interpret this institutional change as a step towards a more integrated Europe, in the sense of an increasing influence of a supranational perspective over the communitarian system or of a step back towards a strengthening of the power of the member States. This institutional viewpoint will be briefly addressed taking into consideration the main theories applied to the European studies: the main conclusion will be that this approach should be counteracted by the consideration of this trend as an administrative evolution of the communitarian system, which is related to pre-existing procedures and forms of cooperation and that might be highly influencing for the further evolution of the same EU's institutional structure. A theoretical analysis of the extent to which the agencies might be considered autonomous from supranational, national and sub-national actors will be performed. The findings of this investigation will provide the suggestion to avoid considering European agencies within the traditional framework of a normative dichotomy between supranational and national responsibility and, on the contrary, taking them in consideration above all for what concerns their "administrative" role (i.e., operating as network "hub" actors)

#### *Chapter 3*

The debate about the differences of the delegation process at the public national or local, and communitarian level starts from the assumption that the environmental settings (in particular factors as the political member States' influence and critical issues as the delegation of power from the member States to the European Commission) present incompatible peculiarities. In fact, for a long time European agencies have been largely overlooked in academic research and few empirical analyses have been performed because of the apparent similarities of these

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<sup>14</sup> Following this methodology, it might be also possible to "categorize" the communitarian agencies with reference to their "decisional autonomy" (Rehman, 1973), depending on their possibility to autonomously state management objectives and on the degree of dependence from the decisional framework imposed them by the "central" organization (the European Commission). Having in mind a "systemic" approach (Baker, 1973) the attention is focused on the degree of interaction of the organizations with their stakeholders and the feedback effects generated by this interaction (see above for the discussion about networks' features, i.e. plurality of the stakeholders and their degree of interdependency).



institutions with some political-administrative structures at the national and in particular at the local level. An analysis of this argument will be performed in chapter 3 considering five issues: the tendency of the number of delegated bodies to increase as the functions to be managed by the central organizations (i.e., European Commission) expand; the problems of co-ordination occurring when institutional fragmentation increases; the possibility of facing accountability tribulations when new mechanisms of control are not properly designed; the real degree of depoliticization occurring because of the agencification process; the debate about the necessity of delegating power to independent and not politically accountable institutions. An analysis on the debate about points of contact and differentiation with the public national and local sector's settings will be performed and in particular the theoretical concepts of separation of the executive responsibility from the policy responsibility and of principal-agent problem of compliance with the consequential necessity of proper accountability and control frameworks' designing will be debated.

#### *Chapter 4*

Chapter 4 is focused on an empirical assessment of a framework for properly describing European agencies' characteristics, taking as a starting point the evaluation of their modes of emergence, formal status (i.e., organizational structure and financial autonomy and audit), and kinds of function. In "managerial" terms, delegation has been seen as a key tool for delivering internal efficiency improvements. From the "political" point of view delegation has been seen as a method to revitalize the legitimacy of public institutions and also to depoliticize these institutions (as said above, in the case of the European Commission the debate about the "depoliticizing" effects of the delegation process is still highly debated). In this chapter the purpose of the research will be to concentrate the attention on the administrative reasons of being of the European agencies, in order to verify the accountability, control, budgeting, and staffing processes and in general to define a communitarian "agency model" and its proper features.

#### *Chapter 5*

This chapter aims to describe the methodological framework used to perform the research. First, the theoretical uniformity of the research is pointed out. Then, a definition of case study approach is given: because of the possibility, by means of this methodological design to develop and test a theory when current theoretical approaches are not adequate because of little empirical validation, the case study approach has been the preferred one.

The decision to focus the empirical validation on two specific cases studies follows the case appropriateness and accessibility and appropriateness of data *criteria*, which are explained in this chapter. The iterative process of restriction of the population of potential objects of analysis to two partially homogeneous sub-sets of subjects is depicted and the final choice of EEA and EMA is justified.

The collection of secondary data by means of documentary analysis, the evaluation of internal documents and the validation of findings by means of direct interviews is described. In the end, the possible methodological shortcomings are stressed out.

## *Chapter 6*

The focus of the analysis in chapter 6 of the dissertation will be devoted to EMA (European Medicines Agency, formerly EMEA - European Agency for the Evaluation of Medical Products) activities, its relationship with its partners (i.e., European Commission) and stakeholders in general (i.e., the pharmaceutical industry) and its role within the EU's regulatory system for pharmaceuticals. This case represents a peculiar situation of technical delegation inside the European Commission, because EMA's creation involved the delegation of some fundamental responsibilities formerly on charge of the European Commission. EMA has been chosen as a case of analysis because of its role inside the communitarian system: on one hand it represents a case of delegation of functions which had been in the past partially responsibility of a European Commission Directorate General (DG) - DG III - but, on the other hand EMA is the hub of a network of national and sub-national organizations in which it plays a "central" role, essential for the good functioning of the same network. Its "independence" from the Commission is counterbalanced by the absence of any formal power of final decision on the authorization of pharmaceuticals' production. An analysis of EMA's relationships with the environment in which it operates and with the actors belonging to this environment (i.e., European Commission, national and sub-national actors) and the degree of influence they have one on the other will be addressed. An analysis of the main features of the networks in which EMA is involved (proceduralisation, trust and competition of communitarian and national regulatory systems) will be performed. In parallel with this evaluation of the "external" relations of EMA with the actors involved in its activities, an assessment of the "internal" processes characterizing EMA will be made in order to define its role of "agency" inside the communitarian setting and the degree of innovativeness of this agency's management processes.

## *Chapter 7*

The second case study deals with the role of EEA (European Environment Agency) inside the communitarian system: an analysis of EEA's structure, tasks and in particular of its relationship with the European Commission and the network created in order to manage the European environment policy will be done with the purpose to check the effects of the creation and development of EEA on the communitarian system, from the "managerial" and "policy management" points of view. The case of EEA is particularly interesting in order to understand the problems and opportunities which might arise when an agency is created. Highly important is to try to assess the accountability processes and control mechanisms concerning this institution: EEA's relationship with the European Commission is extremely insightful and the history of EEA might make known important information about the evolution of the tasks assigned to this organization, the attempts of this agency to create for itself a significant role in the European environment policy management, and the difficulties to define effective mechanisms of control and accountability of its activities by the Commission. EEA is part (better to say, it is the "hub" organization) of several networks and sub-networks and its embeddedness in these different types of relations raises the attention on the assessment of its activities in terms of network management. This case study should give some meaningful

answers to the question whether the creation of an agency in the communitarian setting might be a solution to “managerial or “institutional” problems. For this reason, the same importance will be devoted to the analysis of both aspects of EEA’s activities (i.e., on one hand staff, budget, strategy processes, and control system, and on the other network management, and relationship with the Commission).

### *Chapter 8*

The conclusions are divided in three sub-chapters: in the first one the main features and the evolution of the structural disaggregation and performance contracting dimensions of the communitarian agencies are described and commented with reference to the overall agency model inside EU and to the specific findings as coming out from the cases’ analysis.

It follows a general discussion of the cases studies and an attempt to interpret the results at the light of the principal-agent and exchange theory. Aim of this sub-chapter is to investigate the relationships of EMA and EEA with their “stakeholders” and the effects of overlapping, conflicting and collaborative functions developed with communitarian and not communitarian bodies on their management efficiency. The institutional evolutionary process of those agencies and the possibility to develop reliable performance indicators to assess their performance is also discussed. In the end, few insights about the meaning of “agency model” inside the communitarian context and the usefulness of investigating the delegation modes of governance in the EU and their evolution are provided.

## 2. Addressing the institutional balance: the role of European agencies

The lack of effectiveness and legitimacy of European institutions' governance is seen as one of the most important point behind the claim for its urgent reform: in this view, the basic concepts of constituting, distributing, controlling and legitimizing power are involved (Olsen, 2001b). Legitimacy can be seen as functional-instrumental, that is understood in terms of cost-effective technical performance and improved substantive results (Underdal, 1995). Other scholars (e.g., Meyer & Rowan, 1977) see legitimacy as depending on the degree to which structures, procedures and rules conform to societal beliefs about appropriate institutions: in this sense, institutional legitimacy and policy efficiency do not necessarily coincide. A simple model of institutional engineering assuming coherent and stable political will is unlikely to be an adequate framework for understanding EU's reform: to foster a continuous learning and adaptation should be the objective of any EU's reform (Olsen, 1997b) and in this process is involved the necessity, for the reformers, to convince political leaders and organized interests.

### 2.1 Theorising integration

European Commission's foundation was driven by a functionalist integrative logic which, in conjunction with the need to ensure the continuing core sovereignty of the founding member States, had as main consequence the recognition that a strict separation of legislative, executive and judicial power was unfeasible. At the same time, some elements of "power-balancing" were established by the Treaty: article 4 required that each named European institutions adhere strictly to, and only within, the limits of the individual competencies assigned them by the European Treaties. The main factors behind the Treaty's constrains attain two peculiar communitarian attitudes:

- the "harmonization process" has traditionally induced the Community to adopt a legislative act, which is subsequently transposed by the member States. The Community has never significantly departed from the traditional mode of decentralized integration. The growth of autonomous bodies might have been seen as an alteration of the balance of powers and of the possibility for the member States to control the growth of the Community's competencies (Majone, 1994);
- the lack of European tradition of regulation by means of independent agencies didn't push the national governments to establish these types of agencies at the Community level.

Despite this tradition, during the years, with each Treaty's revision the balance of power in the Treaty has been profoundly altered, representing it a dynamic rather than static principle of governmental organization. The same European Court of Justice has allowed the delegation of a wide range of European tasks to delegated institutions, not listed within Article 4.

The recent changes in the role of the institutions of the European Union – which has been defined in chapter 1 as *politicization* process – have seen:

- a continuing empowerment of the European Parliament – EP – introducing an element of direct democratic participation within European policy formulation;
- an increasing influence of the EP on the Commission (now the Commission's composition has to be approved by the EP) and on its programme of policy making;
- an enhancing power of the President of the Commission to choose his Commissioners.

As a consequence, the growing politicization of the Community's organs has apparently started to challenge member States' influence. Some scholars (Everson *et al.*, 1999) argue that Community's reliance upon European agencies, operating at arm's length from the political branches, and in close association with national bodies (transnational networks) can preserve the institutional balance:

- between the European institutions;
- between the European institutions and the member States;
- between political and technical branches of EU (i.e., the European Central Bank).

On one hand, the use of "depoliticised" agencies might assure the credibility of functional/integrationist policies and, on the other one, might preserve the national influence within the European policies, maintaining the member States the policy-implementation tasks and entering the national administrations in a networked structure.

Before going into details in the analysis, a step behind has to be done: during the 1990s, the dominant view in the "integration" literature was that power in the European Union was shifting away from the member States to the supranational institutions. On the contrary, some scholars assume that, instead of the decline of member States' power, that period has seen a reassertion of their authority by national governments *vs.* the supranational institutions (Kassim & Menon, 2004). The move of EU towards the direction of a parliamentary system seems to have downgraded the role and autonomy of the Commission.

New institutionalism addresses the relationship between member States and the EU's institutions, in order to understand when the former could act independently from the latter; historical institutionalism considers intergovernmentalism as inconsistent, because the current functioning of the institutions cannot be derived from the aspirations of the original designers (Pierson, 1996). Member States lose control over the supranational institutions and as a consequence they can act autonomously. Rational choice institutionalism explains the functions entrusted to the supranational institutions by the member States by means of functional theory of delegation.

Member States may use monitoring compliance and enforcing Treaty revision, solving problems of incomplete contracting, independent regulation and agenda-setting. Using principal-agent theory to model the relationship between the member State principal and supranational agents, the latter might be able to assume functions not originally anticipated by their creators.

Supranational autonomy can be explained by (Pollack, 1997):

- distribution of preferences among member State principal and supranational agents;
- institutional decisions' rules for applying sanctions, overruling legislation, and changing agents' mandate;
- role of incomplete information and uncertainty in the principal-agent relationship;
- bypassing of member governments by means of sub-national institutions or interest groups.

Multi-level governance scholars (e.g., Marks *et al.*, 1996) assume that national governments are constrained in their ability to control supranational institutions because of the following factors:

- multiplicity of principals;
- constraints on change;
- informational asymmetries;
- detailed regulation as a response to mutual distrust<sup>15</sup>;
- unintended consequences of institutional change.

Both those two theoretical perspectives, as it has been shown, stress the limitations of member States to control supranational institutions, emphasising the capacity of the Commission for independent actions: the institutional balance's changing process of the recent period and its consequences on the delegation of functions to decentralized bodies make useful to advance some further considerations.

#### *The "independent" nature of the European agencies*

Commission accountability to the European Parliament has been strengthened at Maastricht: the Commission's term of office has been extended to five years, making it concurrent with the one of the European Parliament and the national governments are now required to consult the Parliament when nominating the Commission's President. Also the Commission's accountability to the Parliament has been strengthened and in general terms, the institutional developments within the Union have enhanced member States' control and limited Commission's influence. For instance, the refusal to reform comitology process and the introduction of the open method of coordination – OMC – reveal this attitude.<sup>16</sup> Another evidence of the marginalisation of the Commission, whilst as it will be shown below many scholars give opposite opinions, can be seen in the creation of the European agencies (Kassim & Menon, 2004): in the White Paper (Commission of the European Communities, 2001a), it is acknowledged their importance and their potential advantage but there are also critiques about their functioning and a restrictive view of their way and field of working. In practice, the attempt of the

<sup>15</sup> 'While State executives are induced to ambiguity in the high politics of Treaty making, they give the Commission latitude to formulate very precise regulations on specific policies' (Marks *et al.*, 1996: 355).

<sup>16</sup> With the OMC, the principle of subsidiarity marks a difference both with the "community method" and the "regulatory model": it is recognized the importance of diversity at the national level in relations, for instance to policy formation and legal frameworks (Hodson & Maher, 2001).

Commission's officials to restrict their effective authority has been documented (Majone, 2003) and the "packing" of their managerial boards with member States' representatives may ensure that the member States challenge the Commission's lines of action in their policy areas. As a consequence, the ability of the Commission to carry out its tasks, crucial for the effectiveness of the system as a whole, might be challenged by the member States' influence: the problematic approach inherent in the intergovernmentalism, on the contrary might degenerate, as the modest evolution of the second and third pillars' policies demonstrate.

Some authors consider a positive evolution to make the Commission more "accountable" to the EP (Lodge, 1996) whilst some others argue that in order to "democratize" EU, local democratic governance should be empowered (Landy & Teles, 2001) and others, on the contrary positively consider EU maintaining its democratic deficit (Gustavsson, 1997). Some others have argued that EU should rely on informal, non hierarchical networks (Joerges, 1999), supplementing the traditional policy making rules within EU or even replacing them (Dryzek, 1990). When focusing the analysis on the agencies, if considered as "non-democratic" institutions, the main point is usually the need to subject them to various checks, in order to include them in the EU's "democratic" regime (Majone, 1998). How to bridge the gap between the intergovernmentalism and the functional approach, having in mind the consequences on the functioning rules of the communitarian delegated bodies?

Considering the peculiar institutional balance of EU, European agencies are considered "independent" because of their partial "independence" of the Commission and not because of their independence of the normal partisan politics of EU – the intergovernmental politics (Shapiro, 1997). In fact, the separation of powers between the European Commission and the Council is based on a differentiation of "technocracy" from intergovernmental politics: as a consequence it could be argued that differentiating the agencies from the Commission because of their "technical" nature is not an adequate rationale.

Shapiro (1997) individuates three reasons behind the agencification process:

- not being the division of "technical" issues from the Commission an exhaustive explanation, it could be argued that in order to increase the technocratic share of EU's governance, it should be needed to split it up in different, separated actors – the agencies;
- in a "neo-functional" perspective (e.g., Haas, 1958) further growth of EU, as happened with the UN Funds and Programs, is possible only by means of the proliferation of small, limited in power, in general specifically "technical" institutions;
- the incorporation into the agencies of scientists' committees and the highly technical specialization of each agency should support the development of an international epistemic community transcending the intergovernmental politics.

### *The "co-ordination" and "legitimacy" issues*

The "agencification" process puts in evidence, even when addressed from an institutional governance perspective, the "co-ordination" and "legitimacy" issues. Concerning those two concepts, four are the main problems:

- the co-ordination assured by the intergovernmental composition of the agencies' management boards cannot effectively be guaranteed because of the problematic co-ordination of the national Governments on their policies' branches;
- the highly specific specialization of the experts participating to the agencies' activity negatively affects the possibility to achieve a co-ordinated work plan between the agencies and between the agencies and the Commission;
- information is not only technical but also political, so that the equivalence "information = technical expertise outside of politics = technocracy = non-democratic legitimacy" might not be valid (Shapiro, 1997: 287);
- if the "technocratic" approach is not valid in order to assure legitimacy to the European Commission's activities, how may it do justify agencies' ones?

Looking at the "co-ordination" issue, it might be argued that the positive short-term effects of covering new fields of European activities by means of agencies, when the Commission has not the possibility to do that, is counteracted by potential negative long-term effects given by the necessity to co-ordinate those agencies. In the next chapters of the dissertation, the mechanisms designed to face this problem will be specifically addressed.

For what concerns the "legitimacy" issue, it might be more relevant, especially in the immediate term: considering, as assumed above, information as "political" tools, a first advantage of a communitarian delegated structure has to be seen in the possibility to move partially away from the Council-Commission-Comitology process, which is not really a transparent policy making process, because of the imbalance in the degree of participation between the various interested stakeholders. With the existence of the agencies, transparency and participation may increase: as a consequence, perceived legitimacy increases, not considering at the moment the "political" value and the problematic use of the information delivered by the agencies.

### *Co-ordination and legitimacy in a "network" perspective*

It may be useful to link the discussion about the concepts of co-ordination and legitimacy to the ones of networks and policy networks.

Being part of a network, an agency poses itself in a context of institutions, in some ways interrelated each other, pursuing similar objectives and facing equivalent problems. It follows that the "context" factors shouldn't influence the agency decisions: the agency should be motivated to pursue its policy commitments and defend its professional standards against the external influences. The "complexity" of the network pushes for preserving the professional reputation – the legitimacy – of the agency in the eyes of the other members of the network, having with the agency an "interactive" relationship. To lose the reputation because of lack of professional behaviour or as a consequence of politically motivated decisions, may



make problematic to achieve an acceptable level of co-operation in the long term, challenging the possibility of good results at the "institutional" level of the network. Participation to a network may assure an efficient division of labour and exchange of information or other resources and it may also facilitate the development of behavioural standards and working practices (Majone, 1997). Sharing these practices and expectations, the effectiveness of the process of reputation enforcement might be assured: as a consequence, the co-ordination of the agencies' activities and the legitimacy of their role are eased.

## **2.2 Beyond intergovernmentalism vs. institutionalism**

If the creation of the European agencies is considered as a signal of the deepening of the European Community regulatory intervention other considerations should be done. The Community action aims at co-ordinating the activities of the member States by means of Directives, and not at taking them away responsibilities: this is the so called "harmonization" process. By means of this process, the Community's competences could be expanded without compromising too much the autonomy of the member States: the growth of the Community's powers is not balanced by a proportional loss of States' powers. The creation of delegated bodies acting autonomously might have broken this *equilibrium*. In the reality, this contraposition of intergovernmental and functional points of view doesn't make completely sense: agencies don't take away power from the member States; they have as a first objective to assure that the communitarian policies are implemented in the same, or comparable, ways. Mutual information, reputation and confidence building are crucial factors for increasing the degree of uniformity of policy implementation, when it is not possible to change the traditional decentralized implementation. Neither the comitology web nor the *ad hoc* meetings of national officials are enough to guarantee this information and methodologies' sharing.

For this reason, in order to go beyond the traditional contraposition of intergovernmentalism vs. institutionalism, the creation of European agencies should be seen as a response to those functional needs (Dehousse, 1997): information and methodologies are shared into the permanent technical and administrative secretariats of the agencies. Being the national administrations – the main policy implementation actors – involved in a network, the stability of those networks may be improved by means of the strict and continuous contacts assured by the participation of their representatives into the agencies' boards. An evident confirmation of this role run by the agencies, at least before the "new wave" of agency's settlement in the last two years, is given by the creation, in 1990s, of agencies dealing almost only with "informative" duties, not having them a coercive power of their own but having as a primary duty to provide policy-makers with the information needed to carry out their policies (Majone, 1997). When power to prepare or take decisions had been given to an agency, it happened because of exceptional occasions: for instance, in the case of the medicines' Community trademark or the licensing of new variety of plants, the failure of the mutual recognition of the national decisions pushed the Community to establish a centralization of the administrative decisions. If the Committees' composition, for

example in the case of EMA, is briefly taken into consideration – more details will be provided in the chapter 6

– it is clear that the “centralized” procedures of authorization are still in the hands of the national representatives. In the case of the trademark registration, again the role of the national offices is highly active and the national representatives into the administrative board are for the most part directors of country’s trademark offices (Combaldieu, 1996).

Those described above are not two isolated cases: almost all European agencies have been set up with administrative boards composed of national representatives. For all these reasons, it is not possible to depict the European agencies as supranational structures possibly threatening the national regulatory authorities but they should be viewed as parts of networks, having as main role to bring together the national institutions. It is also not fully realistic a process of power overtaking of the national institutions by the European agencies: European agencies own little decisional autonomy and the influence of the national institutions and, internally to the agencies, the role of the member States’ representatives make this overtaking process very unlikely.

Functional and intergovernmental theories by this way are in some senses reconciled: delegated bodies in the communitarian setting may satisfy the need to achieve a greater uniformity in the phase of policy implementation and, at the same time, guarantee the institutional balance, presenting themselves not as new centres of power into the Community but as devices at the service of an improved current system of decentralized policy implementation.

#### *The European “institutional balance”*

Using the parameters of analysis introduced above – co-ordination and legitimacy – the role of the agencies as networked organizations with “supporting” functions appears even clearer. The EC Treaty doesn’t state a “separation of powers” but an “institutional balance” which is realized by means of a system of checks and balances between the interests of the Community and those of the member States (Dehousse, 1995). For this reason, the presence of delegated bodies inside the communitarian structure may be easily justified, even if it has been showed in the first chapter that in practice the acceptance of the delegation concept in the Community took a long time. For what concerns the concept of power and the dimension of co-ordination of the agencies’ “power” with the European Commission and member States’ one, it is evident that European agencies own limited “powers” and also in the case of a shift of responsibility from the comitology web to the agencies, this shift doesn’t mean a diminish of the “political” influence of the Commission but an increased “transparency” – if not “democracy” – of the process. In this sense, the creation of European agencies may appear as a net gain in terms of legitimacy because of their dramatic contribute for improving the transparency of the communitarian regulatory process. Their visibility makes easier for all stakeholders to clearly identify their intervention: even if this fact is not always completely true, their intervention represents the “communitarian” intervention and once again this means an improvement of the legitimacy and transparency of the communitarian activities.

The degree of co-ordination of the agencies' activities assured by the greater controls than the ones attaining the comitology committees and the budgetary procedures<sup>17</sup>, and in general the "empirical" sides of the legitimacy and co-ordination issues, will be analyzed in detailed below in the next chapters.

#### *Agencification as an "institutional phenomenon"*

In order to finally escape the dichotomy intergovernmentalism/functionalism and to find a proper way to analyse the institutional *phenomenon* of communitarian delegation instead of trying to explain it as a step towards the constitution of a "European nation State" or back towards the strengthening of the member States, it is useful to assess it as an "institutional *phenomenon*" related to pre-existing procedures and forms of co-operation, at the same time possibly influencing future developments (Kreher, 1997).

Following this approach, EU's agencies may be considered as a peculiar form of governance instrument, and consequently as one peculiar dimension of integration, that is what Kreher (1997) called "administrative integration". If the attention is focussed on the process of European integration, it is clear that integration has never been driven only by the European legislation and by its implementation: a prominent importance has always been assigned to the instruments for monitoring over the implementation and its measures. European agencies, when analyzed along the dimension of their importance as tools of governance, might play a role of extraordinary relevance in this process, both for the European Commission's administration and the member States. The "informative" role of the agencies might assure the improvement of the policy-making and also of the policy implementation processes. European agencies indeed may serve as an impulse to the organization of communitarian structures and procedures.

When analyzing the consequences for the national administrations, it is possible to note that in some policy fields, corresponding to the most relevant agencies (i.e., in the case of EEA), member States are obliged to establish national focal points in order to collect, prepare and transmit the information needed by the agency or to monitor and implement European-driven initiatives. The existence of the agency's boards makes easier for the national experts to share common European procedures and standards which are subsequently usually introduced also at the national level. To assess if national authorities will challenge the role of the European agencies and their powers is out of the aim of this dissertation: what can be said at the moment is that the degree of collaboration the member States have given and will give in the future to the European institutions in the process of networking the policy-making and policy implementation processes is a good test for the compliance of the States with regard to the co-operation and integration issues.

#### *Agencification as an "administrative evolution"*

If this should be the role of the agencies inside the communitarian context, what have to be detected are the instruments at disposal of the Commission and of the

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<sup>17</sup> As said above, in budgetary terms, agencies fall under the "non-compulsory" part of the European Commission budget and the role of the European Parliament in the budgetary approval process is prominent.

member States to control and give a direction to the agencies' activity. To corroborate what said above regarding the potential "independence" of the European agencies from the Commission and the member States, it is the Council to define the scope of the agencies' tasks and the management boards approving the budget and reports are packed with member States' representatives. The influence of the member States shouldn't hidden the importance of the Commission's influence on the agencies: at the moment it is useful to remember that the visibility of the agencies' work is fundamental for their reputation and credibility in front of their stakeholders (first, in front of the European citizens) and so, for the legitimacy of their activities and in the end of their existence. At the same time, the participation of national institutions is particularly relevant for the good functioning of these institutions. Regarding this point, in a comparative perspective, agencies seem to have been created because of "integrationist" reasons. Even if on this point caution is extremely important, because of the absence of empirically testable elements of analysis, when looking to the creation of delegated bodies at the national and local levels in comparison to the same *phenomenon* in the communitarian context some differences are clearly visible. In the US tradition, agencies have been created principally with the aim to avoid control by one political party (Shapiro, 1997); to make another example, in UK the general objective of the "delegation" reform was to increase the efficiency of the public administration (Rhodes, 1996).

On the contrary, the creation of delegated bodies inside EU seems to be a direct consequence of the need to deepen the communitarian regulatory intervention without making the Commission assigned any additional power from the member States, as the settlement of the newest agencies in the 2000s demonstrates. From this point of view, if the concept of "administrative integration" is posed at the centre of the analysis, the setting-up of the agencies may be seen basically as a signal of "administrative evolution".

In the first section of this chapter, the unambiguous positions of some scholars have been listed: some of them see the creation of the agencies as a step backwards of EU's integration and as a signal of the rising power of the member States. Some others, on the contrary, consider the agencies as a signal of the evidence of the increasing "supranationalism" of the European institutions. This chapter has analyzed the most important elements of those conflicting approaches: looking forward to the next chapters of the research, a different framework of analysis will be assumed. To define "what" an agency is, as said above, is not only a "technical" but also a "political" activity: to avoid elements which might bring away from the empirical assessment – considering the "managerial" side of the analysis – of the delegation issue inside the communitarian context, agencies are defined as integrated components of the administrative evolution of the European Community.

It is out of the aim of this dissertation to make clear the political elements laying behind the process of settlement and growth of these delegated bodies: assumed that in order to provide an effective analysis it is necessary to go beyond the traditional dichotomy between the power of the Commission and the influence of the member States, and having put in evidence the main theories dealing with that issue, the delegation *phenomenon* will be assessed mainly from the point of view of its managerial processes' analysis.

### 3. Delegated public governance in the EU: a distinctive model?

This chapter will take into account some dimensions of analysis of the European delegated bodies, trying to give insights about the discussion concerning the “innovativeness” of the communitarian agencies when compared to similar modes of governance at the public national and local level. The administrative *panorama* of the majority of the European public bureaucracies witnesses a significative presence of delegated public bodies: differences and similarities can be found out when analyzing this variety of organizations.

The communitarian “environmental setting”, that is the “supra-national” nature of the European Commission and the carefulness with which the European agencies have been created, reflected in the limited degree of delegation of functions and power conferred to those institutions, are all elements pushing to pose a particular attention when using “ready to be applied” categories of analysis taken from the public management tradition. The issues of growth, co-ordination, accountability and control, depoliticization and power (Flinders, 2004a) will be evaluated in order to find points of contact and differentiation between the communitarian delegated bodies and delegated bodies at the national and local level. Particular attention will be devoted to the analysis of the co-ordination, accountability and control themes, in order to accurately represent in which way the responsibilities of the communitarian delegated bodies have been confined to some peculiar tasks and to assess if the “institutional” fragmentation created by the settlement of those bodies, and the consequential task disaggregation and task specialisation, might have affected the coherence of the European Community policy-making and structure.

The category of delegated bodies analyzed is the one of the bodies created in the framework of the I EU’s pillar – the European Communities: in the next table are listed all EU’s agencies, as defined in the first chapter of the dissertation, so including also delegated bodies created in the framework of the II EU’s pillar – common foreign and security policy; of the III EU’s pillar – police cooperation and cooperation in the area of criminal law; and of the EURATOM Treaty. As said above, only the first one will be analyzed in the dissertation: the reason of this choice stays in the will to find a sample of analysis as much coherent as possible, being the differences between the bodies created in the framework of the first pillar and of the other pillars very relevant.

Agency	Date of establishment	Location	Main tasks
<i>CdT</i> Translation Centre for the Bodies of the European Union	1994	Luxembourg (Luxembourg)	Internal administration
<i>Cedefop</i> European Centre for the Development of Vocational Training	1975	Thessaloniki (Greece)	Social policies Employees’ training
<i>CPVO</i> Community Plant Variety Office	1994	Angers (France)	Intellectual property Products’ communitarian

			movement
<i>EAR</i> European Agency for Reconstruction	1999	Thessaloniki (Greece)	External relations Reconstruction projects' management
<i>EASA</i> European Aviation Safety Agency	2002	Koeln (Germany)	Transports Internal market enhancement
<i>ECA</i> European Chemicals Agency	2004	Helsinki (Finland)	Intellectual property Internal market
<i>ECDC</i> European Centre for Disease Prevention and Control	2004	Stockholm (Sweden)	Public health
<i>EEA</i> European Environment Agency	1990	Copenhagen (Denmark)	Environment
<i>EFCA</i> European Fisheries Control Agency	2004	Vigo (Spain)	Internal market
<i>EFSA</i> European Food Safety Authority	2002	Parma (Italy)	Agriculture Public health
<i>EMA</i> European Medicines Agency	1993	London (GB)	Public health Products' communitarian movement
<i>EMCDDA</i> European Monitoring Centre for Drugs and Drug Addiction	1993	Lisbon (Portugal)	Public health Social policies Crime monitoring
<i>EMSA</i> European Maritime Safety Agency	2002	Lisbon (Portugal)	Transports Internal market enhancement
<i>ENISA</i> European Network and Information Security Agency	2004	Heraklion (Greece)	Information Internal Market
<i>ERA</i> European Railway Agency	2004	Lille-Valenciennes (France)	Transports Internal market
<i>ETF</i> European Training Foundation	1990	Turin (Italy)	External relations Social policies
<i>EUMC</i> European Monitoring Centre on Racism and Xenophobia	1997	Vienna (Austria)	Free citizens' movement Human rights
<i>EUROFOUND</i> European Foundation for the Improvement of Living and Working Conditions	1975	Dublin (Ireland)	Social policies Employees' circulation
<i>EU-OSHA</i> European Agency for Safety and Health at Work	1994	Bilbao (Spain)	Public health Social policies
<i>OHIM</i> Office for Harmonisation in the Internal Market (Trade	1993	Alicante (Spain)	Intellectual property Products' communitarian

Marks and Designs)			movement
ESA <sup>18</sup> EURATOM Supply Agency	1960	Luxembourg (Luxembourg)	Nuclear materials supply
CSUE <sup>19</sup> European Union Satellite Centre	2002	Torrejón de Ardoz (Spain)	Research and analysis of satellite information
ISS <sup>20</sup> European Institute for Security Studies	2002	Paris (France)	Security studies
Europol <sup>20</sup> European Police Office	1992	The Hague (Netherlands)	Crimefight
Eurojust <sup>20</sup> European Body for the Enhancement of Judicial Co- operation	2002	The Hague (Netherlands)	Judicial activity co- ordination

Table 1: The European delegated bodies

### 3.1 Comparing EU's and State's delegated modes of governance

#### *The growth of the delegated bodies*

Even though delegated bodies are considered a new *phenomenon* in the public management literature, the majority of the States' bureaucracies have been structured in independent bodies, before than in departments or Ministries<sup>21</sup>. What is clear and demonstrated is the continue increase in the number and functions of the delegated bodies in the recent European administrative tradition. As usually happens with reference to bureaucratic bodies, also the number of delegated bodies has never been dramatically reduced, despite some attempts to do that. This evolutionary process presents the peculiarity of having being constantly and gradually increasing: the numbers and functions of those bodies have increased and, with few exceptions, they have never been drastically cut. A comparison over time shows that delegated bodies at the national level have been seldom abolished (3% in 1980s and 6% in 1990s) but in few cases re-organised or subject to re-definitions (Van Thiel, 2004). For some authors this trend is irreversible (Osborne & Gaebler, 1992), others justify this *phenomenon* referring to the fact that the use of delegated modes of governance may have as main effects "blame avoidance" or "patronage" (Pollitt & Talbott, 2004). Many theories explain the steady imitation through national public administrations: the main ones are theories on innovation diffusion (Rogers, 1995), policy transfer (Bennet, 1981), and isomorphism (Powell & DiMaggio, 1991). Tolbert and Zucker (1982) argue that the incremental expansion of certain delegated bodies may create legitimacy to their use and so doing, imitation.

<sup>18</sup> ESA has been created in the context of the EURATOM Treaty.

<sup>19</sup> CSUE and ISS have been created in the context of the second EU "pillar" – Common foreign and security policy.

<sup>20</sup> Europol and Eurojust have been created in the context of the third EU "pillar" – Police cooperation and cooperation in the area of criminal law.

<sup>21</sup> For instance, details about cases of delegation in the public administrations of New Zealand, Sweden, Finland and Denmark see Flinders & Smith, 1999; Greve, 1999; Leeuwe & Van Thiel, 1999; Hood & Schuppert, 1998; Wistrich, 1999.

Another characteristic of this process is the absence of a coherent legal scheme defining a clear framework regulating their activity, in the case the country adopting this mode of governance doesn't have a firm public law structure. Only in the recent years this latter peculiarity has been slowly changing. For instance, let's take in consideration the Spanish and Italian cases: in Spain the first law promulgated in order to organize the functioning rules of those bodies is dated 1958 (*Ley de Entidades Autonomas*); in the 1977 a new general public administration legal framework has been created but the new independent bodies settled up in the 1990s have been treated as exceptions.

In Italy, independent agencies have been created for the most part during the 1990s while the so called 'Administrative Independent Authorities' (independent institutions with regulatory, inspecting and safeguarding powers), in some cases already active in the Italian public administration in the early seventies, have been formally established in the 1990s: in the 1999, nineteen 'Agencies' were created or completely reorganized. A law defining and regulating their activity in details is dated only 1999 (D.lgs 300/1999)<sup>22</sup>.

Also at the EU's level these two main characteristics, continual expansion and absence of a clear legal framework, can be found. The first agencies have been created in the 1970s; the second "wave" of agencies' expansion is dated 1990s and the last one has been witnessed in the year 2004. It should be also noted that this steady expansion has never been counteracted by the suppression of those bodies or by a diminution of their functions. On the contrary, new types of agencies, with increasingly important roles, especially in the "regulatory" field, have been created. For instance, the first three "regulatory" agencies (CPVO, EMA and OHIM) have been established in the 1990s; the last two (EASA and ECA) only three years and one year ago. Before their creation, they were existing only agencies with "co-ordination/information" and "management" functions (see next chapter for further details). The lack of a clear communitarian legislation dealing with the delegation issue and the already cited "Meroni doctrine" slowed the increase of the growth of these bodies but they couldn't stop it. The absence of cases of suppression of those agencies is also highly revealing about the persistence of this growth process.

The unclarity of an exact legal position of the agencies and the fact that their independence from the member States and from the Commission is extremely various (but usually quite limited) but also their autonomy in tasks' execution reveal, on the contrary, the absence, and perhaps the necessity of a clearer legal framework inside EU, concerning agencies' classification and role. The report "White Paper on Governance" (Commission of the European Communities, 2001b) states that "one of the characteristics of existing planned agencies is the absence of a reference framework to which each agency would adjust according to its own needs: mandate, methods of operation and means of control. For each of them, the decision to create them is motivated by the need to respond to the particular circumstance of the moment...the result is a variable geometry typology depending on the criterion used to classify agencies".

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<sup>22</sup> See chapter 1 ("Administrative reforms and delegated bodies – The Italian case" sub chapter) for details about the distinction between "agency" and "Authority".



The Commission's Legal Service (Commission of the European Communities, 2001c) only few years ago proposed a conceptualisation proposal, defining between others the legal personality, independence and staff regulations of the EU's delegated bodies. The definition of a communitarian regulatory framework modelled on the US Administrative Procedure Act (APA) has also been requested several times. The "Financial Regulation" of the European Council, applicable to the general budget of the European Communities (Commission Regulation, 2002), about the financial regulation of the bodies referred to in the Article 185 has been approved only three years ago.

As shown above, it is clear that the creation, growth and regulation of the communitarian delegated bodies present many similarities with what happened at the national and local level into the member States: stated against the peculiar setting in which it happened, this *phenomenon* seems to be rather surprising but fully confirmed. Some authors even argue that a supranational organisation as EU may itself force national States to adopt delegated forms of governance such as agencies (Pollitt *at al.*, 2001).

#### *The co-ordination of the delegated bodies*

The increase of number of delegated bodies cannot be denied: this process might have as a direct consequence the necessity to design new and more effective mechanisms of co-ordination. At the national level, this theme has been widely debated and usually linked to the necessity to improve the accountability and control mechanisms and, at the same time, to provide strategic coherence to the institutions disaggregated in organizations presenting variable degrees of independence and autonomy. The concept of "network" as a co-ordinating tool has often been taken in consideration as a new and more effective way of dealing with organizations not controllable solely by means of hierarchical procedures. The same debate has often been faced into the European Union. Below, the accountability and control system operating at the communitarian level will be evaluated: here the attention is focussed on the role the delegated bodies may have as "hubs" of networked organizations.

Flinders (2004b) puts in evidence as, for instance, in UK, some agencies as the Food Standards Agency and the Strategic Railway Authority, have been set up in order to "re-organize" and put under control a set of isolated and uncoordinated organizations. In Italy, the Environmental Agency (APAT), on the "European side" represents the Italian National Focal Point and the National Reference Centre, being it part of the European Topic Centres' network; on the "Italian side", it operates as the hub of the national network of environment institutions and it works in close relation with the Ministry for the Environment.

At the European level this evolution in the role of the agencies can be also witnessed: all "regulatory" agencies have been created in the last two decades. Their main function is to operate in relation with three different actors:

- the European institutions;
- the national institutions;
- the non-European regulatory institutions.

These agencies are designed to be involved in an inter-organizational relationship with, on one side the European institutions (in particular, the European Commission) and on the other one, the national or local regulators (in general, national or local delegated bodies). By means of this set of links, the European Commission, getting more and more involved in new regulatory activities, might assure the co-ordination of national and local bodies' activities and at the same time the control of the European agencies not assuming direct functions and not replacing, which would be politically unrealistic, the national institutions. When not dealing with regulatory issues, some European agencies have a similar task: to ensure consistency and co-ordination of information exchange across member States and the Commission.

If this typology of agencies is considered, it is possible to find that CPVO and OHIM, dealing the first one with plant variety and the second one with marks and design, are both "authorization" agencies aiming to give uniformity (and co-ordination) to the internal market. ECA, EASA (both settled up very recently) and EMA have been created with similar tasks even though only EASA has a "decision-making" power.

On the other side, agencies as ENISA, EFCA, EFSA (all of them created in the last three years on the example of EEA, established in 1990) have as formal main task the one to provide consistent information and usually they rely on a network of national and sub-national offices linked to them, defined the "hub" organizations (i.e., see the EIONET network of EEA). The mechanisms of networking and the modes of governance of this particular type of organizational structure will be specifically dealt with, when the case studies of EMA and EEA will be addressed in the parts VI and VII of the dissertation.

These bodies have usually also significative relationships with non-European bodies: for instance EMA and the Food and Drug Administration in the US can adopt co-operation strategies (Flinders, 2004a). EEA collaborates actively with UNEP (United Nations Environment Program); EASA and EMSA might co-operate in the future, once fully active, with ICAO (International Civil Aviation Organization) and IMO (International Maritime Organization).

Another element to be kept in mind when addressing the co-ordination issue is the mode of emergence of these bodies: it is important to note that the fragmentation of some fields of action hasn't been dealt with until external events accelerated the growth of consciousness of the need of settling up a "co-ordinating" body. For instance, the two more revealing cases are the BSE incident which forced to re-think the European food policy and the Erika catastrophe which had a significative role in pushing for the creation of a maritime co-ordinating body as EMSA.

The element of "co-ordination", if fundamental when facing the problem to create an effective interconnected system of bodies dealing with a particular policy, and so when addressing it from a "macro" point of view, is equally important, if not more, when analysing the "micro" mechanisms assuring that the delegated bodies can operate in autonomy but not in conditions of independence, both from the European institutions and the member States' influence. The intergovernmentalism of their boards, on one side might assure member States' control; on the other one, accounting and managerial rules giving to the Commission or other European

institutions (i.e., the European Court of Auditors) the possibility to intervene on the delegated bodies' decisions can help to maintain these bodies under a coherent communitarian "umbrella".

The attention in this study will be focussed on the analysis of the mechanisms of control and audit already existing in the EU, in order to check how they can counteract the task disaggregation occurring when delegated bodies are set up and to organize their activities in a coherent framework. From now it can be said that, because of the differentiated nature of the Commission and its structure, arranged on organizationally autonomous directorates, the Commission cannot assure a unique strategy of action to all agencies. This approach might also be counterproductive because of the different missions and tasks of the delegated bodies: role of the President of the Commission is to give consistency to the activity of the same Commission; dealing each single DG with the delegated bodies related them. The existence of significative over-lapping, in the sense of delegated bodies referring to more than one DG or the presence of conflicting relationships between a DG and a delegated bodies, as it will be more clear when the cases of EEA and EMA will be analysed in details, make more difficult to reach an acceptable level of co-ordination of these bodies' activities. A definitive and uniform legislation concerning duties and powers of the agencies and their financial, staff and budgetary features has been requested for a long time because of the reasons above stated.

#### *The accountability mechanisms*

In the public management literature, bureaucrats operate in a structure, usually a department, headed by a political figure, usually a Minister. The Minister is accountable to the Parliament, and to the public at the elections. This scheme operates at the central as at the local level of government. When organizations in some ways insulated from a direct political control are created, the accountability problem raises. As a consequence, proper mechanisms to maintain these organizations under the scrutiny of a politically appointed figure and, in general terms, to be accountable, are needed.

In Europe, different traditions deriving from different legal contexts, co-exist: for instance, as said in the first chapter, Scandinavian countries have been the first ones to introduce delegated modes of governance inside their administrations and the "accountability issue" has never been so crucial. In Sweden, the vast amount of delegated bodies operates in a fairly autonomous way and the Ministries have with them a relation of reciprocal respect of the respective fields of action. There is a similar situation in Germany, even if in a more fix structure with much more relevant "federal" elements. In the Netherlands and UK the existence of delegated bodies is widely accepted but the debate about the proper mechanisms to be developed in order to make these organizations accountable to the central bodies is still high. The evolution of the "quangos" in UK, the relevant changes in their number and the evolution of their degree of independence from the ministerial bureaucracy seems to be a never-ending process. In Italy, the legalistic and hierarchical tradition (Capano, 2003), where elements as the separation of political decision-making from administrative implementation and the importance of the legality principle persist, seems to have reconciled the creation of the independent

agencies with the old bureaucratic values. The consequence is that most part of the Italian agencies still heavily relies on the control of the competent Ministry, being in a certain way reduced their degree of managerial discretionary power.

One of the main reasons brought to justification for the creation of delegated bodies is the need to insulate some of their activities from the political control. The most significative consequence, when looking to the accountability problem is that the political authority can in some cases shift the effects of unpopular or poor decisions or outcomes on the delegated bodies, not being them subjected to direct "popular" scrutiny. The European tradition shows that a direct relationship between the Parliament and the delegated bodies is in some cases almost absent: some scholars as Van Oosterom (2002) and Dohler & Jann (2002) refer that this direct relationship in Germany and Netherlands doesn't exist (for other examples see Araújo, 2002; Bogt, 1999; Hogwood *et al.*, 2001; Talbot, 1996). But, do mechanisms other than the parliamentary control exist? And does it make sense to speak of accountability problem in the communitarian setting?

In the communitarian setting, the agency control provisions are the following ones (Commission of the European Communities, 2001b):

- procedural control: the procedural guarantees govern the agency's deliberations and its adoption of acts, in accordance with the principle of transparency. The procedural control constitutes the main guarantee of the quality of the agency's output, the independence of the *criteria* applied by it in the adoption of the acts, and its due regard for all pertinent opinions;
- democratic control: it is exercised directly by the European Parliament. The aim is to ensure on the one hand that the agency fulfils its obligations within the scope set by its mandate and on the other hand that the human and financial resources allocated to the agency by the Community budget are properly used;
- executive control: it results from the supervision of the agency's activities and management by the two branches of the "executive", the Commission and the member States, as represented in the agency's management bodies;
- external financial control: it is exercised by the Court of Auditors, with regard both to the financial management of the agency and its performance;
- judicial control: the agency has legal personality and falls within the Community law; as a consequence third parties may have recourse to the Court of Justice or the Court of First Instance concerning the legality of acts adopted by it, once all possible recourses *via* the appeal bodies have been exhausted.

Legal accountability, which involves detailed external monitoring over established standards and mandates, by means of oversight and auditing processes is prominent in the communitarian context, but signals of professional and political accountability may also be found in the relationship of the agencies with their stakeholders (on one side, first the Commission and the other EU's bodies; on the other side, the "clients" or in general terms the beneficiaries of the agency's actions).

Each agency must have stated in its founding statute a clear, finite and well-defined list of the body's objectives: the founding statute represents a sort of "majoritarian"

confirmation of the public's will to give a policy area to a "non-majoritarian" supervision. For this reason European agencies must be created by a unanimous vote in the Council (see next chapter for details). The well-defined and focused statutory objectives serve as a yardstick for the evaluation of the technical performance of the agency (Everson, 1995). The appointment of the Executive Director by the Management Board (usually comprising representatives of the member States, of the Commission, of the European Parliament and sometimes of stakeholders' organizations) on Commission proposal is another "soft" control mechanism. Only in one case (CEDEFOP) it is the Commission to nominate the Director on Management Board's proposal; in three cases (CPVO, EMA, OHIM), because of the high "regulatory" tasks of the agency, the Council is involved in the choice; in only one case (EFSA) it is involved also the European Parliament.

The same composition of the Management Boards can be considered a way to "pack" the agencies under the European institutions' and member States' control. The presence of member States' representatives (in all cases), of Commission's representatives (in 19 cases on 20), of representatives nominated by the European Parliament (6 cases), by the Council (2 cases) and by the stakeholders (8 cases) reveals the carefulness in guaranteeing, on one side the most ample representation of all interested parties, and on the other side the will to have another control device in the hands of the member States, of the European institutions and also of the "public"; that is of the "clients" or of the "beneficiaries" of the agencies' activities.

The budgetary discipline, which will be further analysed below, guarantees an "*a priori*" supervision because the Commission should be informed of the structure and extent of the proposed agency's budget. The discharge is given by the Parliament on Council's recommendation. "*Ex-post*" accountability is secured by the fact that a completed yearly account has to be presented to Parliament and Council.

The "autonomy" of the agencies is affected also by their financial dependence from the Commission. Only few agencies are given the possibility to self-finance themselves by means of fees charged to "customers". This is the case of CPVO, EMA and OHIM and in part of EEA. In the future, when the settlement costs will have been covered, this will happen also for EASA.

In budgetary terms, agencies fall under the so-called "non compulsory" part of the European Commission's budget: for this reason, in addition to its power of discharge, the European Parliament may also impose strict accountability requirements, such as reporting procedures and attendance before parliamentary committees.

In the following table are summarized Commission's contributions and other funds as resulting from the official data of the year 2003. The case of EEA and EMA cover seven years in order to put in evidence the fact that coming out those agencies from the "birth" phase (this is true especially for EMA, created in 1993; for EEA also some other considerations count), they have increasingly started to increase their self-financing quote.

Agency <sup>23</sup>	Year	Commission's contribution	Other funds	Notes
Cdt	2003	100%	0%	Fees paid by other communitarian bodies
Cedefop	2003	96,5%	3,5%	
CPVO	2003	0%	100%	
EAR	2003	97,4%	2,6%	
EASA	2003	100%	0%	provisional "other funds" in 2005: 65% <sup>24</sup>
EFSA	2003	99,7%	0,3%	
EMCDDA	2003	87%	13%	
EMSA	2003	100%	0%	
ETF	2003	100%	0%	
EUMC	2003	98,9%	1,1%	
EUROFOUND	2003	98,2%	1,8%	
EU-OSHA	2003	98,77%	1,23%	
OHIM	2003	0%	100%	
EEA	2003	76%	24%	provisional "other funds" in 2005: 19,43% <sup>25</sup>
	2002	87%	13%	
	2001	91%	9%	
	2000	97%	3%	
	1999	99%	1%	
	1998	95%	5%	
	1997	99%	1%	
EMA	2003	27,9%	72,1%	provisional "other funds" in 2005: 70,31% <sup>26</sup>
	2002	33%	67%	
	2001	22,3%	77,7%	
	2000	24%	76%	
	1999	29,8%	70,2%	
	1998	51,4%	48,6%	
	1997	51%	49%	

Table 2: EU's agencies' funds (year 2003)<sup>27</sup>

<sup>23</sup> Some of the agencies listed in table 1 (i.e., ECA) are not present here because of the absence of official data, given their recent creation.

<sup>24</sup> EASA (2004).

<sup>25</sup> Office for Official Publications of the European Communities (2004a).

<sup>26</sup> Office for Official Publications of the European Communities (2004b).

<sup>27</sup> Official Journal of the European Communities, 2004/C41/38; C324/4; C324/11; C324/18; C324/25; C324/33; C324/41; C324/48; C324/56; C324/70; C324/78; C324/86; C324/94; C324/101;

Other instruments of control are in the hands of the European Ombudsman, who guards against instances of maladministration of the agencies: some agencies have made own some codes of conduct (Vos, 2001). For instance, this is the case of EMA which has committed itself in its founding statute to respect principles such as equality, proportionality, no abuse of powers and so on. The European Anti-Fraud Office may also fight fraud and corruption related to agencies' activities.

In some cases, board of appeals acting like a court of first instance prior to appeal to the Court of Justice are integrated in the structure (i.e. CPVO and OHIM). The technical decisions of CPVO are subjected to appeal before Board of Appeal acting like a court of first instance prior to appeal to Court of Justice. The Commission may control the acts of the President of CPVO and OHIM, in respect of which Community law does not provide for any control on legality by another body, and of acts of the administrative council relating to the budget.

This Commission's *quasi-judicial* role doesn't affect the independence of the agencies because the checks are carried *ex-post* and cannot question the appropriateness of the decisions concerned: this form of control is thus "preventive", encouraging the agency's managers to take care to comply with substantive and procedural requirements (Yataganas, 2001). Also in other two "new" agencies (EASA and ECA) board of appeals are integrated in the structure.

See the table below for details.

Agency	Board of Appeal
CPVO	Decides on appeals against decisions concerning plant variety rights
ECA	Decides on appeals against decisions of the agency
EASA	Checks if the Executive Director has correctly applied European Legislation
OHIM	In connection with: examiners, opposition divisions, administration of trade marks and legal division, cancellation divisions, takes decisions regarding the procedures

**Table 3: EU's agency's boards of appeal**

Having in mind the control mechanisms listed above, it is useful to underline that EU's agencies have in some fields replaced an institutional framework as the one involving the tripartite relationship "Council-Commission-Comitology" which has been defined by some scholars as one of the least transparent policy-making processes in the democratic world (Shapiro, 1997). The introduction of this delegated form of governance may have improved this process, especially in terms of "exposure": at the same time the problem of "blame-shifting" remains almost unchanged.

For instance, let's consider the case of EMA: it is the Commission to take the final decision on the approval of medicines but it does that on the base of the recommendations of the EMA experts. So, who is really responsible for the

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C324/108. 2003/C319/19; C319/26. 2002/C326/21; C326/31. 2001/C372/14; C372/23. 2000/C373/11; 373/18. 1999/C372/11; C372/18. 1998/C406/27; C406/31.

European medical products' authorization policy? EMA, because it gives the scientific opinion, or the Commission, because of its decision-making power?

### *The budgetary control*

As with all national budget systems, Community budgetary law provides for a very comprehensive control of implementation: internal controls are carried out by each institution and external controls are carried out by Parliament and Court of Auditors. The internal control is carried out by the authorizing officers of each institution and covers the operations involving expenditures and revenues under the Community budget. The "accounting officer", appointed by the Management Board, is responsible for the implementation of payments, collection of revenues, and in general for the treasury management.

The external control is competence of the Court of Auditors.

The discharge from the European Parliament represents the "political" aspect of the external control of budget implementation and it is the decision by which the European Parliament, acting on Council's recommendation, "releases" the Commission from its responsibility for the management of a budget by marking the end of the budget's existence. This discharge procedure may produce one of three outcomes: the granting, postponement or refusal of the discharge.

Parliament examines the accounts and financial balance sheet mentioned in Article 275 of the EC Treaty, the Court's of Auditors reports with the replies of the Commission and other institutions concerned and the discharge recommendation of the Council. The outcome of the discharge procedure is sent to the Commission, which must take appropriate action in response and send the follow-up report to the Parliament by 15<sup>th</sup> December of the second year following the financial year which has closed.

Each delegated body may adopt its own financial rules on the base of the framework of financial regulations 1605/2002. From an assessment of the financial regulations adopted by each delegated bodies, no relevant changes in comparison to the general financial regulation can be found. In any case, the changes, in accordance with the specific management needs of the body, may be adopted only with the consent of the Commission. As part of the introduction of the new Financial Regulation, the main changes concerned the responsibility of the Commission's internal auditor *vis-à-vis* the budget of the agencies; the accounting rules applying to the agencies; the responsibility for the discharge of the budget and for the establishment plan.

The Management Board of the body is responsible for taking decisions on financial and budgetary matters and the Director of the agency (in "budgetary" terms defined the "authorising officer") is the person in charge for implementing these decisions and ensuring the legality and regularity of revenues and expenditures.

Three points, in the framework of the "principle of equilibrium" are particularly important to be underlined:

- the budget revenues and payment appropriations must be in balance;
- commitment appropriations may not exceed the amount of the Community subsidy, plus own revenues and any other revenues;
- the Community body may not raise loans.



Each year, no later than 15<sup>th</sup> June, the Management Board sends to the European Parliament and to the Council an analysis and an assessment of the authorising officer on the Annual Report of the previous year: this analysis is also included in the Annual Report of the Community body. Also the establishment plan must be submitted to the budgetary authorities (European Parliament and the Council of European Union) for approval.

The annual accounts of the Community body include the financial statements of the Community body and the reports on the implementation of its budget. The accounting officer sends to the Commission's accounting officer (no later than 1<sup>st</sup> March) of the following year its provisional accounts, together with the report on budgetary and financial management during the year. The Court of Auditors makes its observations (before 15<sup>th</sup> June). The Director receives the Court of Auditors' observations, draws up the final accounts of the Community body and sends them to the Management Board. Having received the opinion of the Management Board, the Director sends the final accounts to the Commission's accounting officer and to the Court of Auditors, the European Parliament and the Council (before 1<sup>st</sup> July of the following year). The final accounts of the Community body are published in the Official Journal of the European Communities on 31<sup>st</sup> October of the following financial year.

As it should be now clearer, the budgetary control on the delegated bodies should guarantee the Commission on the fairness of the budgetary procedures: the "*a priori*" supervision of the Commission on the structure and extent of the proposed agency's budget and the power of discharge given to the Parliament on Council's recommendation, and the "*ex-post*" accountability assured by the presentation of the yearly accounts to Parliament and Council show that appropriate instruments of control on the budget and accounting management of the delegated bodies have been designed. This point is particularly relevant at the light of the actors involved in the process. All main European institutions are informed on the budgetary procedures: the European Parliament, the Council and the Commission. Internally to the delegated bodies the responsibilities of the Management Board and of the Director are clearly stated. In addition, the fact that both these figures are usually expressions of the joined will of member States and EU's institutions should avoid the loss of control on the budgetary process.

The importance of the role of the Courts of Auditors, as competent body for the external control, is not diminished by the lack of judicial nature of its decisions: its role of audit body should assure, also because of the frequent interaction with each delegated bodies in the budgetary process, the goodness of the financial management and the legality of the accounts. The "political" side of the external control is assured by the discharge power given to the European Parliament, on Council's recommendation.

In this decision it can be seen the will to ensure to the member States and the "public", the possibility to validate the fairness of the delegated bodies' budgetary processes. On one side it is called to give an opinion the highest expression of the member States' representation in the EU system – the European Council – on the

other one, the final “word” is given by the body – the European Parliament – expression of the citizens’ vote.

The internal auditing processes and the role of the “Boards of Appeal” existing in some agencies (i.e., CPVO, ECA) will be addressed in the next chapter, because not directly involved in the budgetary process.

#### *Depoliticize by means of delegated bodies*

The decision to transfer functions from an organization directly under the supervision and the responsibility of elected politicians to an organization enjoying autonomy from the operational and decisional point of view, is usually first justified with the necessity to put these organizations to “arm’s length” from the political control. In this sense a depoliticization should occur: some decisions are insulated from the political will (Pollitt & Talbot, 2004).

If efficiency factors pushing for the creation of an agency are not taken into considerations, the “political” justification stated above isn’t totally acceptable.

First of all, it should be considered the “real” degree of depoliticization occurring when some functions are delegated to an autonomous body. Some scholars (e.g., Thatcher, 2002) put in evidence that the independence of autonomous bodies from the elected politicians is sometimes not real. Thatcher, studying the relationships between autonomous bodies and their “clients” and their decision-making processes, observed that in some cases (i.e. in Italy), party politicians made use of political powers to overturn the decisions of the autonomous bodies, especially in the case of regulatory bodies. This “reality-theory” gap has been observed also in other cases, as for instance in the relationships between the boards of the nationalized industries and the Government in UK (Flinders, 2004a).

Another case of loss of independence may occur when the autonomous bodies, if dealing with regulatory matters, are “captured” by their “clients” (Stigler, 1971).

In this case, regulatory capture refers to a situation in which there is too much closeness between the regulatory body and the regulated bodies and this can affect the fairness of the regulatory activity. In some cases the necessity not to insulate some activities from the political realm is consequence of the “public” will: some topics are too “sensitive” for the public audience and it is not accepted that a not politically “accountable” body might deal with them.

At the European level, all these issues present a significative degree of relevance.

The “real” independence of the European agencies is matter of discussion: only few of them have a “decision-making” power (CPVO, EASA, OHIM, EAR) while in other cases as for instance EMA, even if its tasks go beyond a purely information-gathering role, the decision-making power is reserved to the Commission on its advice. As seen above only few agencies may self-finance themselves and also in the case of a relevant degree of self-financing, as in the case of EMA, the possibility of being “captured” by interest groups (in this case, the pharmaceutical companies) is high. The decisional power of all agencies is always greatly dependent on the Commission’s will and the increasing role of the European Parliament may further reduce the possibility of initiate autonomous activities.

The composition of the management boards reveals the necessity to guarantee an appropriate equilibrium between the member States' and the communitarian institutions' influence. The presence of stakeholders' representatives may represent a danger of being "captured" in the regulation but at the same time it represents a tool for guaranteeing a proper participation of the "public" to the activity of the agencies and also, as some scholars argue (Metcalf, 1999b) an attempt of "co-optation" of the stakeholders. As seen above, the "resource dependency" of the most part of the agencies from the Commission or from its "clients" (CPVO and EMA for instance) is also particularly significant when the "depoliticization" issue is taken into account.

At the same time, Commission's officials have several times tried to downgrade the political implications of the agency model for the Commission, trying to depict the agencies' role as a purely information-gathering one. The case of EEA is highly revealing in this sense. The former Director of EEA has tried to partially change the role of EEA in order to make it assume a more "political" role. The increase of the budget contributions coming from sources other than the Commission (in 2005 it is foreseen a degree of "non-communitarian" funds higher than the 80%) might be a significant indicator of this attitude.

Another debated issue is the relevance of "information" as a political dimension: regulation by information is not neutral (Shapiro, 1997) and as a consequence, trying to put the label of purely "information-gathering" bodies to European agencies might not be a successful strategy. It is interesting to note that to find a point of *equilibrium* between the necessity to guarantee an adequate level of decisional autonomy to the delegated bodies, maintaining at the same time a reasonable degree of accountability at the eyes of the stakeholders, of the "public" audience, and of the "principals" (i.e., the Commission) is an highly delicate topic, both at the national and local level and at the supra-national one, having in mind that the communitarian setting presents further elements of institutional complicatedness.

#### *The power issue and the delegated bodies*

Aim of this sub-chapter is not to focalize again the attention on this issue but to try to find possible points of contact or differentiation with the delegation process occurring at the national and local levels and the one at the communitarian level with reference to the effective empowerment of EU's delegated bodies and to the rational staying behind their establishment. At the national level, see for instance the "Next Steps" programme in UK, the contractualisation of Ministries in New Zealand or the performance-based organisations (PBOs) in the US, agencification has been seen as a way of, for instance:

- rationalising;
- specifying more clearly the goals and means of policy delivery;
- creating more "strategic" tools for policy-making.

In administrative or managerial terms, agencification has been seen also as a key tool for delivering internal technical efficiency, re-organising institutions in performance oriented and more easily manageable units (Talbot *et al.*, 2000).

After an empirical assessment of the features of all delegated bodies operating inside EU, it can be affirmed that this rational doesn't represent the privileged one for explaining the creation of the communitarian bodies. It has already been cited the "political" scenery having brought to the diverse waves of "agencification" inside EU: in the next chapter it will be clearer that the common features characterising the communitarian "agency model" have little to do with national and local reasons, at least from a managerial point of view, leading to reorganize centralized public bodies in delegated ones.

European agencies haven't been created, or not only, because of "managerial" needs. Their settlement answers in particular to the following needs:

- to reduce the overload of functions of the Commission;
- to reinforce the regulatory role of EU without reducing member States' influence;
- to respond to external events having put in trouble the Commission role (i.e., BSE crisis, Erika disaster);
- to integrate in the communitarian system, expertise not readily available (i.e., the case of EMA);
- to create "hub" organizations in order to play the role of "co-ordinators" of network of national and sub-national bodies (e.g., EEA, EFSA);
- to provide services to the Commission (i.e., CdT).

This cannot be a definitive explanation of the reasons staying behind the establishment of EU's agencies; as Majone (2002b) argues, the existing framework of agencies might be more the product of a complex power struggle rather than of a rational organizational design. But this dissertation aims to describe "what" a European agency is, not only "why" it exists (this latter kind of analysis pertains more to the political science realm): this theme has been debated in details above and now the attention has to be focussed on the definition of the product of those supposed "political struggles" having led to the creation of the EU's delegated bodies.

### **3.2 Are EU's and national/sub-national delegated bodies really different?**

In this chapter, the first question which it has been tried to give an answer to, concerns the possibility and in some cases the opportunity to evaluate the diffusion of the delegated mode of governance inside EU by means of categories of analysis taken from the public management tradition. Before reasoning on the development of an unequivocal definition of "European agency", which may give useful insights for a clearer understanding of its peculiarity, and as a consequence give help to define own proper scientific dimensions to analyze the communitarian delegated bodies, the first step done has been to make a comparison between the way of being of this mode of governance in the public national and local tradition and in the "new", from a scientific point of view, communitarian setting.

The findings may help in better understanding how to interpret the increasing creation of delegated bodies inside EU and, at the same time warning about an explanation of this process by means of "ready to be applied" answers.

The first point of contact deals with the need, recognized by the same European Commission, of a unitary legislation concerning the organization, the activities and the mechanisms of control of the delegated bodies. At the national level, a relevant convergence has been found: to the increase in number and functions of the delegated bodies has sometimes not corresponded a parallel attention of the legislators for their regulation. The unclear legal position of the European agencies has been one of the main problematic factors playing against a proper development of this mode of governance inside EU and its legitimation.

Recent legislations, as the financial regulation above cited, go towards this direction but the need for an omni-comprehensive set of law regulating the state of being of the EU's agencies is still felt. Inside EU there is still not a common vision about the role of the agencies in the Community system: the same Commission (Commission of the European Communities, 2001b) has pointed out that there is the risk to define European agencies as a "tolerated anomaly" inside the institutional setting of the Community. In the absence of a common constitutive framework integrating the European agencies into the Community machinery, the governance of the agencies themselves might be not ensured in an optimum fashion, as some of the findings of this research show.

Another point of contact regards the necessity to create delegated bodies in order to co-ordinate fields of action where the former actors were operating in a disperse framework. The examples cited above should clarify that as a consequence of the increasing functions loaded to the Commission and of managing relationships with a plurality of national and sub-national actors, one of the most appropriate mode of governance to deal with these factors has been the creation of a delegated body, responsible as "hub" organization. In chapter 2, agencification inside EU has been interpreted as an "administrative evolution": taken in consideration the atypical, with respect to the national and local settings, institutional context in which the European agencies have been created, this interpretation should be taken into consideration.

If in some cases, at the national and local level the creation of delegated bodies answered to the need to reorganize a set of un-coordinated or territorially dispersed institutions, this is even more possible at the communitarian level. Here the presence of significative elements of multi-level governance, the need no to overcome the State's influence and the necessity to regulate some fields of action (i.e., pharmaceutical products approval) in collaboration with a multitude of national, sub-national, public and private institutions, may partially explain the increasing process of delegation inside the EU system.

The accountability of the delegated bodies is the third topic analysed in this chapter: one of the key justification for creating independent body at the national level, other than the "efficiency" justification, has been identified in the need to insulate certain activities from the political influence. As a consequence, an organizational relationship to link Ministers and bureaucracy should be adopted (Flinders, 2004a). Some researches, i.e., some studies by OECD (2002), show on the contrary that in many cases there is a failure in developing parliamentary scrutiny mechanisms allowing to effectively oversee agencies' activities or that there is not a direct relationship between the "political" and the "operational" levels.

At the communitarian stage, delegated bodies are subjected to accountability mechanisms which make them reliable to the Parliament (democratic control) and Commission in a rather satisfactory way. The relationship with the other European institutions is guaranteed by a financial regulation which is the basis for the regulation of each delegated bodies. The relationship with the Parliament and with the Council is quite strong and the Commission plays a significant role of "controller" on the agencies' activities. The relationship between the "political" level (Parliament and Council), the "policy-making" level (Commission) and the "operational" level (delegated bodies) is accurately regulated.

Delegated bodies are subjected to a limitation of their autonomy also by other measures: the resource dependency from the Commission, the very limited possibility of "decision-making" (executive control), the presence in their Management Bodies of representatives of the European institutions and of the member States are some of the "control" mechanisms guaranteeing a adequate level of influence on the activities of the delegated bodies. To these mechanisms the external financial control and the judicial control have to be also added.

The fourth point – the depoliticization issue – presents fewer points of contact between the national and the communitarian levels of analysis. Being the institutional setting so different, to speak of depoliticization of the European agencies doesn't make completely sense. The main finding to be underlined is the risk for the European agencies to be "captured" by their stakeholders. This is a risk run also from the national regulatory agencies but at the communitarian level some scholars (Metcalf, 1999b) see the "co-optation" of stakeholders' representatives in the Management Boards as an opportunity more than a fright. The situation can be slightly different in the case an agency heavily depends on the funds of its "clients" (i.e., EMA).

To conclude, as said above, wondering if the increasing process of agencification might have been provoked by power struggles or by the search for a managerial efficiency improvement is not easily testable and to compare the communitarian situation with the national one may be sometimes misleading.

Chapter 3 has been concentrated on "macro" elements of analysis: the next one will predominantly deal with the "micro" level of analysis.

Here the two main points discussed have been:

- inter-institutional relationships;
- stakeholders' relationships.

The role of the agencies in a networked relationship with other national and sub-national actors has been debated when addressing the "control" issue: it has been confirmed that the creation of some agencies, especially of the "regulatory" ones has been consequence of an "administrative evolution". This evolution should assure an acceptable level of co-ordination between organizations operating in the member States, because of the agency's role, assuring at the same time the influence of the member States on the national implementation of the communitarian policies and guaranteeing to the Commission its "decision-making" role.

The co-optation mechanisms and, in general terms, the relationship with the stakeholders have been also debated. The presence of stakeholders' representatives in the Management Boards of EMA, Cedefop, EFCA, EMSA, ENISA, ERA, EUROFOUND and EU-OSHA reveals the dimension of this *phenomenon*. It is not clear if this presence of representatives "external" to the Commission might be intended as the need to answer to a lobbying pressure already existing in the comitology process or as an opportunity to ease the relationship with the stakeholders' categories the agencies deal with. In any case, this presence might in some ways help the agencies to have an immediate feedback from those categories on their policy decisions.

It is now helpful to formulate some conclusions about the degree of decisional autonomy of the communitarian delegated bodies as coming out from the analysis performed above. Referring to Rehnman (1973), it is interesting to evaluate the degree of dependence from the decisional framework imposed by the "central" organization (here, the European Commission). It is possible to argue that the decisional autonomy of the agencies is rather high, even though under a steady control. The main constraints come from the necessity to depend, in many cases, from a financial support of the Commission and in the need to submit to the Commission the Annual Reports for an approval. In addition to the "external" dependency, the European agencies are constrained by an "internal" dependency, given the relevant influence has on them the presence inside their decisional bodies of European institutions', member States' and stakeholders' representatives. Of course, this issue is less relevant when dealing with purely "operational" agencies; on the contrary its importance becomes higher when speaking of "regulatory" agencies. The same considerations can be referred also to the degree of interaction of the agencies with their stakeholders (Baker, 1973), and the feedback effects of these relationships.

The final considerations rising from the assessment of the issues of growth, coordination, accountability and control, depoliticization and power analyzed in order to find points of contact and differentiation between the communitarian delegated bodies and those bodies at the national and local level are:

- in order to get a complete picture of the introduction of delegated modes of governance inside the communitarian system, especially for what concerns the "regulatory" bodies, it is useful to conduct an analysis within a more general understanding of the characteristics of the distribute public governance modes at the national level;
- the creation of the European agencies can be considered as an "administrative" *phenomenon* and in this sense their establishment has some points of contacts with the national processes of governance delegation but it is also important to use those categories of analysis with carefulness (in particular the "efficiency" ones). So doing, it might be easier to understand this process as a wider change of the governance structure of EU, at the light of the new functions loaded to the Commission;
- the creation and the increasing growth of the delegated bodies inside EU should be analyzed with cautiousness. It doesn't still exist a comprehensive

framework defining rules and functions of the "European agencies": these bodies still look like a "residual" organizational mode of governance more than acknowledged "institutions" inside EU; the role of the European Parliament is increasing inside the agencies but a legal framework is still needed; it is hardly recognizable an "efficiency" rationale behind the creation of the European agencies, which looks like products more of power struggle or external events' pressure than of a reasoned organizational evolution.



#### **4. European Community agency: a wary interpretation**

In order to provide scientifically serious insights about the interpretation of the delegated mode of governance within the communitarian context, a reflection about agencies currently operating in the communitarian system is needed. A comparative analysis of their characteristics may reveal differences and points of contacts between them, aiming to give a definition, if feasible, of an "unequivocal" model of communitarian agency.

How can be similarities and differences in a comparative perspective best evaluated, in order to define a "model" of agency? To do that, below some parameters for the comparison will be taken into account. First, the modes of emergence of the EU's agencies will be considered: their founding regulations, their procedures of regulations and the dynamic processes of foundation will be analysed. As a second point, their formal statutes are addressed. To do that, three are the sub-categories utilized: organizational structure (i.e., legal 'personality, boards' composition, personnel policies); financial autonomy and audit (i.e., funding and financial rules, internal and external audit); performance management (i.e., strategic plans, presence of activity-based budgeting and indicators of performance). In the end, the diverse kinds of functions performed by the agencies will be addressed.

The last one is a very delicate point: vary attempts of classification have been proposed in the past and it is rather difficult to "choose" the best one. A "tentative" to build up model of classification will be done, taking as a starting point the review of the previous classifications proposed in the scientific literature, trying a categorization and including in the analysis also the communitarian agencies established in the last two years, when information are already available. By this way, it would be possible to identify, if existing, an evolutionary trend in the agencification process, individuating changes occurred in the categories of analysis proposed here. Aim of this chapter is to depict a comprehensive framework by which defining the agency model inside EU as evolved during the years, with reference to the tasks performed, the management characteristics and the relationships between the agencies, the European institutions, and other stakeholders.

The findings of this chapter will be also useful for evaluating the structural disaggregation and performance contracting categories of analysis. The broad empirical analysis of this chapter, covering all agencies now operating in the communitarian context, allows also giving the first answers to the research questions.

##### **4.1 Mode of emergence**

Most existing decentralized agencies settled up in the first two "agencification waves" have their legal basis in the Article 308 of the Treaty<sup>28</sup>: this article is used as

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<sup>28</sup> Article 308 of the EC Treaty states that: "If action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament, take the appropriate measures".

a residual competence, where an action is necessary but the EC Treaty doesn't provide any specific power. Most of those agencies are products of legislative decision-making, that is of ordinary statutes in the form of "Council Regulation" derived from Article 308. The Council takes the appropriate measures if action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community, and the Treaty has not provided the necessary power (Kreher, 1997). The scope of Article 308 presents two important limits: first, it cannot be used to change the institutional structure of the Community and alter its balance of power; second, this article may not be applied if other Treaty provisions are available. The former limit influences the power to be conferred upon the agencies (Vos, 2000): it determines that agency powers must not trespass upon those of the Treaty institutions; the latter one refers to the generally residual character of the article.

This point is crucial: the increasing number of delegated bodies inside UE would claim for the development of a set of articles in the Treaty clearly defining the powers delegable to those bodies and introducing a separate and specific legal basis for their establishment. Recently, the settlement of the "youngest" agencies has been based on the provision of the Treaty which constitutes the specific legal basis for the policy field in question (Bergström & Rotkirch, 2003) but this approach might become problematic in the case the need to establish delegated bodies takes place in policy areas in which EU owns limited powers: organisational delegation inside EU should be considered an institutional *phenomenon* and for this reason a separate and appropriate legal basis is needed and a clearly defined intervention of the European Parliament in the founding phase is now foreseen.

After the analysis of the legislative procedures of the existing agencies, the first impression is of being in front of a homogeneous picture: the consultation procedure applied for the first, chronologically speaking, ten European agencies has been the same in all cases. By means of the consultation procedure, the influence of the European Parliament has been highly limited and, in addition, the proposals of the Commission had to be approved unanimously by the Council: the Governments, voting unanimously could establish a delegated body, when it was necessary in order to attain the overall objectives of the EC Treaty, as argued by the Article 308 (amending Art. 235). In these ten cases, nine agencies have the Art. 308 as legal basis: in one case, EEA, the Council Regulation was based on the Art. 130S (now Art. 175).

In the last decade it is also happened in two cases – EMA and CPVO – that the Council changed the legal basis on which the Commission's proposal was based. For instance, in the case of EMA, the Commission proposed to use Art. 100A: the Council changed it because to base the proposal on this article would have required the co-operation procedure which guarantees more influence of the Parliament and a qualified majority voting in the Council.

After 1997 and in particular with the third "wave" of the agencification process, things have changed. Between 2002 and 2004, eight agencies have been created (EASA, ECA, EDCDP, EFCA, EFSA, EMSA, ENISA, and ERA): all of them have been settled up with the co-operation procedure, that is with a Council and European

Parliament Regulation. This fact may reveal the increased importance of the European Parliament as referred in the first chapter of the dissertation. It is important to underline also that, in addition to EEA, in seven cases the legal basis is not the Art. 308 but other ones, in details<sup>29</sup>: EASA's settlement is based on Art. 80; ECDCP on Art. 152; EFCA on Art. 37; EFSA on Art. 37, 133 and 152; EMSA on Art. 80; ENISA on Art. 95, and ERA on Art. 71.

If the global trend of the agencification process is observed, it may be noted that the main point to be underlined is the increasing involvement of the European Parliament in the settlement decision: formerly it had been harshly counteracted by the Council's pressure; in the recent period the involvement of the Parliament has become compulsory. The second point of relevance is the increasing reference to articles of the Treaty other than the 308: the new agencies are based on the provisions of the Treaty which constitute the specific legal bases for the policy field in question.

If in the future it should be expected an omni-comprehensive legislation regulating both the fields of intervention and the founding rules of the communitarian delegated bodies is too early to be said: at the moment it is to be signalled the definition of a financial regulation, valid for all the agencies, and the increased reference in the founding regulations to Treaty articles others than the 308. Unfortunately, to see in these elements the possibility for the decentralized agencies to be recognized as a formally institutionalized mode of governance inside EU is still not possible.

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<sup>29</sup> The EU agencies' founding regulations currently operative are:

CdT: Council Regulation 2965/94/ECC of 28 November 1994, modified by Council Regulation 2610/95/ECC of 10 November 2005;

Cedefop: Council Regulation 337/75/ECC of 13 February 1975;

CPVO: Council Regulation 2100/94/ECC of 27 July 1994, modified by Council Regulation 2506/95/EC;

EAR: Council Regulation 2454/99/ECC of 15 November 1999, modified by Council Regulation 2415/01/ECC of 10 December 2001;

EASA: Council and European Parliament Regulation 1592/2002/EC of 15 July 2002;

ECDCP: Council and European Parliament Regulation 851/2004 of 21 April 2004;

EEA: Council Regulation 1210/90/EEC of 7 May 1990, modified by Council Regulation 933/1999/EC of 29 April 1999;

EFSA: Council Regulation 178/2002/EC of 28 January 2002;

EMA: Council Regulation 2309/93/ECC of 22 July 1993;

EMCDDA: Council Regulation 302/93/ECC of 8 February 1993, modified by Council Regulation 3294/94/EC of 22 December 1994;

EMSA: Council and European Parliament Regulation 1406/2002/EC of 27 June 2002;

ENISA: Council and European Parliament Regulation 460/2004/EC of 10 March 2004;

ERA: Council and European Parliament Regulation 881/2004 of the 29 April 2004; ETF: Council Regulation 1360/90/ECC of 7 May 1990;

EUMC: Council Regulation 1035/97/EC of 2 June 1997;

EUROFOUND: Council Regulation 1365/75/ECC of 26 May 1975;

EU-OSHA: Council Regulation 2062/94/EC of 18 July 1994, modified by Council Regulation 1643/95/EC of 29 July 1995;

OHIM: Council Regulation 40/94/EC of 20 December 1993, modified by Council Regulation 6/2002/EC of 12 December 2001.

Having analysed the "formal" background of the agencies' settlement, it is now time to take into consideration the reasons having pushed for their creation and the possible link existing between the functions already performed by the Commission and the ones delegated to the agencies. The settlement of an agency usually answers to external events (i.e., EMA with the BSE crisis and EMSA with the Erika disaster) or to contingent needs: because of the lack of the acceptance of the delegated mode of governance as an institutional recognized management form, this is an inevitable consequence. The recent agencies' settlements are not different: if something new should be recognised it is the increasing delegation to agencies of responsibilities in fields where the intergovernmental influence is higher (i.e., fisheries, maritime or aviation safety policies). This could be the effect of the need to regulate policy fields already under control of the member States: in order not to take out of the member States' influence their sovereignty in these fields, that is to give the Commission the power to act instead of them, to establish an agency represents an "easier" solution to be accepted by them.

The rationale behind the creation of an agency may be of different nature: for instance the idea to create the EMCDDA was of a member State (French in 1995, with its President Mitterrand) and it was the President of the Commission, Jacques Delors to launch the proposal for the settlements of EEA.

In more general terms:

- some agencies have been created on the model, and in order to replace it, of the comitology system (i.e., EMA);
- some to supplant a procedural mechanism within EP and the Commission (i.e., EMCDDA);
- some to replace programmes already active inside the Community (i.e., the CORINE programme in the case of EEA; the REACH programme in the case of ECA; other examples are Cedefop, EUROFOUND and EU-OSHA).

In some cases, and especially in the recent years, the creation of agencies has been the effect of the transference of functions from the intergovernmental level to the communitarian one. The most relevant cases are the EASA, EFCA (also settled up for being in charge of the CFP, Common Fisheries Policy), EMSA and ERA: all of them have been created between 2002 and 2004. This has been partially the case also for other agencies: EEA and EMA, the first one with reference to environmental information gathering, the second one to the certification of some types of pharmaceutical, have undertaken competencies previously held by the member States. In other cases, where the "operational" nature of the agency is more relevant (i.e., CdT, ETF, EAR), the reasons should be the need to answer to more practical and executive needs.

In two cases, the emergence of an agency has been the consequence of the decision to establish a new Community regime: this is the case of CPVO (plant variety) and OHIM (trademark). Before their settlement, the registration was on two levels: the national and the international (in particular for the trademarks). This could have posed problems of validity because for example the registration of a trademark at the international level (the so-called "Madrid agreement") wasn't recognized by some European member States. To this "category" of agency partially belongs also EMA

which has established a new Community regime of centralized registration, supplementing the formerly existing national and decentralized procedures (Gardner, 1996).

#### 4.2 Formal status

The second parameter of analysis is the agency's formal status. In order to give a complete picture of the agency's governance structure and to define a "model" of agency, the agency's formal status is specified in three dimensions of analysis: organizational structure; financial autonomy and audit; performance management.

##### *Organizational Structure*

All European agencies have legal personality: this means that they shall benefit from the powers granted to legal persons in the laws of all member States. One of the most relevant practical consequences is the possibility to acquire or dispose of property and to be parties to legal proceedings. Being the agencies created in the framework of the communitarian rules, even though they possess legal personality in the national law, this fact has consequences on their internal rules: i.e., the agency's staff is subjected to the same rules of the other EU's officials.

Before going into details in the organizational structures' analysis of the agencies, it is useful to give a general overview of the main organisational features of all twenty communitarian decentralized agencies: in the following two tables, these features are summarized:

Agency	Management Board	Advisory Forum	Scientific Committee
CdT	1 r. <sup>30</sup> per member State 2 r. of the Commission 1 r. from each body or institution calling upon the centre's services		
Cedefop	Per member State: 1 r. of the Government, 1 r. of Employer's organization, 1 r. of Employee's organization, 3 r. of the Commission		
CPVO	1 r. per member State, 1 r. of the Commission		
EAR	1 r. per member State, 2 r. of the Commission, 1 observer from the European Investment Bank		
EASA	1 r. per member State, 1 r. of the Commission	Representatives from aviation personnel, manufacturers, commercial and general aviation operators, maintenance industry, training organisations and air sports	
ECA	1 r. per member State	Forum for exchange of information on enforcement activities	Committee for Risk Assessment, Committee for Socio-Economic Analysis, member State Committee.
ECDPC	1 r. per member State, 3 r. of the Commission, 2 experts appointed by the Parliament	1 r. per member State's National Authority	

<sup>30</sup> "R." stays for "representative"

EEA	1 r. per member State, 2 r. of the Commission, 2 experts appointed by the Parliament		Up to 20 experts appointed by the Management Board
EFCA	1 r. per member State, 4 r. of the Commission, 4 r., without right to vote, of the fishing industry		
EFSA	14 members appointed by the Council (in co-operation with Parliament and Commission), 1 r. of the Commission	1 r. per member State	1 r. per member State, 1 r. of the Commission (observer status)
EMA	1 r. per member State, 1 r. of the patient's organization, 1 r. of the doctor's organization, 1 r. of the veterinarian's organization, 2 r. of the Commission, 2 r. of the Parliament		CHMP (Committee for Medical Products for Human Use): 1 r. per member State, 1 r. per each EEA-EFTA State, up to 5 experts co-opted by CHMP; CVMP (Committee for Medicinal Products for Veterinary Use): as CHMP; HCMP (Committee for Herbal Medicinal Products): 1 r. per member State, 1 r. per each EEA-EFTA State; COMP (Committee for Orphan Medicinal Products): 1 r. per member State, 1 r. per each EEA-EFTA State, 3 experts appointed by the Commission on EMA's proposal, 3 r. of the patient's organization, 1 r. of the Commission
EMCDDA	1 r. per member State, 2 r. of the Commission, 2 experts appointed by the Parliament		1 r. per member State; the Management Board may appoint up to 6 experts more
EMSA	1 r. per member State, 4 r. of the Commission, 4 r., without right to vote, of the professional sectors		
ENISA	1 r. per member State, 3 r. of the Commission, 3 r. of the stakeholders	Experts representing the relevant stakeholders	
ERA	1 r. per member State, 4 r. of the Commission, 6 r., without right to vote, of the professional sectors		
ETF	1 r. per member State, 2 r. of the Commission	Appointed by the Management Board: 2 experts per member State, 2 experts per eligible country, 3 experts from the social partners at the European level	
EUMC	1 independent person appointed each by: member State, Parliament, Council, 1 r. of the Commission		
EUROFOUND	Per member State: 1 r. of the Government, 1 r. of the Employer's organization, 1 r. of the Employees' organization, 3 r. of the Commission		15 members appointed by the Council on proposal of the Commission
EU-OSHA	Per member State: 1 r. of the Government, 1 r. of the Employer's organization, 1 r. of the Employee's organization, 3 r. of the Commission		Obligatory consultation of the Commission and the "Advisory Committee on Safety, Hygiene and Protection at Work" in respect of the work programme

OHIM	1 r. per member State, 1 r. of the Commission		
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**Table 4: Governance bodies' composition of the EU's agencies**

Agency	Director	External audit	Budget's discharge
CdT	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
Cedefop	Appointed by the Commission from a list submitted by the Management Board	European Court of Auditors	Parliament, on Council's recommendation
CPVO	Appointed by the Council on Commission proposal heard the opinion of the Management Board	European Court of Auditors	Management Board (the Commission checks the legality of the agency's budget and of those acts of the Director, whose legality is not checked by another body)
EAR	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EASA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
ECA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
ECDPC	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EEA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EFCA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EFSA	Appointed by the Management Board from a list of persons submitted by the Commission, heard the European Parliament	European Court of Auditors	Parliament, on Council's recommendation
EMA	Appointed by the Council on a list of at most 3 names submitted by the Management Board	European Court of Auditors	Parliament, on Council's recommendation
EMCDDA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EMSA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
ENISA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
ERA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
ETF	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EUMC	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
EUROFOUND	Appointed by the Commission on list submitted by the Management Board	European Court of Auditors	Parliament, on Council's recommendation
EU-OSHA	Appointed by the Management Board on Commission proposal	European Court of Auditors	Parliament, on Council's recommendation
OHIM	Appointed by the Council on a list of at most 3 names submitted by the Management Board	European Court of Auditors	Agency's Budget Committee: it is made of 1 r. per member State and 1 r. of the Commission

**Table 5: Director's appointment, external audit and budget's discharge**

For what concerns the organisation of the agencies, if a unique model is to be defined, first of all the common features of the agencies must be individuated.

In general terms, a European agency has a tripartite structure consisting of a director (called "executive director" or "president"), a supervisory board (referred as "management", "administrative" or "governing" board) and a scientific committee.

The Director acts as the agency's legal representative and his/her first duty relates to the preparation and implementation of the decisions and work plans adopted by the supervisory board, and he/she is usually appointed for a period of three/five years. The supervisory board usually nominates the Director: the director is appointed by the Management Board on Commission proposal (in 14 cases on 20); in two cases it is the Commission to appoint the director on Management Board's proposal (Cedefop, EUROFOUND). In four cases it is the Council to be responsible of the appointment: this happens when the agency is involved in "regulatory" activities (i.e., granting authorizations) having direct consequences on the member States' influence, that is in the cases of CPVO, EFSA, EMA and OHIM. This reveals that these four agencies have the highest degree of autonomy from the supranational level (especially in the case of EMA and OHIM: CPVO's and EFSA's Directors are appointed on Commission proposal) but the lowest degree of autonomy from the member States.

The Management Board is usually appointed for a period of three/five years and its main function is to adopt the agency's annual and multi-annual work plan, the budget and propose the budget for the discharge. If the composition of the Management Boards is assessed, agencies may be classified in three different categories (with four exceptions):

- agencies with Management Boards comprising representatives of the member States and of the Commission (CPVO, EASA, ETF, OHIM);
- agencies with Management Boards comprising representatives of the member States, of the Commission, and of the other stakeholders or clients (i.e., employers', employee's, professional sectors', other European institutions' representatives: to this category belongs eight agencies);
- agencies with Management Boards comprising representative of the member States, of the Commission and of "experts" appointed by the Parliament (ECDCP, EEA, EMA, EMCDDA).

Four are the agencies not belonging to none of the above cited categories: EAR, in which an observer from the European Investment Bank participates to the Management Board's activities; ECA, in which the Management Board is made only of member States' representatives; EFSA and EUMC, where only the Council and the Parliament participates to the nomination of Management Board's members.

Some agencies have also an "Advisory Forum" and one or more "Scientific Committees" giving opinions on technical questions submitted them or acting as information providers. The composition of the Advisory Forum (seven agencies own an Advisory Forum) is made in some cases of stakeholders' representatives or, more frequently, of member States' representatives and their function is usually to be a forum for information exchange and discussion or, especially in the case of Advisory Forums made exclusively of member States' actors, as a body



“controlling” and “giving advice” to the Management Board on the “policy guidelines” to be followed.

The Scientific Committees are usually appointed by the Management Board for a three/five-year term and vary in terms of scope of tasks, size and composition. Usually their scope is to give scientific support to the Management Board and they are particularly important in the case an agency is called to give technical advice or making scientific evaluations. Scientific committees exist in the organisational structure of ECA, EEA, EMA, EUROFOUND, EU-OSHA: experts seconded from the member States or experts appointed directly by the Management Board (EEA and partially EMCDDA) or by the Council (EUROFOUND) are essential for the agency’s management because of the “scientific” activities performed by these agencies. These Scientific Committees may serve on one side as “hubs” for collecting information and expertise from national and sub-national organizations, and on the other one, to present the member States’ point of view on some issues, even though this latter function is usually performed by the Advisory Forums.

The most interesting point is the one of EMA, which will be analysed in depth as a case study in chapter 6: various Scientific Committees exist and the experts are nominated by the member States but also by the Commission, by stakeholders’ organizations or by the same committees.

#### *Financial autonomy and audit*

This topic, in some measure addressed in chapter 3, is a significative indicator of the autonomy of the agency in relation with the Commission and the member States. The financial responsibility of the agencies is limited by the fact that their budgets are part of the EU’s general budget. At the same time it has been showed that some agencies may become in some ways self-financed charging fees on their services and so doing, be partially (and in the case of CPVO and OHIM totally) independent from the financial point of view. It should be stressed the fact that when fixing fees, the agencies are not autonomous: this decision and its regulation is subjected to a procedure defined in the Founding Statute, in which both the Commission and the member States own significative influence. To make an example, in the case of OHIM, it was the Commission, referring to the agency’s regulation, to adopt a regulation on the fees payable to the agency.

Another relevant topic refers to the provision within the founding regulations for the establishment and implementation of the budget. Before the application of the general Founding Regulation in 2002, there was no uniformity. For the agencies created in 1975 these provisions were contained in a Council Regulation, adopted after consultations with the European Parliament and the Court of Auditors, foreseeing the European Parliament as the institution giving the discharge.

For the second “wave” agencies the situation was different: in some cases, the internal financial rules had been adopted by the Management Boards, after consultations with the Commission and the Court of Auditors (i.e., ETF); in some other cases (i.e., EEA and EMA) after consultation only with the Court of Auditors. Now the situation presents a higher degree of uniformity: in the case an agency wants to adopt an internal regulation different from the general one, the Commission should approve it.

The modes of internal control can also differ: in some cases a financial controller is appointed by the Commission (this is the case in particular of the "1975 agencies") or by the agency's Management Board or Budget Committee. The "internal auditor" advises the Community body on dealing with risks, issuing independent opinions on the quality of management and control systems and issuing recommendations for improving these conditions. He/she also assesses the suitability and effectiveness of the internal management systems and the quality of the internal control systems. He/she reports to the Management Board and to the Director. It is important to underline that one of the tasks of the internal auditor is to submit to the Community Bodies an annual internal report setting out the number and type of internal audits conducted, the recommendations made, and the actions taken on these recommendations. A report on the internal audits is sent to the European Parliament, to the Council and to the Commission.

All decentralized agencies are subjected to the external control of the European Court of Auditors. The Court's main task is to conduct an external, independent audit of the Community's accounts. The audit is not of judicial nature, since the Court of Auditors has no power of sanction.

The Court of Auditors:

- expresses its opinion on sound financial management;
- assesses the reliability of the accounts and the legality and regularity of transactions involving revenue collected and payments to final beneficiaries;
- prepares special reports setting out the findings of controls usually conducted over a number of years and covering specific areas of management.

In line with other public audit institutions, the European Court of Auditors undertakes two different types of audit, namely "financial audit" and "sound financial management audit".

According to the Treaties and the Financial Regulation, it is duty of the Court of Auditors to audit the financial statements on the revenues and expenditures relative to all bodies and agencies set up in the EU. In general terms, these comprise a balance sheet, an economic outturn account, a cash-flow table, a statement of changes in capital and explanatory notes. The objective is to establish whether the financial statements show a true and fair view of the results for the year and the financial situation at the year end: that transactions, assets and liabilities have been fully and correctly entered into the accounting records; that they exist; they belong to the audited body; and are correctly presented in the financial statements. An assessment is made of the appropriateness of the accounting principles used, and of significant estimates made by the managers. The Treaties and the Financial Regulation require the Court also to audit the legality and regularity of the transactions by which the agency finances and implements its budget. The objective is to ensure that transactions have been executed in accordance with the relevant rules and regulations, that they exist in reality, have been correctly calculated and that the beneficiaries of EU's aid have fulfilled their obligations. The audit covers all aspects from receipt or payment by the agency through different levels of administration down to individual elements of agency's revenue or receipt by the final beneficiary.

The objective of the sound financial management audit is to evaluate how well the agency has applied the principles of sound financial management - economy, efficiency and effectiveness - to the management of EU's funds. Such audits are also known as "performance audits" and "value for money audits".

The European Court of Auditors has power of decision over its selected audits including the topics, the audit approach to be followed, and how and when to present its observations and publicise its findings. The Court carries out its audits in accordance with its own audit policies and standards, which adapt generally accepted international standards to the European Union context. In particular they are based on INTOSAI Auditing Standards and International Standards on Auditing issued by the International Federation of Accountants.

The European Court of Auditors reports on any irregularities and suspected fraud.

When a case of suspected fraud, corruption or any other illegal activity becomes known to the Court, either through its audit work or when the case is reported by a member of the public, the matter is immediately communicated to the European Anti-Fraud Office (OLAF).

#### *Performance management*

Before going in details in the analysis of the main performance management systems established by European agencies, it is worthwhile to underline that each Directorate General also sets out its "Annual Management Plan", submitted to the European Commission Secretariat: the plan is aligned with the "Annual Policy Strategy" and the "Legislative and Work Programme". Being much policy work multi-annual in character, the Director General every year prepares an "Annual Activity Report" referred to the previous year, in which are stated the activities developed. The Commission organises its resources by means of an "activity-based budgeting" which allows a system of "management by objectives" stating objectives, indicators and outputs to be reached every year and on a multi-annual term. An impact assessment of the DGs' activities is also usually performed.

What does happen at the agency's level? Agency's managers are required to deliver similar work plans' documents (i.e., Annual report, Annual Working Plan, Multi-Annual Policy Frameworks) and usually it is the Management Board to be in charge of these tasks: the execution is responsibility of the Director. Aim of this procedure is to give the possibility to the Commission, and in general to the other EU's institutions to "control" the effectiveness of the agency's management and in general to verify that the activities of the agencies are in line with the tasks and objectives of their founding statutes.

EU's agencies apply diverse types of performance management systems: the most significant examples are summarized below.

Agency	Performance Management
CdT	Global quality plan
Cedefop	Performance indicators
EEA	Strategic indicators of performance
EMA	Integrated quality management system and audit advisory committee

EMSA	IPSAS Accounting Standard
ETF	Evaluation plan
OHIM	Performance indicators and quality time standards

**Table 6: EU's agency's performance management systems**

CdT periodically reviews its processes and identifies areas of improvement: a monitoring system is developed and indicators and time measures identified. CdT, from 2004 evaluates its overall performance according to the principles set out in the EFQM model and to that end carries out satisfaction surveys among its clients and staff. It is the "Quality Management Section" to be responsible for co-ordinating activities, evaluating the findings in a consistent manner and advising internal and external participants in the total quality plan (CdT, 2004).

Cedefop, when defining its medium-term priorities provides a concise indication of the target audience, objectives/methods and performance indicators. To continuously improve the quality of Cedefop's performance, a regular evaluation is made. Evaluation quality standards include ways to assess the quality of the outcomes of the work carried out in all areas and at all levels of the organisation, whether in quantitative or qualitative terms, according to the nature of the outcomes (Cedefop, 2004). Having being Cedefop's financial rules recently changed, performance indicators have been redefined in order to ensure an appropriate and systematic monitoring. A mid-term assessment of the implementation of the medium- and long-priorities is performed: the priorities are formulated flexibly and are linked to current policy priorities.

EEA's performance is measured in a management system using objectives and measures in four inter-related perspectives: financial (i.e., budget and sound financial management), client (i.e., relevance, timeliness, and image), business (i.e., data handling, publications timeliness, impact of publications) and learning and growth (i.e., capability, motivation). In 2004, a "balanced scorecard" has been developed in order to monitor the indicators defined in the management plan: the objective is to achieve the EMAS accreditation.

The EEA's policy cycle is also fully detected: every stage is documented and monitored. EEA's policy cycle is the following: issue identification, issue framing, policy measure identification, policy measure development, policy measure implementation, policy measure effectiveness. The indicators focus on those aspects regarded as policy relevant: in general indicators quantify information by integrating different and multiple data sets (EEA, 2004).

Management and internal control systems are part of EMA's corporate governance and are consolidated in an integrated management system: the integrated quality management system is based on a periodical internal audit of the key processes, based on priorities, the level of risk associated with the processes, and the results of the previous audits. It is the "Audit Advisory Committee" to be responsible for the auditing and it is operative from 2005 (EMA, 2005).

EMSA organises its work on a project basis: when a project is approved, a definition of objectives, a project leader and team are nominated. A system of time-tracking is

defined so that the project's tasks and outcomes can be constantly monitored with reference to what agreed before the start of the project in terms of time and resources. In financial terms, it should be underlined that from 2005, EMSA has adopted the International Public Service Accounting Standards (IPSAS) in order to better monitor its assets and liabilities. The current set of financial reports developed using Business Objects System are strengthened (EMSA, 2005).

ETF is compliant with internal control standards: ETF's policy and procedure improvements are identified systematically and implemented during the financial year. By means of this process, the action plan is redefined in order to meet the requirements of the internal control standards and to adjust issues identified by the Court of Auditors and the Internal Audit Service. External evaluations are periodically performed. In 2004, a new monitoring and evaluation policy has been implemented: the evaluations regard country, project and thematic assessments (ETF, 2004).

OHIM reviews its processes on a constant basis: recently an external evaluation by Deloitte & Touche has been performed. In 2003 it has been also launched a programme aiming to reorganize OHIM's departments and re-design the working procedures. Time quality standards have been set up and a quality programme aimed at speeding up the procedures have been developed. Time targets for the treatment of the applications are now more severe and performance against targets are regularly monitored (OHIM, 2004).

Here above, some performance management policies implemented by EU's agencies have been analysed. It should be underlined that external evaluations of the agencies' managerial processes and performances are constantly carried out by the Commission and, as said above, the Court of Auditors annually evaluates agency's financial management. It should also be remembered that external evaluations by consultancy firms are sometimes performed.

In this chapter it has been aimed to put in evidence which systems to improve the performances of the agencies had been internally put in essence. Most of the agencies have tried to modernize their management systems and in some cases to conform to international quality standards.

On one side, the agencies are pressed to improve the goodness of their systems of performance evaluation by the constant process of assessment performed by the EU's institutions (in particular, the Commission and the Court of Auditors), on the other side, the need to be reliable at the eyes of the stakeholders and in more general terms of their "public" is another element pushing for better managerial performances. This is even truer in the case the EU's agency owns "authorization" responsibilities as for instance in the case of OHIM or performs "regulatory" tasks (i.e., EMA and EMSA).

### **4.3 Kinds of functions**

The third dimension of analysis concerns the kinds of functions carried out by the EU's agencies: in order to go towards the identification of an "agency model" inside EU, it is important to find categories of classification of the agency's tasks by means of which to perform a comparison of homogeneities and differences.

The Council's (and European Parliament's) regulations establish the agencies, define the goals (primary objectives), the tasks and obligations and sometimes the priority areas of work (secondary objectives). This is a first revealing factor for defining an adequate classification of the agencies with reference to their types of functions. In the first chapter the Everson's (1995) and Kreher's (1997) classifications have been reported, specifying that the one by Bergström and Rotkirch (2003) has been chosen as the most convincing. In this chapter, the characteristics of the agencies' functions will be further analysed, in order to support the goodness of this classification, and giving some insights about attempts done by other scholars. In the next table, all existing EU's agencies will be classified using the Bergström's and Rotkirch's classification proposal.

Agency	Type of agency	Decision-making power	Notes
CdT	Administration	No	
CPVO	Authorization	Yes	Also "Regulatory"
EASA	Authorization	Yes	Also "Regulatory"
ECA	Authorization	No	Also "Regulatory"
EMA	Authorization	No	Also "Regulatory"
OHIM	Authorization	Yes	Also "Regulatory"
CEDEFOP	Co-ordination/ Information	No	
EAR	Co-ordination/ Information	Yes	Also "Management"
ECDPC	Co-ordination/ Information	No	
EEA	Co-ordination/ Information	No	
EFCA	Co-ordination/ Information	No	
EFSA	Co-ordination/ Information	No	Also "Regulatory"
EMCDDA	Co-ordination/ Information	No	
EMSA	Co-ordination/ Information	No	Also "Regulatory"
ENISA	Co-ordination/ Information	No	
ERA	Co-ordination/ Information	No	
ETF	Co-ordination/ Information	No	
EUMC	Co-ordination/ Information	No	
EUROFOUND	Co-ordination/ Information	No	
EU-OSHA	Co-ordination/ Information	No	

Table 7: EU's agency's classification (by macro functions)

The classification above used adds to the Bergström and Rotkirch's one, a specification of the decision-making power owned by some agencies, and introduces the "regulatory" type of agency. EFSA and EMSA, which couldn't be defined as "authorization" agencies, partially own regulatory powers, even if they still don't have the possibility to grant authorizations. At the same time, not all "authorization" agencies own decision-making power. The most revealing case is the one of EMA: its task is to give scientific advices to the Commission with reference to the pharmaceutical requests of central authorization but the final decision is on the Commission. In practical terms the possibility of having a request rejected because of the Commission's opposition is quite rare.

The case of EAR is quite untypical: it might be defined a "co-ordination/information" agency but it has decision-making powers and it can be also defined a "management" agency, because of its tasks – management of reconstruction projects, on behalf of the Commission –.

Before going into a synthesis of the peculiarities of the above cited categories of agencies, some details about the functions performed by these delegated bodies may be useful. Everson *et al.* (1999) tried to classify EU's agencies in five categories, relying on an analysis of ten kinds of functions. These functions are:

1. internal market facilitation and administration: maintenance within the member States of common standards, set within the comitology framework, forming the basis for the mutual recognition of the quality and admissibility of goods and services flowing across national frontiers;
2. risk regulation: involvement of the agencies in complex task of risk regulation (to be precise: risk assessment and management);
3. facilitating technical interaction between the member State administrations: easing the functioning of the internal market by establishing contacts or networks between the national administrations, called upon to play the central role in the quick identification of and reaction to problem of *post*-marketing control;
4. policy-making facilitation: augmenting the policy-making and regulatory capacities of the Commission providing it with further expertise;
5. policy control: check of the autonomous policy-making capacities of the Commission, providing it with independent sources of information;
6. policy impetus: adding further sources of policy impetus to the EU's decision-making processes, networking with private and public parties, which a directly involved in the collation and assessment of information;
7. encouraging co-operation between the social stakeholders and EU and member State's Governments: providing for a central node for interaction between labour, management and Government in the matter of development of better social and labour conditions;
8. social policy: acting as an impetus for a European social policy, collating information and statistics upon which joint member State or future EU's policies might be based;

9. facilitating intergovernmental co-operation: forming a basis for governmental agreements on policy co-ordination, easing the co-ordination amongst the social partners or playing an informational role;
10. administrative facilitation: providing additional expertise and skills through the supervision of sub-contracted services.

To this function's categorization follows an attempt to define five different types of agencies:

- adjudicational/Standard overseeing agencies: they supply the comitology system with the information necessary for the setting of standards, networking with national administrations to ensure implementation. They may have direct powers over industry in the matter of authorisation (functions: 1,2) ;
- market facilitating agencies: they facilitate the consolidation of the internal market by the direct administration of patent awards schemes laid down in the agencies' founding statutes (function 3);
- policy facilitation through information provisions and check on policy through information provision: they collect information from governmental national administration, supply the Commission with information on which to base policy and review national implementation (functions 4, 5);
- policy impetus agencies: they bring the social partners together in a closer collaboration through collection and diffusion of information or simply gather information from national administrations and the general public (functions 6, 7, 8, 9);
- administrative facilitation agencies (function 10).

Applying to the existing EU's agencies this classification, the result is the following:

Agency typologies	Agencies
Adjudicational/Standard overseeing agencies	EMA, EU-OSHA
Market facilitating agencies	CPVO, EASA, ECA, OHIM
Policy facilitation through information provision	ECDPC, EEA, EFCA, EFSA, EMSA, ENISA, , ERA
Policy impetus agencies	CEDEFOP, EMCDDA, EU-OSHA, EUMC, EUROFOUND
Administrative facilitation agencies	CdT, EAR <sup>31</sup> , ETF

**Table 8: EU's agency's classification (by micro functions)**

In details, the agencies perform the following functions:

<sup>31</sup> As said above, EAR's characteristics are so peculiar that defining it a purely "administrative" agency might be misleading.



Agency function	CdT	CEDEFOP	CPVO	EAR	EASA	ECA	EMA	ECDCP	EEA	EFCA	EFSA
Internal market facilitation and administration			X		X	X	X			X	
Risk regulation			X		X	X	X		X		X
Facilitating technical interaction between member States			X		X	X	X	X	X	X	X
Policy-making facilitation		X			X	X	X	X	X		X
Policy control					X	X	X	X	X	X	X
Policy impetus		X			X			X	X		X
Encouraging co-operation between the social stakeholders and EU and Member State Governments		X							X	X	X
Social policy impetus		X									
Facilitating intergovernmental co-operation		X	X		X			X	X	X	X
Administrative support	X			X							

Table 9: EU's agencies micro functions (I)

Agency function	EMA	EMCDDA	EMSA	ENISA	ERA	ETF	EUMC	EURO FOUND	EU-OSHA	OHIM
Internal market facilitation and administration	X		X	X					X	X
Risk regulation	X									
Facilitating technical interaction between member States	X		X	X					X	
Policy-making facilitation	X	X	X	X			X	X	X	
Policy control	X	X	X				X		X	
Policy impetus		X	X			X	X	X	X	
Encouraging co-operation between the social stakeholders and EU and Member State Governments		X				X		X	X	
Social policy impetus						X		X	X	
Facilitating intergovernmental co-operation		X				X		X	X	
Administrative support					X	X				

Table 10: EU's agencies micro functions (II)

It should now be clear that many communitarian agencies' classifications have been proposed and the *dilemma* to balance synthesis and completeness of information is hardly solvable. The above proposed classification is very precise and exhaustive but it might be confusing if a "model" of agency is searched. This is the main reason which brings me to prefer the first one: if the organizational mode of delegated governance has been analysed before and many common features between the diverse EU's agencies have been found, to give an unequivocal definition of agency,

relying on the kind of function performed can be less difficult. Points of contacts can be found between EU's agencies of the same "category".

It has been listed only one "administration" agency: for this reason, and because of the fact that CdT plays a purely "technical" role on need of other EU's bodies, the focus of the analysis will be on the other two "models" of agency.

The "authorization" agencies, CPVO, EASA, EMA and OHIM (ECA is still not active, so it is not possible to give verified opinions on this organization) are all charged with the operation of a system intended to ensure uniform application of a defined regime. CPVO and OHIM are active in a system directed to the protection by registration of intellectual property rights (plant varieties and trade marks); EMA and EASA in a system for authorization of pharmaceutical and aeronautical products. The procedure for examination of an application is based on the collaboration between the agency and the national authorities. A significative differentiation among these agencies is the following: while in the case of CPVO, EASA and OHIM the final decision is taken by the agency itself, in the case of EMA, the agency only gives an opinion leaving the decision to the Commission.

The Management Boards of CPVO, EASA and OHIM are made of member States' and Commission's representatives: EMA's Management Board sees the presence of representatives of the main stakeholders' organisation. It is interesting to note that in the cases of CPVO, EMA and OHIM, the Director is appointed by the Council on proposal of the Management Board (in the case of CPVO, the Commission is also involved in the decision) while EASA's director is appointed, as usually happens, by the Management Board on Commission proposal. This is revealing of the particularly "delicate" role of these agencies in their policy fields, with reference to member States' influence. Differences can be found also, with reference to CPVO and OHIM, in the budget's discharge phase and in the presence of "quasi-judicial" organs, and, in the Scientific Committees of EMA, not existing in the other "authorization" agencies.

EFSA and EMSA, classified as "co-ordination/information" agencies with also regulatory tasks, don't own decision-making power but present some peculiarities: EFSA's Management Board members are appointed by the Council (and 1 of them by the Commission); EFSA has a Scientific Committee; EFSA's Director is appointed by means of a procedure in which it is involved also the European Parliament. In the EMSA's Management Board are represented the stakeholders' associations. Having these agencies been created only in recent times, it is too early to give a judge about them: for the moment it is only possible to argue that because of their characteristics, they should be placed in the "co-ordination/information" category more than in the "authorization" category because of the lack of decision-making power and above all, because they are not charged with the operation of a system intended to ensure uniform application of a defined regime.

The "co-ordination/information" category is the one to which most existing EU's agencies belong and it is also the more "heterogeneous", both from the point of view of the kinds of function (see also Everson's classification about this point) and of their organizational features. These agencies have all been established to provide information needed by the Commission and the member States, within their

respective sphere of competence. The suppliers of information of these agencies are not limited to the national administrations but involve also international organisations, sub-national actors and non-governmental bodies.

First of all, there are agencies which are supposed only to collect, analyse and distribute information which are available to the EU's bodies and at the national level but also other interested parties (i.e., this the case of EUROFOUND, ETF).

Another "sub-group" of this third type of agencies refers to delegated bodies that, in addition to purely "information" tasks, are mandated to create and co-ordinate European experts' networks, in collaboration with national and sub-national organisations (Kreher, 1997). The creation of these networks, of which these agencies are usually the "hub" institutions, eases the possibility that information at the European level is based on equivalent comparable data from the national and sub-national levels and that an harmonization of measurement or data comparison methods is carried out: for instance, EDCP, EEA, EMCDDA, ENISA EU-OSHA belong to this sub-category. The same EFSA and EMSA, even if they own "regulatory" tasks, can be included in this agency's typology. If the organisational features of these latter delegated bodies are addressed, it might be noticed that in addition to representatives of the member States and of the Commission, in their Management Boards are included experts or representatives of the stakeholders' groups. Almost all these agencies share the same characteristics with reference to Directors' appointment and external audit and budget's discharge procedures.

To put a label on EU's delegated bodies, using as a framework of analysis their kinds of function seems to be rather simple: the two main categories identified ("authorization" and "co-ordination/information") are in some ways clearly defined and, especially in the case of the former one, the belonging of an agency to this type of institution is usually confirmed by its organizational modes, which is pretty typical. The "co-ordination/information" category seems to be more heterogeneous, but if their organizational modes are carefully assessed, the points of contacts are more numerous than the differentiating ones. The main distinctive feature is the existence of a network of organisations on which these agencies rely in order to collect data. What seems to be very interesting, in the perspective of building up a "model" of agency is the existence of a link between the formal statute (specified in organizational structure, financial autonomy and audit, and performance management) and the kind of functions performed. It will be scientifically very useful in the next years to carefully assess the evolution of the agency model because already now some elements of innovativeness are clearly surging, especially with reference to the modes of emergence (in particular the Treaty articles to which are referred the Founding Statutes) and to the creation of agencies with regulatory and informative duties (i.e., EFSA and EMSA) but not having at their disposals decision-making power.

#### **4.4 Does an EU's agency model really exist?**

Essential elements of a common framework for describing EU's agencies can be individuated, in order to possibly find an agency "model" as stems out from the evolutionary process referred to the delegated bodies' features change in the last

thirty years. Some principles characterizing EU's agency model are now summarized:

- specialisation: the mandate of the agency and the range of its powers are delimited and identified in their founding statutes;
- autonomy: the agency has legal personality and is managed by an Executive Director. The Director shouldn't neither solicit or accept any instructions from any government or other EU's body, except in cases provided for by the regulation setting up the agency;
- transparency: the procedures whereby the agency adopts acts and operates should guarantee transparency and equal access to the deliberation and decision-making processes for all parties concerned;
- parity of the executives: in the agency's Management Board, member States are always represented. The Commission should also be equally represented: this is not true for all agencies and in absolute terms the representation of the Commission is not comparable to the one guaranteed to the member States. This approach has been in some cases slightly changed in the recent years: in the EFCA's and ERA's Management Board have been appointed 4 representatives of the Commission, 3 in the ENISA's one. 14 members of the EFSA's one are nominated by the Council and not directly by the member States. In the case of agencies with a social remit but no decision-making power (i.e., CEDEFOP, EU-OSHA, EUROFOUND) this principle is adapted to their particular needs, with a greater representation of the social partners;
- representation of stakeholders: representatives of the "professional sectors" are appointed in some Management Boards (i.e., EFCA, EMSA, ENISA, ERA) but without right to vote. The fact that they cannot vote during the board's deliberation is explicable: only the representatives of the public body are accountable to the authorities responsible for the democratic control on the compatibility of the agency's activities with its mandate and with the general interest;
- no representation of the European Parliament: independent experts appointed by the European Parliament seat in five Management Boards (ECDCP, EEA, EMA, EMCDDA, and EUMC). In one case (EFSA), the Parliament co-participates to the members' appointment. "Direct" representation of the Parliament on the Management Board would conflict with the Parliament's constitutional role. The agency is part of the executive and as such must be subjected to the legislature, but the participation of the legislature in the executive, amounts to setting Parliament up as both judge and judged in term's of the agency's supervision;
- direct democratic accountability: the agency is subjected to a sort of "democratic control". The Parliament may hear the agency's representatives, i.e., the Director, at any time but in particular on publication of the Annual Report on agency's activity. The Parliament, on Council's recommendation, is responsible for granting discharge in respect of the agency's budget following a proposal from the Management Board;

- Executive Director's appointment and responsibility: he/she is usually appointed by the Management Board following a Commission's proposal (with few exemptions discussed above). He/she is responsible for managing the agency and adopts the decisions stemming from the agency's mandate;
- Management Board's responsibility: the Management Board usually appoints the Director following a proposal by the Commission and can dismiss him/her; draws up the agency's internal rules of procedure following a proposal by the Director; approves the annual activity programme and the budget. It approves the annual activity report and proposes discharge of the budget to the European Parliament;
- Advisory Committees: they are made of independent experts and are required to issue opinions for consideration by the Executive Director concerning draft agency acts (i.e., recommendations, decisions, etc.);
- audit: EU's agencies are subjected to external audit by the European Court of Auditor. The internal auditor is in some cases a financial controller appointed by the Commission (this is in particular the case of the "1975 agencies") or by the agency's Management Board or budget committee, and reports to the Management Board and the Executive Director.

Those above are the main common features characterising an "EU's agency model". Anyway, differentiation between the delegated bodies inside EU is still high and it is fundamentally consequence of two factors: the mode of emergence and the tasks assigned them.

The evolution of the agencification process inside EU has followed what it has been called in this dissertation "the three waves". Relevant points of contacts have been pointed out between the agencies settled up in one of these three historical moments. The first insight comes from the different articles referred in the Founding Statutes: the increased importance of the European Parliament and the choice to use the co-operation procedure for the establishment of an agency is revealing of a new attitude inside EU. An increasing "recognition" of the value of the delegated modes of governance as a proper tool for the delivery of communitarian services and the management of selected policies can be pointed out. In parallel, an effort has been made to develop a "communitarian procedure" to be followed in the settlement and regulation of the agencies. In the "third wave", EU's delegated bodies in new policy fields have been established: the creation of two "authorization" agencies as EASA and ECA and of "information/co-ordination" ones such as ERA and EFSA is consequence of the increased need of the Commission to be responsible of the management of functions previously held by the member States: in the recent times a "model" of agency as a "hub" inside networked relationships of national and sub-national actors, has become the most usual in the communitarian context.

The other factor to be taken into account and from which the main *criterion* of differentiation follows, is the kind of function performed by an EU's agency. Above, an attempt of classification has been made: it is now clear, on the basis of the analysis performed, that to be an "administrative", an "information/co-ordination" or an "authorization" agency provokes consequences on the structure and the rules of functioning of the agency.

For instance, only "authorization" agencies own decision-making power (with the exception of EAR) and boards of appeal internal to the agency exist only in the cases of CPVO and OHIM, because of their particular function of new "community regime" regulators. Representations of stakeholders' organisations or in general of the social partners inside the management bodies of the agencies answers to the need to involve, and in some ways coopt, the beneficiaries of the agencies' activities.

The differentiation existing between the European agencies may reflect the different states of integration in the respective policy fields. This evaluation is confirmed by the increased use of delegated bodies in policy fields where the need for an "integration instrument" couldn't be waited for (i.e., maritime policy field). The agreement of the member States on an increasing settlement of new agencies confirms this impression and underlines the "administrative" nature of the increased establishment of delegated bodies: if they are created as a consequence of a political will, the rational for their creation should be searched for, more and more in a demand for a delegation of functions which neither the Commission nor the member States can held alone. Agency's establishment now doesn't seem anymore consequence of "a necessity to be satisfied at time" (Schäfer, 1996) but as the result of an "ordinary" institutional transformation. For this reason it is even more important to find a unique "model" of agency, to be adaptable to the tasks' peculiarities of every agency: this is the direction towards which the EU's agencification process is going and signals of this evolution can be easily recognized in the founding regulations, in the boards' composition and in the rules of management's appointment but also in the relationship with the Commission and in the requirements to be respected by the agencies to be accountable to the other EU's bodies.

Further studies in the future will verify if this evolution will continue and if the European agencies will be more and more recognized as an indispensable institutional tool for managing the increasingly diverse and complex communitarian policies.

## Part 2

### Methodological framework, empirical validation and findings' discussion

#### 5. Research design, data collection and analysis

##### 5.1 Evaluating exploratory and explanatory study

This dissertation presents a theoretical uniformity: the majority of the parts have been designed as exploratory studies and they should be considered as a unitary research, starting from the definition of the object of study – delegation process in the European system – its detailed explanation at the light of the background literature analysis, the evaluation of the theoretical approaches to the argument and an empirical analysis aiming to provide useful insights for a scientific and empirical assessment of the *phenomenon* in order to test the research questions and to develop reliable conclusions.

The exploratory research design is based on theoretical assumptions assuming that the purpose of the study is well defined and the *criteria* of evaluation of the object of study are clearly stated. Explanatory design, on the contrary, assumes as a starting point clearly defined propositions to be tested by means of experiments and surveys<sup>32</sup>. One of the key challenges for researches studying EU, but in general public and above all “supra-national” institutions, is to try to combine overall theory with detailed empirical knowledge about the processes of change occurring inside these types of organizations. Although the rather rich empirical base in the field of European studies, the established systematic knowledge of the actual dynamics processes inside the European system are relatively poor (Haverland, 1999) and as a consequence it is difficult to formulate strong and refined statements and propositions and test them in a rigorous statistical mode (Sverdrup, 2000).

Basically two are the different modes of conducting social and management analysis (Trondal, 2001): where the empirical *phenomena* are at the centre of the examination and the purpose is to account for this in great detail (Pfeffer, 1997) and where the aim of the research is to construct theories and hypotheses, being the theoretical argument at the centre of the analysis, and empirical data are applied in order to elucidate this argument (Elster, 1989). Following the latter approach, the empirical field is used as a laboratory for testing hypotheses and illuminating general arguments (Haas, 1958; Olsen 2001a). The aim of this study, even though in the framework of an exploratory design, is to outline a theoretical argument accounting for processes of administrative change – delegation – inside the communitarian system, following an inductive pattern of analysis.

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<sup>32</sup> Andersen (2003), referring specifically to the European studies argues that two are the major types of theoretically guided studies: theory as interpretative and explanatory framework and theory elaboration and construction. Theoretical interpretation and explanation is the systematic application of concepts and theories, in order to make sense of an empirical *phenomenon*; theory elaboration and construction compares specific implications of concepts and theories with case-study data, aiming to develop and modify existing theoretical generalizations and their scope, by means of a careful analytical inference with the purpose to improve tools of theoretical explanations.

Inductive analysis (Patton, 1990) means that the patterns, themes, and categories of analysis “emerge out of the data rather than being imposed on them prior to data collection and analysis”. According to Dey (1993: 99), a natural creation of categories occurs with “the process of finding a focus for the analysis, and reading and annotating the data”. These categories, when related to an appropriate analytic context, must also be rooted in relevant empirical material: a meaningful pattern is searched for moving between the logical construction and the actual data recollected. The meaning of a category of analysis is to bind up on the one hand with the bits of data to which it is assigned, and on the other hand with the ideas it expresses (Dey, 1993: 102).

Once defined, the categories of analysis must be meaningful both internally, in relation to the data understood in context, and externally, in relation to the data understood through comparison (Dey, 1993). When a particular category is adopted, a comparison is already implied. By means of this process of constant comparison, descriptive categories might be created (Lincoln & Guba, 1985) and exploratory analysis performed. Assumed that the meaning of the categories evolves during the study, because decisions are made about which data may or may not be assigned to the previously defined category of analysis, the fit between data and categories should be one of continuous refinement. In order to do that, flexibility is required to accommodate the observations in the framework of the new directions of analysis.

Several resources may be useful to the process of category generation: “inferences from the data, initial or emergent research questions, substantive, policy and theoretical issues, and imagination, intuition and previous knowledge” (Dey, 1993: 100). In order to utilize those resources optimally, categories have to be adapted to the context of the data, extending, changing and eventually discarding useless categories of analysis. The last point is particularly important for this research: the communitarian setting presents relevant peculiarities according to its institutional and organisational uniqueness. To use purely “managerial” instruments of analysis might bias the interpretation of the findings: for this reason, considerations about the EU’s “environment”, the supranational character of the communitarian setting and the existence of “political” *criteria* of analysis are also advanced.

Being the attitude of the dissertation basically managerial, and relying it profoundly on the theoretical tradition of public management literature, the main sources taken into consideration come from the extensive debate about the application of these schemes of analysis to the study of European issues as a peculiar field of study. In addition, significant insights coming from research in the fields of economics, law and political science give a constructive supplementary dimension to some of the topics discussed in the research. The increased attention of the academic interest about EU’s issues should assure the fair quality and importance of the materials consulted. To go also partially in directions further than the managerial ones, gives the possibility to track in a proper way the decision-making processes and the institutional changes beyond the evolution and the increased application of the “delegation” model inside the communitarian system (Kassim & Menon, 2003).



## 5.2 Case study approach

Empirical observations – by means of case study analysis – are gathered in order to clarify the validity of the theoretical concepts built up at the light of the main arguments coming from the most insightful literature on European management and delegation in general. When very little is known about the *phenomena* under analysis, the use of case studies can bias the attitude of the researcher, expecting him/her that the clarification of conceptual dimensions or causal mechanisms in one case will have implications for the understanding of other similar cases (Andersen, 2003) but some scholars argue that when theory is weak and concepts vague (Ragin & Becker, 1992) this approach is recommended. It is very rare that case studies allow for generalization: the design of this study, the relatively poor pre-existing literature about the argument, and the sample and size of samples of the research might have limited the possibilities for generalization.

But in this dissertation the use of case study approach, following a prefixed theoretical path and a deep empirical analysis of the delegation model existing in the EU's system allows, if not to make an "analytical generalization" as in the Yin's assumption (1994), to perform a significative "fine tuning" of the existing theories on delegation<sup>33</sup>.

Given this assumption, this opportunity might be assured by the concern about the rigorous use of a well developed theory, set of theories, or also a set of basic scientific assumptions. When a background theory is used, or a set of theories is reviewed in order to guarantee the development of a solid theoretical basis, and it is the base to establish a ground for comparing the empirical results of the cases studied, and when the cases support the theory or give useful insight for a further evolution of the same theory, there might be the possibility to make a significative theory "fine tuning".

Case study approach might allow developing and testing a theory in a case when the current theoretical approaches seem not adequate because of their little empirical validation with reference to the specific research field (Allison, 1971). By means of case study approach it is possible to fulfil the aims of the research: first to describe a new, from the theoretical point of view, observable event (Kidder, 1982). In this sense, the theory-building process should rely on past literature review and empirical observations or experiences as well as on insights of the theorists to build up incrementally powerful theories (Eisenhardt, 1989). The scarce knowledge about the topic, the urgent need for a new perspective or, as an extreme case, the absence of previous empirical findings, pushes for the creation of a novel theory or the application of different methodological tools of research. In addition, by means of case study method it is possible to test theoretical arguments under conditions where possible biasing "noises" from independent variables are controlled. In this sense, the application of an inductive methodology, which is facilitated by the case study

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<sup>33</sup> Yet limitations to the case study design of some studies of public agencies have been underlined by scholars as Warwick (1975) or Meyer (1979). Comparative studies (i.e., Buchanan, 1975) leave questions about the adequate applicability of categories of analysis taken from the private sector. Some other studies (i.e., Hickson *et al.*, 1986) show sectoral differences even within analogous task or functional categories where small differences might be *a priori* expected.

approach, might give the possibility to reveal relationships and other findings that were not previously considered or recognized<sup>34</sup>.

Some scholars involved in the study of delegation processes inside the communitarian system, have been criticized because of their lack of clarity about the schemes of analysis adopted. On one hand the confusion about the applicability of "private" *criteria* of analysis to supranational public institutions and, on the other hand the presence of intervening factors as the political influence and the institutional setting have by large disturbed the evolution of a unitary school of thought and of a proper and reliable methodology to be applied to this research topic. This theme has been specifically addressed in chapter 3 of the dissertation. Here it is worthwhile to underline that in this research, this problem is faced trying to conciliate the most important literature contributions in order to find a valuable and extensively applicable method of analysis. Case study approach to European agencies' evolution analysis has been criticized because in many former researches case studies have been frequently seen in isolation from other cases, not underlying the importance of assessing the process outcomes, and avoiding to build up a reliable framework of analysis. This dissertation tries to solve this problem investigating a little but significantly revealing set of cases, linking its analysis to a deep theoretical review and interpretation and to a collection of noticeably formulated interrelated theoretical questions.

A major concern in case study literature regards the possibility to achieve analytical control over the object of study: it means to be able to focus on certain conceptual properties or relationships between variables, while at the same time striving to eliminate variations that might create problem (Andersen, 2003). In practical terms, an accurate sampling choice based on a detailed pre-existing knowledge of the *phenomenon* analysed might ease the possibility to perform a reliable research.

One of the main problems to be addressed when using case study approach is the attempt to bridging the gap between theoretical explanation and analytical description: when studying a specific case it might happen that empirical implications are consistent with but not unique to the empirical issue to be explained. On the contrary, in some cases, a detailed empirical analysis might not match with the assumed theoretical background.

A "critical" strategy of research, aiming to apply conceptual lenses accurately specified to empirical cases, gives the opportunity to re-define the theoretical assumptions relying on the analysis' findings. By this way, if the case studies under observation reveal a loosely connection with the analytical framework formerly

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<sup>34</sup> Some examples of case study approach applied to EU issues' analysis can be found in the literature: being European studies a sort of cross boarding field, different scholars have approached them with peculiar attitudes. To underline the more remarkable examples, it should be cited the case of Schmidt's analysis of policy reform (1994); Laffan's use of case study approach for researches on Commission officials' attitudes (1998); Moravcsik's application of this methodology for documenting States' interests in treaty negotiations (1998). Closer to this research focus and to the methodological approach here used, are the cases of Kohler-Koch & Eising (1999) on European Union's governance and of Wallace & Wallace (1998) on EU's policy-making.

developed, it is possible to adapt the methodology applied to the *phenomenon* under observation and to re-shape the research focus.

In the scientific community it seems that management researchers agree on the possibility to use case study approach to address complex *phenomena*, in order to give scientific insights about theoretical predefined research questions. In the case of exploratory researches, where a concrete situation is studied on the base of predefined *criteria*, case study approach is particularly fitting because of the variety of specific instruments of analysis at disposal of this methodology and because the final aim of this kind of research is rarely the generalisation of the results obtained (Fattore, 2005).

Case study analysis has been performed in order to empirically investigate the theoretical assumptions of the dissertation, previously defined in the more general framework of the overall system of EU's delegated bodies. To develop the research questions, the analysis has been focused on the strategic and operational processes of the communitarian delegated bodies, taken as units of analysis. The choice to analyse two cases studies (EMA and EEA) responds to the necessity to select two cases presenting particularly insightful characteristics, revealing the complexity of the EU's institutional setting and giving the possibility to put under control different dimensions of the communitarian institutional system as for instance the extensive relationships of those agencies with communitarian, national and sub-national actors, and the existence of a networked institutional framework in which the agencies under study play a "hub" role. By means of this approach it might be possible to understand common managerial patterns to the communitarian strategic and operational processes.

### **5.3 Case selection and appropriateness**

The complexity and multiplicity of the research questions addressed in this study make the population appropriateness issue particularly sensible: in general terms, the setting is constituted by all delegated bodies existing in the communitarian framework. Qualitative research focuses on few case studies that are purposefully selected to permit understanding of a *phenomenon* in-depth and to maximize discovery of patterns that emerge from the particular context under study.

The heterogeneity of EU's agency typologies (see chapter 4) pushed for an accurate case selection: the population of potential cases have been progressively restricted in order to consider delegated organisations in which involvement of "external" actors, others than the communitarian ones, could have been maximised in the decision-making and operational processes.

Hypothesis generation begins with the analysis of initial observations. This process undergoes continuous refinement throughout the data collection and analysis process, continuously feeding back into the process of category coding.

According to Bruner *et al.* (1972), "to categorize is to render discriminably different things equivalent, to group the objects and events and people around us into classes and to respond to them in terms of their class membership rather than their uniqueness". Categorizing EU's agencies allowed reducing the complexity of the environment under analysis, to identify the cases, and ordering and relating them.

The categories created clustering the data at disposal has become the basis for the organization and conceptualization of data (Dey, 1993).

The decision to focus the analysis on EMA's and EEA's cases has been taken following two main *criteria*:

- case appropriateness;
- accessibility and appropriateness of data.

Once restricted the population of potential objects of analysis to two partially homogeneous sub-sets of subjects ("information/co-ordination" and "authorization" agencies), and having defined a "model" of communitarian agency and its uniqueness if compared with similar organisations at the national level, two specific subjects, belonging each to one of the two sub-sets selected, have been chosen.

In purposeful case selection, the appropriateness of the selection strategy should be judged on how well the selected case will facilitate the answering of the research questions. Following Patton (2002)<sup>35</sup>, the two "information-richest" cases studies have been selected, in order to grasp from them key "issues of central importance to the purpose of the research" and the choice has tried to answer to the necessity to select subjects of study allowing to draw "inferences concerning casual relations among the variables under investigation" (Yin, 1994).

The two subjects selected have been considered the best examples of communitarian delegated body presenting a significative involvement of external stakeholders into decision-making processes, critical relationships with the agents (mainly the Commission) and a direct involvement in a networked institutional framework in which those two organisations play a "hub" role and foster the development of "soft" co-ordination tools in order to manage the relationships with national and sub-national, public and private bodies participating to the network's management.

The decision to study those two cases was also consequence of an accurate review of past researches on EU's agencies. The existence of different typologies of delegated bodies inside EU and the differences of task of each possible unit of analysis within the categories of agency individuated was first taken into considerations. The further step has been to consider the cases where the highest number of study dimensions (operational, strategic, network management) might have been assessed. In this sense, the cases chosen are the best ones fulfilling this requirement.

Accessibility and appropriateness of data (Glesne, 1999) have been the second *criterion* used to choose to perform an evaluation of EMA's and EEA's cases.

The creation of new regulatory agencies in the last years has been taken into account. It has been evaluated the possibility to take into consideration cases of delegated bodies established in the recent years because of the possible degree of innovativeness they might represent in the communitarian setting. The "administrative evolution" apparently occurring inside EU and the role those new agencies should play into the EU's institutional framework have been considered.

In the end, a different choice has been taken because of four main reasons:

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<sup>35</sup> Patton (2002: 30) argues that "the logic and power of purposeful sampling lie in selecting information-rich cases for study in depth. Information rich cases are those from which one can learn a great deal about issues of central importance to the purpose of the inquiry".

- the absence, or the poor existence of documents issued by those agencies (i.e., Annual Reports, evaluation reports by the Commission);
- the possibility to incur in biasing factors given to the newness of those agencies (e.g, with reference to the resource dependency from the Commission, more evident in the first years from an agency's settlement);
- the impossibility to perform a longitudinal study and to show the process of growth and maturation of an agency;
- the existence of formerly developed scientific framework of analysis, specifically designed on some EU's agencies, to be taken as starting points for the study.

Once chosen the two cases, it has been verified the possibility to perform a study as much complete as possible. To do that, the existence of reliable secondary sources, the accessibility to internal documents issued by the same organisations and the chance to perform a triangulation of the documentary analysis by means of personal interviews have been evaluated.

#### **5.4 Data collection**

As it is typical in exploratory research, data have been analysed building individual case study and then comparing each case study in order to review the conceptual framework previously developed (Eisenhardt, 1989). Data have been collected through interviews, observations, and secondary sources.

Secondary data came mainly from Annual Reports, a source frequently used to study strategic and operational behaviour of an organisation (Bowman, 1984; Staw *et al.*, 1983): by means of Annual Report's analysis it is possible to collect comparable data (Bettman & Weitz, 1983) and to assess the tasks performed by an organization (Salancik & Meindi, 1984).

Primary sources have been semistructured interviews with individual respondents. Using secondary sources and interviews the cases studies have been analysed: the iterative process behind this process was conducted on the base of a continuous research of similarities and differences with the other cases considered in the more "general" chapters (chapters 3 and 4) aiming to define the peculiarity of the agency model inside the communitarian setting. Although similarities and difference had been found with the other cases, it has been preferred to put in evidence the existence of peculiar strategic and operation processes as coming out from the two single case studies and then generalise the findings against the scientific framework previously defined.

The collection of available secondary data by means of documentary analysis represented the first phase of the empirical study. The data collected come not only from public documents (i.e., Annual Reports available on the agency's web site) but also from internal sources. The aim of this first phase has been to investigate the communitarian setting and to build up an extensive description of the delegated bodies inside EU. Being documentary analysis an imperfect way of data generation, it has been necessary to perform a further data collection.

Data collected analysing public or internal documents may be not fully reliable: organisations might not want to make public internal efficiencies or, more generally,

they might make a "political" use of the information (see EEA's case study for details). For this reason, the necessity to triangulate these secondary data with data coming from other sources and from direct interviews was evident. A comparison of the data collected by means of documents and interviews and an iterative re-interpretation of the data at the light of the new findings has been also performed.

The first documents taken into considerations have been, once evaluated the findings of past scientific researches regarding EU's agencies, reports concerning the "performance" of those organisations. Two kinds of reports have been evaluated: the official evaluation reports issued by the Commission and the evaluation reports made by external and independent scholars on behalf of the Commission and of the European Parliament.

The second step has been to individuate documents dealing with the three main dimensions of analysis:

- strategic and operational management;
- financial, accountability and audit;
- relationships with the "stakeholders".

Once defined the dimensions of analysis, a comparison of the agency's Founding Regulations and the financial rules adopted by each single agencies in the framework of the new general communitarian financial regime has been performed. In order to individuate the main elements of strategic decision-making process and what as been defined above the "level of outputs", multi-annual reports and work plans have been evaluated. When possible, transcriptions of the Management Boards' meeting and the decisions finally adopted, have been also taken into considerations in order to identify elements of influence of Commission's representatives (and of the other main "stakeholders": e.g. patients' representatives).

The analysis of the accountability, budgetary and audit documents has followed an iterative process: first, the documents issued by the same organisations have been studied; then it has been performed a comparison with the official documents finally discharged by the Commission and the European Parliament. The last step has been the study of the Court of Auditors' official reports: this phase of the research has been important in order to underline the "financial performance" of the agency and its possible evolution. In the end, the audit reports of the Internal Auditors of the agencies have been taken into considerations and when existing, also the certifications performed by external firms have been used in the research.

The evaluation of the relationships with the stakeholders have been designed in three phases: evaluation of the "internal" relationships (in particular with the Commission, the European Parliament and the Financial Office of the Community); evaluation of the "external" relationships (with the "clients" of the agency as the pharmaceutical companies; the "beneficiaries" as the patients' organisations; the national and sub-national bodies operating in collaboration with the agency as the EIONET's components); evaluation, when possible, of member States' influence (considering the role of member States' representatives in the agency's Management Board). Also at this stage of the research, strategic, operational and financial documents have been taken into account.

The study of those documents has been also directed to reframe the research questions and their operationalisation. The dimensions of analysis have been refined and on the base of the appropriateness of the data at disposal a first draft of the research has been written down.

The last step has been to triangulate the findings on the field with direct interviews. To go deeper in the analysis a comment on the first research's statement has been asked. Questions to agency's officials and management bodies' members probed their level of involvement in the following areas:

- visioning the evolutionary process of the agency;
- relationship management with major stakeholders;
- expectations and aims;
- managerial alignment with the communitarian actors' and external stakeholders' expectations;
- potential problems and resistance to the changes encountered;
- change management strategies adopted to overcome resistance.

A further triangulation at this point was necessary: the "internal" point of view had to be confronted with the one of the Commission's officials having relationships with the agency under study and with the position of the "external" stakeholders' representatives and of officials of the national and sub-national bodies operating in the networked institutional framework managed by the agencies. For this aim, semi-structured interviews have been performed, where their positions about the points touched upon during the interviews with agency's officials and management bodies' members have been questioned.

### **5.5 Methodological warnings**

Some shortcomings might be pointed out when analyzing in details the methodological issues involved in the examination of the delegation process in the European context.

First of all, the increase of importance of the delegation process inside EU is relatively new. For this reason the unavailability of widely accepted "ready to be applied" concepts and methods has to be carefully considered.

As pointed out above, another main problem when studying an institutional change process is the complexity of controlling it because different independent variables, of different nature (i.e., political factors) might influence the assessment of the process evolution and the conclusions drawn by the empirical analysis. It is really demanding to isolate causes and effects of the delegation process from other external and internal dynamics and intervening variables. A process-tracking effort, a detailed analysis of the documentary data issued by the same organizations and a direct confirmation of the data gathering process by means of interviews with key actors inside the studied organizations have been designed in such a way to challenge those methodological problems.

In the end, the consciousness of the fact that processes of institutional change take time, forces to be particularly cautious about the generalization of the results of the study. The ongoing process occurring inside the European Commission, and more widely inside the European system as a whole, might preserve from stating

definitive conclusions. A careful review of the main past contributions on this topic, a detailed analysis of the empirical data available about the cases taken into consideration, and a scientific research process supported by strong methodological clarity, considerable literature scrutiny and robust analytical process of research construction should guarantee the robustness of the dissertation's conclusions.

An expansion of the research time-horizon, a further enlargement of the sample and the improvement of the scientific investigations' findings about delegation process inside EU might obviously add new dimensions to the scientific debate to which this dissertation aims to give a useful contribution, providing valuable insights for a further study of this issue.



## 6. EMA: a “professional” organisation promoting health

EMA, considered as an independent organisation with a corporate identity and a legal personality, owns a significative degree of independence and it can be considered an example of “decentralisation”, in the sense that its tasks have been decentralized to it by a “central” organisation: the Commission, and to be more precise the DG Enterprise and Industry (formerly named DG III). At the same time, EMA is the main actor of the “centralized” evaluation procedure of pharmaceuticals, operating in a communitarian regulatory network.

EMA’s management processes are here assessed on three dimensions: its risk assessment duty, its co-ordination task and its operational responsibilities. EMA is in charge for providing professional and independent risk assessment advice: it is of Commission’s responsibility the decision on the so called “risk management”.

EMA is defined a “professional” organisation: as it will be explained below, its professional autonomy and independence of judge are fundamental elements in order to guarantee the co-ordination of the actors involved in the communitarian regulatory system and to manage the connections among its stakeholders, both the ones involved in the pharmaceuticals’ evaluation and the ones asking for their products to be evaluated.

From the “operational” point of view, EMA is not a mere executor of administrative tasks on behalf of a central organisation - the Commission - but it manages the regulatory network and behaves as the crucial node for its functioning, being it also a forum for the scientific discussion about the pharmaceutical regulatory system.

In this chapter, EMA’s management processes will be taken into account, first of all in order to give an exhaustive picture of EMA as an agency, having in mind the recent changes occurred in its structure and the consequences on its role inside the regulatory network; an evaluation of the institutional framework of EMA, of its relationship with the “internal” (i.e., the Commission) and the “external” stakeholders (i.e., pharmaceutical industry, patients, national institutions) will be done, and the influence EMA has on the institutional environment in which it operates will be evaluated, at the light of the findings concerning the evolutionary process of the pharmaceutical European policy of the last decades.

2005 represents an important year for EMA: it marks the 10<sup>th</sup> anniversary of the agency’s settlement and this year the new legislation, which also reshapes the structure and the tasks of EMA, will fully enter into force. For this reason, a definition of the “state of the art” at this moment, is particularly useful: an evaluation of EMA’s core business and of its activities, a discussion of its role in the definition and progress of a communitarian pharmaceutical policy and the evolution of the “weight” of EMA inside EU and in the relationship with the national regulatory agencies are the main points here addressed.

All these topics are relevant to the performance of an agency: because of the peculiar nature of EMA, the “managerial performance” issue cannot be addressed as a solely argument of discussion but it should be integrated in a wider analysis of EMA as an agency – a “professional” agency – in its institutional – “networked” – framework.

*EMA and FDA in a comparative perspective*

To evaluate communitarian agency's processes using "traditional" public management schemes of analysis might be difficult: in chapter 3 the main reasons staying behind this assumption have been argued and the rather poorness of the EU's management tradition, and as a consequence of a correspondent scientific evaluation of its performance, is another revealing indicator of the problematic applicability of the national experiences to this peculiar supra-national institutional setting.

The auxiliary body, in the communitarian context, never enjoys independent legal status *vis-à-vis* the central Community administration in order to safeguard it against political or bureaucratic interference, as would be the case with fully independent entities. The decision to establish a body auxiliary to the Commission is not so much to be attributed to a need to guarantee such bodies a certain degree of independence from the political, bureaucratic and economic power, as to a desire to discipline the matter in a decentralised fashion: in the case of EMA, the decentralised organisation aims to create and manage a plurality of relationships involving the central Community administration, the national and communitarian institutions (Chiti, 2000). EMA's independence cannot be evaluated as a proper tool for performing self-contained tasks in a decentralized way, being the agency insulated from the political influence as it is usually done in the national tradition. EMA as an organisation should be taken into consideration in its structure and role, relating them to the functions it performs in the communitarian regulatory framework.

Stated against these observations, it is useful to focus the attention on the elements differentiating EMA not only from the national agencies but, first of all, from the most referred example of pharmaceutical regulatory agency: the US Food and Drug Administration (FDA).

Even if these two organisations present extremely different characteristics it is important to point out some elements of comparison, before going into the details of EMA's analysis. What most differentiates FDA and EMA is the fact that unlike FDA, EMA does not stand alone but alongside national agencies responsible for pharmaceutical regulation in individual EU's countries. Until 1995, national agencies were fully responsible for the pharmaceuticals' regulation and only with the increased need to avoid duplication, share data and improve the safety and efficacy of the communitarian regulation, it became fundamental to develop a centralized procedure of pharmaceuticals' evaluation (which still now doesn't stand for the all typologies of pharmaceutical).

EMA's staff is more than 200 times smaller than the FDA's one and also its budget is significantly less: if the fields of action of those two organisations are looked to, it is first revealed that FDA is involved in "food" and "drugs" regulation while EMA's competence is limited to drugs' regulation. Food discipline is in charge of a recently created agency (EFSA); after having been responsibility of the DG XXIV (Consumer Affairs). Another element of differentiation attains the "pharmaco-vigilance": in Europe it is still very poor and even if with the recent EMA's organizational change, the situation should improve, at the moment big differences between the national systems deeply affect the possibility to reach an acceptable common level of pharmaco-vigilance across the member States. The interviews

performed with some experts reveal that this is one of the most controversial points concerning the evaluation of EMA's process of change: to make some examples, in Italy there is an institution dealing with this activity but pharmaco-vigilance is intended as a sort of "self-vigilance" in which doctors signal problem with drugs' use to the central authority, while in other countries, as for instance Sweden and France, the control system is much more evolved.

The lack of responsibility of risk management and regulation enforcement is perhaps the most important factor revealing the fundamental difference between FDA and EMA and leading the analysis towards a consideration of EMA as an organisation in itself, to be put into a peculiar institutional framework with its own functioning rules.

FDA is responsible for enforcement of regulations; EMA is not because the EU's system is designed in such a way that the enforcement is left to the national authorities. Risk management is the other differentiating point: as said above, EMA gives a scientific and independent opinion on request of central authorization to the Commission but it is the Commission to have the "last word" on the authorization. This fundamental issue will be widely discussed above in order to find the reasons staying behind this kind of relationship between the Commission and EMA and its consequence: from now it is highly revealing to note that in these ten years (1995-2005), of the 304 requests of central authorizations approved by EMA, only 16 received a negative opinion by the Commission as a final decision.

At the light of what said above, it is clear that the differences are much more evident than the similarities: for this reason, even if FDA represents an extraordinary example of regulatory agency in the pharmaceutical field, the institutional setting, and the organisational differences of EMA suggest to focus the analysis on EMA itself.

## **6.1 Describing EMA**

A brief description of EMA, as coming out from the 2004 change may be useful, before assessing EMA's management processes and its relationships with its stakeholders.

### *The European system for the evaluation of medicinal products*

EMA has been created first as an answer to the problems faced by the communitarian systems of pharmaceutical control already existing. The first attempt of communitarian regulation was the Directive 65/75 stating that pharmaceutical products should respect quality and safety standards. By means of the Directive 75/319, a new procedure of national authorization was introduced and a communitarian committee for the pharmaceuticals was created inside the Commission. Directive 83/570 tried to solve the problem of the excessive slowness of the existing procedures but only in 1987 a procedure based on a double authorization (of the national agencies and of the Commission) was introduced.

After few years of discussion, EMA was created in 1995: if the communitarian system is analysed as a whole, it might be noted that its main function is to authorize medicinal products for human and veterinarian use so as to protect health and facilitate the free circulation of pharmaceuticals within European countries. In general terms, the tension between the policy objectives of "public health" and "free

trade” seems to be solved by art. 152 of the EC Treaty, which reveals that Commission’s main aim is to safeguard public health. As it will be shown in the conclusions, if the EMA’s case is specifically addressed, this tension has never been really solved.

EMA has been created as part of the redefinition of the whole system of evaluation and authorisation of the medicinal products and it should be considered in this sense very different from the national and local agencies, usually created for performing executive tasks on behalf of central (politically accountable) organisations. As a consequence, the role of the agency should be seen as predominant in the system: EMA is the main actor in the relationships with the actors involved in the regulatory system, and not solely involved in a relationship of subsidiarity with the Commission.

#### *EMA’s tasks and procedures*

EMA’s mission statement is to contribute to the protection and promotion of public and animal health by:

- mobilising scientific resources from throughout the European Union to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health professionals;
- developing efficient and transparent procedures to allow timely access by users to innovative medicines through a single European marketing authorisation;
- controlling the safety of medicines for humans and animals, in particular through a pharmaco-vigilance network and the establishment of safe limits for residues in food-producing animals<sup>36</sup>.

EMA is in charge for co-ordinating the human resources of the member States and for monitoring the use of pharmaceutical products for human and veterinarian use, as a main actor in the centralised procedure but intervening also in the decentralised procedure: in fact, the European system for the authorisation of medicinal products is based on two procedures, in both of which EMA is involved (EMA, 2004):

- centralised procedure: it is compulsory for medicinal products derived from biotechnology and is available at the request of companies for other innovative new products. The application are submitted directly to EMA and at the conclusion of the scientific evaluation, undertaken in 210 days within

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<sup>36</sup> The complete EMA’s statement mission is “to protect and promote public and animal health by developing efficient and transparent procedures to allow rapid access by users to safe and effective innovative medicine and to generic and non-prescription medicines through a single European marketing authorisation, controlling the safety of medicines for humans and animals, in particular through a pharmaco-vigilance network and the establishment of safe limits for residues in food-producing animals, facilitating innovation and stimulating research, hence contributing to the competitiveness of EU-based pharmaceutical industry, and mobilising and coordinating scientific resources from through the EU to provide high-quality evaluation of medicinal products, to advise on research and development programmes, to perform inspections for ensuring fundamental GXP provisions are consistently achieved, and to provide useful and clear information to users and healthcare professionals” (EMA, 2004)

the agency, the opinion of the Scientific Committee is transmitted to the European Commission to be transformed into a single market authorisation applying to the whole European Union;

- decentralised procedure (mutual recognition procedure): it is applied to the majority of conventional medicinal products and is based upon the principle of mutual recognition of national authorisations. It provides for the extension of marketing authorisations granted by one member State to one or more other member States identified by the applicant. In the case the original authorisation cannot be recognised, the points in dispute are submitted to EMA for arbitration and the opinion of the Scientific Committee is then transmitted to the European Commission.

In the evaluation phase are involved approximately 2.300 experts appointed by the member States: pharmaceuticals' companies may ask for scientific consultancy in any moment before the presentation of the request.

The centralized procedure follows these rules: 70 days after the receipt of the request it is issued the first evaluation; after 120 days, EMA asks to the company a list of questions and presents the first evaluation. After 180 days, it is decided if to grant the hearing. After 210 days, EMA gives an opinion, if no additional information are needed: on the base of this opinion, which is presented to the Commission before the 240<sup>th</sup> day after the presentation of the request, the Commission takes the final decision (in 90 days), with the assistance of the EMA's committees.

The decentralised procedure, at the moment still the most used one, is based on the mutual recognition of the national authorizations: following this procedure, the authorization for a medicinal product to be marketed is spread to one or more States indicated by the company requiring the authorization. In case of controversies, due to problems in the mutual recognition process, the subjects involved may ask for EMA's intervention.

The role of the national agencies is important for assuring a constant control of the products approved: it has to be noted that the pharmaco-vigilance task of EMA has been recently underlined as one of the main important function to be improved. In addition, member States have to send to the agency a list of experts willing to collaborate in the working groups or in the Scientific Committees of EMA.

#### *EMA's structure and management*

EMA's Management Board has the overall responsibility for what concerns setting the agency's policy and supervising the management. Its composition consists for the most part of representatives of the Governments of the member States; in addition representatives of other communitarian bodies and of the other stakeholders are present inside the board.<sup>37</sup> Members of the Management Board are appointed for a three-year term.

The "executive" of EMA is made by the EMA's Secretariat, based in London, which is the numerically biggest unit inside EMA: it is leaded by an Executive Director

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<sup>37</sup> To be precise, EMA's Management Board is made of 1 representative per member State, 1 of the patient's organisation, 1 of the doctor's organisation, 1 of the veterinarian's organisation, 2 representatives of the Commission and 2 of the European Parliament.

appointed by the Management Board for five years who is responsible for organising and managing the five main Scientific Committees, directly involved in the medicinal products' evaluation.

The Scientific Committees, headed by an independent chairman and composed of experts in the proper fields are the followings:

- CHMP (Committee for Medical Products for Human Use): 1 representative per each member State, 1 per each EEA-EFTA' State; up to 5 experts co-opted by CHMP<sup>38</sup>;
- CVMP (Committee for Medicinal Products for Veterinary Use): 1 representative per each member State, 1 per each EEA-EFTA' State; up to 5 experts co-opted by CVMP;
- COMP (Committee for Herbal Medicinal Products): 1 representative per each member State;
- HMCP (Committee for Orphan Medicinal Products): not for approval but only designation; it is made of 1 representative per each member State, 1 per each EEA-EFTA's State, 3 experts appointed by the Commission on EMA's proposal, 3 representatives of the patient's organisations, 1 representative of the Commission.

Scientific Working Parties (SAWPs) and Scientific Advisory Groups (SAGs) may, from 2005, be established by the Scientific Committees. Specific units inside EMA are responsible for organising the work of the Committees and their sub-groups.

In addition, "technical" bodies dealing with "communication and networks", following the legal and administrative aspects of the agency's management and an "integrated quality management and audit" unit, operate in the agency.

The staff of EMA has steadily evolved from zero to 349 units foreseen for the year 2005. A contract-basis employment, managed directly by the agency, applies for all employees of EMA and the secondment from the national institutions is strictly limited and controlled.

The work of evaluation, under the supervision of the Scientific Committees, is done by committees of experts chosen in the lists proposed by the national authorities of the member States. These experts work independently from their home institutions and are subjected to a strict control to avoid problems of conflict of interests. Their services are paid for by EMA out of fee income from applicant companies and it is of EMA's competence to provide the logistical arrangements for the realization of the evaluation process.

EMA's management processes cannot be evaluated as standing alone but in connection with the network management in which EMA is involved. From the organisational point of view, inside EMA it can be found a unit dedicated to manage and develop a communication network to facilitate exchange of information and in general to increase the quality of the contacts between EMA and the national agencies. The Unit for Support to Pharmaceutical legislation (JRC-SPR), belonging to the European Commission Joint Research Centre's Institute for Health and

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<sup>38</sup> It is important to note that there are two boards for authorization for human use: the pre- and post-authorization boards.

Consumer Protection has replaced in 2001 the former ETOMEPE Unit (European Technical Office for Medicinal Products). This unit's task is now primarily to support the IT network that connects the national competent authorities.

*The process of institutional change: description*

New rules on pharmaceuticals' regulation were published on April 30<sup>th</sup>, 2004<sup>39</sup>: the role of EMA is increased (and its name changed from EMEA to EMA) and the product approvals should be speed up. These new rules aim to simplify authorization procedures and improve transparency without changing the basic principles of the existing system in which the centralized authorization coexists with the decentralized one based on mutual recognition.

This new procedure, directly effective in the national law of the member States, will oblige more categories of medicines to be evaluated by the centralized procedure: at the moment the centralized procedure is used for the authorization of biotechnology products. With the new legislation it will include treatment for AIDS, cancer, diabetes, neurodegenerative disorders and orphan diseases. In four years, this procedure will be extended to medicines for autoimmune diseases and viral diseases. Other aim of the new procedure is to increase and accelerate the availability of products: a "fast-track" registration procedure for products of significant therapeutic interest has been introduced, allowing these products to be assessed and authorized in an expedited way. In addition a so called "conditional marketing authorization" has been introduced: by means of this kind of procedure it is allowed for a one-year authorization to be granted, provided that there is an important expected health benefit for the patients concerned and that the company agrees to carry out additional monitoring and clinical studies, which will be reviewed at the end of the period. The same procedure should be in the future applied to medicinal products for "compassionate use".

Particular importance will be devoted to the "transparency" theme: an overall increase in transparency and an improved access to information on the results of the pharmaceutical decision-making process will be made available. In this sense it should be also seen the decision to provide a clearer definition of "medicinal product", which now includes new therapies and the so called "borderline" products between the medical sector and other sectors.

One topic touched by the new regulation, crucial for the good functioning of the pharmaceutical regulatory system, is the "data exclusivity". The new policy has been called "8+2+1": the data submitted by companies for approval of medicines will be protected for ten years across EU from the time of first approval excluding the possibility, for that range of time, to market generics, being this period extendible for a further year if a further innovative indication for the medicine is authorised. Eight years after the date of the marketing authorization of the innovative product, a

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<sup>39</sup> These new rules consist of: Regulation on authorisation and supervision of medicinal products for human and veterinary use and on the EMA (OJ, L 136, p.1, replacing Regulation 2309/93); Directive on the Community code relating to medicinal products for human use (OJ, L 136, p. 34, amending Directive 2001/83/EC); Directive on the Community code relating to medicinal products for veterinary use (OJ, L 136, p. 58, amending Directive 2001/82/EC); Directive on traditional herbal medicine products (OJ, L 136, p. 85, amending the Community code Directive 2001/83/EC).

generic company may submit an abridge application, seeking to rely upon the innovator's data. This new rule goes towards the requests coming from the pharmaceutical industry: at present some EU's countries offer six, and some of them only three years of protection of the trademark.

The pharmaco-vigilance, which it has been pointed out above as one of the most delicate aspects of EMA's activities, is also taken into account by the new legislation. The responsibility of EMA will be strengthened: for every medicinal product approved it will be asked to the company producing the pharmaceutical product to appoint a person in charge for collecting data about collateral effects and for producing periodical reports to be submitted to EMA. A financial support will be also established in order to co-ordinate at the central level the activities of data evaluation and information spreading.

Also the "corporate governance" issue has been taken into account by the new legislation: a new quality policy and new internal control standards have been recently adopted. EMA's quality policy aims to assist the effective planning, operation and control of processes within the agency, by a continuous interaction with the European network. In addition, new internal control standards have been adopted and in 2004 it has been formalized the Internal Audit Function, which has an advisory function for integrated quality management inside the agency, ensuring at the same time the agency's risk management and is linked with the European Commission's Internal Audit Service. Provisionally, an Audit Advisory Committee was established in September 2004: its task is to advise the Executive Directory on the outcomes of the audit reports issued by the Court of Auditors, the Internal Audit Service of the European Commission, the IQM/Audit function of the agency and any other external audit organisation (EMA, 2004).

If the organisational architecture of EMA is considered, some significant differences with the previous architecture can be pointed out:

- the composition of the Management Board has changed to reflect the enlargement of EU to 25 members. Previously, there were two representatives per member State on the board; now each member State can appoint only one member (the same happens with CHMP, ex CPMP and CVMP);
- the representativeness of patients', doctors' and veterinarians' organisations is an innovation and it is in line with the trend to include stakeholders' representatives in the Management Board, particularly relevant in the "new" agencies as for instance, EFCA, EMSA, ENISA and ERA;
- CHMP and CVMP have the possibility to appoint up to five co-opted members each, in order to gain additional expertise in particular scientific areas;
- the HMCP (Committee for Herbal Medicinal Products) was not existing in EMEA: its role is to provide member States and the European institutions with the best possible scientific opinions on questions relating to herbal medicinal products, having as a task, between others, to establish a draft list of herbal substances;



- the new legislation gives EMA the responsibility to set up structures and procedures for providing scientific advice on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products: both the CHMP and CVMP have each set up a Scientific Advice Working Party to fulfil this responsibility;
- the new legislation allows the Scientific Committees to establish Scientific Advisory Groups (SAGs) in connection with the evaluation of specific types of medicinal products. The SAGs' role is to provide, on request of the committee concerned, an independent recommendation on scientific and technical matters relating to products under evaluation or any scientific issue relevant to the work of the respective committee: anyhow, the ultimate responsibility for final opinions, once taken into account the SAGs' opinion, rests with the respective Scientific Committee.

### *Evaluating the change*

The debate about the effectiveness of this institutional change is already started.

For instance, one of the main controversial points of debate attains the Management Board's composition: some of the experts interviewed see in this change a signal of the decline of the independence of this body. In the past, the presence of two representatives per member State usually had as a consequence that one out of two was coming from a national agency, traditionally independent from the Government in many States, and not from the governmental structure. Now, most part of the Management Board's members come from the national Health Ministries. Some experts see in this change the possibility that the Management Board will lose its "technical" independence to become a "political" forum. Further studies in the future might face the challenge to empirically assess the consequences of this change.

For what concerns CHMP and CVMP the discussion is similar but even more significant, given the "scientific" nature of these two committees. A possible counteractive measure is represented by the possibility to appoint experts: to appoint them are the same members nominated at the national level but a higher level of technical independence should be guaranteed. The same logic follows the settlement of a Scientific Advice Working Party by CHMP and CVMP.

The creation of the HMCP, seen by someone as a step backward because of the poor innovativeness of this kind of medicines, should be seen in connection with the simplified registration procedure for traditional medicinal products included in the new legislation: this registration aims to guarantee the quality, safety and efficacy of these products in the European market and facilitates the possibility to include a traditional medicine under the EU's registration.

From the interviews performed, the main problematic points left untouched by the new EMA's regulation are:

- EMA is still depending on DG Enterprise and Industry, while the national agencies depend on the Health Ministry;
- EMA still depends on the pharmaceutical companies' fees and not on "public" funds;

- the main parameters of evaluation of the pharmaceutical products are their quality, efficacy and safety and any added value (i.e., public health) is considered;
- the increased importance given to the pharmaco-vigilance is only formal because EMA's role is limited to data evaluation and information spreading while the crucial activity of data collection remains in the hand of the pharmaceutical industry;
- the criteria of evaluation of the committees and the results of the evaluations have been made more transparent but the pharmacological data at the base of the approval of a pharmaceutical product are still secret;
- the co-existence of the centralized and de-centralized approval systems, at the light of the recent member States' enlargement, might slower the harmonization procedures;
- the creation of the HMCP recognizes scientific validity to products evaluated with scientific standards less severe than the ones used for the new pharmaceutical products.

*Pharmaceuticals' regulations: a technical case-by-case approach*

EMA's main task is to manage and monitor the process of evaluation of the applications coming from the pharmaceutical companies. The system of evaluation operates within strict deadlines: this is a consequence of the "commercial" value associated to the medicinal products' evaluation. For this reason it is very important that the tasks concerning this operational process are handled in an effective way.

The reform of the EU's regulatory system for pharmaceuticals made necessary the creation of EMA and the decentralisation of responsibilities formerly held by the Commission. Being EMA part of a policy management system, it is not possible to approach this decentralisation in the way it is usually done when it occurs within an organisation. When speaking of decentralisation, in this case within the Commission, it is supposed a hierarchical framework of accountability: in the case of EMA this decentralisation process goes in parallel with a decentralisation among networked organisations, in some cases linked by non-hierarchical forms of co-ordination. EMA's role in the pharmaceutical regulation is both consequence of a decentralisation process delegating it functions formerly on charge of DG III, and of the necessity for EMA to be the organisation primarily responsible for managing a centralised procedure of evaluation where on one side the relationship is with the Commission and on the other one with a network of stakeholders.

Here below, the most significative features of the process of evaluation and authorization of the medicinal products are presented, in order to assess later in which way it may affect the accountability processes designed to take "under control" EMA and to assess the co-ordination tools developed for managing the co-ordination of the stakeholders involved in the networked system having EMA as "hub" organisation.

The organisational structure is complex and fragmented because of the decision to base the pharmaceutical regulatory framework on reciprocal commitments involving different subjects expressing different approaches within the same overall administrative system (Chiti, 2003). What comes out from the interviews is that

what is most criticized of this regulatory framework is the fact that interested parties other than the applicants, lack of procedural rights. In fact, pharmaceutical regulation adopts an exclusively technical approach regarding the risk factor: the main *criterion* used for the evaluation of the medicinal products is the potential hazard on persons. "Social" factors, and in general a broader consideration of the cost/benefits ratio is required by many experts.

This point becomes even more "dramatic" if the relationship between the scientific assessment (risk assessment) and the evaluation of convenience (risk management), which stays at the base of the relationship between the Commission and EMA, is considered. Being EMA not able to take a final and binding decision over the evaluation of a medicinal product, the Commission should, when taking the authorization decision, take into account the scientific opinion given by EMA, and integrate it with a wider evaluation of convenience.

Interviews and an accurate review of the communitarian legislation reveal that the reality is different. Even if it is not taken into consideration the fact that the vast majority of the authorization requests "approved" by EMA, has been equally accepted by the Commission, it might be noted that the possibility of disagreement between EMA and the Commission is qualified as "exceptional" and it is the Commission to have the duty to justify in a detailed way its position.

Regulation 2309/93 formalizes that, dealing with the centralised procedure, the scientific opinion is preponderant for the final decision and the request can be denied by the Commission, on the basis of the available information, in three cases:

- if the quality, safety or effectiveness of the pharmaceuticals have not been demonstrated by the applicant;
- if the information submitted are not exact;
- if the illustrative information of the medicinal product are not in compliance with the Community law.

The almost "automatic" process by which, once it has been established that the medicinal product meets the "scientific" and "legal" requirements, it has to be approved by the Commission has been heavily criticized because it lacks of any discretionary evaluation involving elements other than the technical ones.

It is important to underline the "control" aspect which this procedure reveals: more than the lack of decision-making power, it is the fact that EMA's responsibility is limited to purely technical evaluations that may limit the possibility of "stealing" tasks from the Commission. The limitation of a *phenomenon* of "power spreading" promoted by the agency, is one of the most sensitive topics.

On the other side, many experts argue that even if the control of the Commission would be both "procedural" (about the way the agency conducted the evaluation) and "of merits" (about the correctness of the agency's decision), in the end the Commission doesn't own the technical competences to overrule the agency's decision.

This type of procedure attributes a fundamental role to scientific assessment and limits the possibility of the Commission to give a discretionary evaluation: this fact creates some problems. The division between the Commission and EMA in the authorization process is not based on a political vs. scientific judge being both of

them expressing purely scientific and technical evaluation. This procedure has been defined "case-by-case": an overall strategy of elaboration of programmes of "public health" is not possible if the Commission has to follow a purely technical logic. Many experts underline how this procedure makes difficult to find useful links with other sectors as the environmental protection, food safety or to develop a general principle of "public health" not limited only to the technical requirements of the medicinal products. The same Commission is limited in the possibility to give to the agency guidelines about the *criteria* to be used in the evaluation of the pharmaceutical products.

This system, which many consider as being too much biased towards the pharmaceutical companies' interests, has been considered positively by some other authors because of the relevance of the scientific assessment and in particular because the settlement of an agency relying for its activity on a European network of experts, involves in the procedure a set of national, supra-national and mixed organisations. This improves the degree of expertise's quality and makes higher the number of experts at disposal of the agency, which couldn't have been possible if the Commission would have been the solely responsible for the medicinal products' authorization process. From the organisational point of view, this is the most important factor to be underlined when the position of EMA with reference to its "networked" relationships is assessed. To EMA refers the most part of the stakeholders: the pharmaceutical industry; the national agencies responsible for the pharmaco-vigilance activity; the national experts co-opted in the evaluation process; the health-care professionals administrating the drugs and the authorities in charge for the selection and use inside the national health care structures.

On the other side, the fact that only the pharmaceutical companies are guaranteed the participation in the procedure and that social, cultural and in general "public health" *criteria* are not contemplated creates significative shortcomings to the system. In addition, the fact that the centralised procedure, recently widened, is used in a limited number of cases might, as some experts underlined, reduce the impact of the communitarian regulation.

## **6.2 EMA and its networked institutional setting**

The need to regulate the pharmaceutical sector without threatening the authority of the national regulators pressed for the creation of EMA as a "hub" body, at the heart of a networked institutional framework bringing together all the stakeholders of this specific policy area. If this process is evaluated by means of "managerial" conceptual lenses, the creation of EMA pushed for the development of a set of links between the agency, the Commission and the national and sub-national actors.

The final product of this process has been a greater uniformity of the Community law's application (at least in what it has been defined the "centralised procedure") and a system of decentralized implementation involving in some ways all the interested stakeholders. In this sub-chapter the explanation of the relationships developed by this process will be provided; in the next chapters the accountability and co-opting mechanisms regulating this network will be assessed.

The way EMA has been designed makes co-operation and networking unavoidable from many points of view:

- the composition of the Management Board and of the Scientific Committees comprehends representatives of all the stakeholders interested to the communitarian pharmaceutical policy;
- the limited size of the staff and of the budget covered by the Commission pushes for a stricter relationship with “external” expertise and for “selling” the “products” of the agency on the “market”;
- networking permits a more efficient division of labour and exchange of information but it also gives the possibility to increase the effectiveness of the social mechanisms of reputational enforcement (Majone, 1997).

The same EMA describes itself as a “decentralised networking agency” aiming to “act as a pro-active interface between national competent authorities without dismantling their structure”. As a consequence, one of the most important functions of EMA, at the operational level, is to manage this interdependence and to do that, on one side it developed an internal structure and on other side promoted a network of relationships with its stakeholders.

#### *EMA's network links*

First of all, the relationships EMA developed with the communitarian bodies are considered. Three are the kinds of Directorates General involved in relationship with EMA: internal services, external relations, communitarian policies.

For what concerns the internal services, EMA has contacts, as the majority of the EU's agencies, with the DG Budget, DG Internal Audit Service and DG Personnel and Administration. EMA, because of its role in the relationships with non-European and member candidates or international institutions, is linked also to the DG Enlargement and DG External Relations.

If the areas touched by EMA's activities are taken into consideration, the other DGs in contact with EMA primarily are:

- DG Agriculture and Rural Development;
- DG Employment, Social Affairs and Equal Opportunities;
- DG Enterprise and Industry;
- DH Health and Consumer Protection;
- DG Research.

Of course not all these links are of the same nature: for instance, the links with the DG External Relations are explainable with the need for non-EU countries to make more modern their pharmaceutical policies, because of their underdevelopment or in the perspective of a forthcoming membership inside EU or with the will to cooperate with other international institutions dealing with health care policies as for instance WHO (World Health Organisation).

On the contrary, if the relationship with the “communitarian policies” Directorates General is considered, some explanations are needed.

The main contact with the Commission is DG Enterprise and Industry, which is the Directorate General formerly responsible for performing EMA's tasks, the “principal” of EMA and the DG in some ways directly responsible for the “evaluation” of EMA's performance.

The budget's topic is particularly sensible: EMA's budget is part of DG Enterprise and Industry's budget but EMA is increasingly self-financing its activity and this is one of the most controversial points of debate. From the 0% of self-financing by EMA itself in the year of its settlement, this percentage has increasingly become larger. It became higher than 50% after only four years from EMA's creation, to be precise in 1999 with the 70,2% of self-financing: from that date this percentage only faintly changed going from the highest percentage of 77,7% in 2001 to the lowest of 67% in 2002. The provisional percentage for the year 2005 is 70,31%. As it should be clear considering this data, from the budgetary side the influence of DG Enterprise and Industry steadily lowered but as a consequence increased the need to "go on the market" for getting fees from the pharmaceutical industry.

The contacts with the other Directorates General are explicable in the sense that all of them are affected by or affect EMA's activities of regulation: the debate about the "technicality" of the EMA's evaluation process is a signal of the plurality of interests and policy fields touched upon by EMA's tasks.

Going beyond communitarian relationships it may be noted that EMA is in relation with:

- other EU's bodies: the European Parliament and the Commission are represented in the Management Board and have several powers over the approval of the Annual Report and budget of the agency. Relationships with the Court of Auditors and the Council are also mandated as for all the other EU's agencies;
- pharmaceutical industry: the pharmaceutical companies pay for the EMA's services and are directly affected, on demand, by the authorization process of their products;
- national regulators: they are in charge for putting at disposal of EMA the list of experts to be used in the medicinal products' evaluation process. Before the re-organisation of the Management Board's composition they were used to have one representative in the board. Now the member State's representative usually belongs to the national Health Ministries;
- patient's, doctor's and veterinarian's association: their representatives are present in the Management Board (without the right to vote) and they may be appointed to participate to the activities of the Scientific Committees;
- national regulators in candidate and non-EU countries: EEA-EFTA representatives participate to the activities (without the right to vote) of the Scientific Committees;
- international health care organisations: in several occasions EMA promotes meetings and co-operation activities with other international organisations as WHO on health care themes.

#### *Operational and strategic management*

In the previous chapters it has been underlined that the main "operational task" of EMA is to manage and monitor the evaluation process: if the operational management of an organisation is assessed, usually it is made reference to the activities that in the end produce the outputs on which its performance is judged and

so doing it is assumed that operational management tasks are carried out as internal functions within the organisation (Metcalf, 1999a). On the contrary, it might be shown that EMA works in a networked environment and for this reason its performances have to be evaluated taking into consideration this peculiar operational setting. The limited size of its staff would make impossible for EMA to autonomously handle with the considerable amounts of applications it receives every year. For this reason, EMA is obliged to rely on experts coming from the member States, called to participate to the working sessions of EMA's Scientific Committees. This network perspective is fundamental to understand the work of evaluation EMA performs by means of those experts, under the supervision of its Scientific Committees. With reference to this point it is possible to differentiate between EMA's operational and strategic management responsibilities.

Operational management is referred to as the supervision of EMA's main task: the procedure of evaluations of the pharmaceutical companies' applications. EMA's responsibility is to monitor the work of its Scientific Committees, in the context of the EU's staff and financial regulations, assuring an acceptable level of efficiency of the evaluation procedure.

When speaking of strategic management, the analysis is referred to the role of EMA inside its networked institutional framework. If EMA is considered as a "professional organisation" (Mintzberg, 1983), because of its task ("professional" evaluation) and the consequence this peculiarity has on the definition of its performance (the "goodness" and the "scientific reliability" of the evaluation EMA performs) it is necessary to be careful.

EMA is a "professional" organisation of a particular kind because of its role in the EU's regulatory framework and because of its responsibilities in managing the relationships with the organisations belonging to its networked environment. Some experts interviewed, underline how it would have been impossible to create an agency with EMA's tasks on the model of the American FDA: EMA's main aim from the "strategic" point of view is to create a connection between national and sub-national bodies and the Commission, not frightening the existence and the role of the national and sub-national bodies, and promoting not hierarchical coordination tools based on trust, confidence and, in general terms, "professional" competence.

The creation of this network may foster, if it works in an effective way, the "reputation" of EMA and its credibility first at the eyes of the Commission – but also of the pharmaceutical companies, paying for EMA's services and every day more the main funding sources of EMA, and, in the end, at the eyes of the "public", that is the final consumers of the products positively evaluated by EMA. For this reason, it becomes fundamental to develop strict links with the providers of the expertise by which EMA performs its tasks: the national authorities (or in more general terms, the Health Ministries).

EMA's Management Board provides the point of contact between operational and strategic management: on one side its main task is to monitor the evaluation process and to deal with the operational functions to be performed by EMA; on the other side the composition of Management Board creates a strong link between

representatives of the Commission, of the national authorities (or Health Ministries), doctors and veterinarians (responsible for “putting in contact” the medicinal products with the consumers) and the same consumers.

Pharmaco-vigilance is another relevant point of discussion: here a networked relationship with the national regulatory bodies and also with doctors and veterinarians is fundamental for the good functioning of the system. As underlined above, differences at the national level are extremely relevant and a variety of pharmaco-vigilance systems going from a centralized agency, to a control put in essence by the same doctors and veterinarians can be found. The delay of EMA in modernizing its pharmaco-vigilance system is the direct consequence of the impossibility to centralize pharmaco-vigilance without going against member States’ influence (or, as some experts say, not to go against the interests of the pharmaceutical companies financing EMA). With the 2004 change, an improvement of the communitarian pharmaco-vigilance system is expected but the capacity to harmonize the national systems and to give EMA a power of intervention in the national contexts may be fundamental for performing this activity with better results.

In chapter 2, it has been addressed the topic of the controversy between intergovernmentalism vs. institutionalism and the hypothesis that the agencification *phenomenon* may be seen as the result of an increased “administrative integration” has been proposed: this may be the case of EMA.

If the composition of the Management Board and the working rules of EMA’s Scientific Committees are assessed, it might be assumed that the reasons behind them cannot be explicable only in terms of national interests or supra-national pressures. If a “managerial” perspective is taken, it might be noted that this “co-optation” strategy may answer to the need to create effective links between all the actors involved in the EMA’s networked institutional framework.

It has been shown that to create a European FDA would have been impossible, not only because of staff and budget limitedness but also because of the member States’ pressure not to totally give up their tasks and their national structures. For these reasons, to have “co-opted” national representatives in the Management Board and national experts in the Scientific Committees might be an answer to this necessity and to the one to create those relations of trust and confidence needed to develop non-hierarchical tools of network’s co-ordination fostering communication channels, information spreading and personal contacts.

If this topic is approached from an “europeanization” perspective, it should be assessed if the participation of national experts, especially in the Management Board’s sessions (four per year) more than improving EMA’s network performance may also be counterproductive for the coherence of EMA’s policy because of member States’ pressures on their representatives.

This is not a purely empirical issue even if one may be tempted to treat it only in empirical terms: institutional factors may affect the degree of independence of the national representatives and their behaviours at the communitarian level. The mandates the national representatives have from their national bureaucracies may vary (i.e., because of tradition, bureaucracy’s structure, contingent interests) and also



their attitudes may change (i.e., because of the influence of their work at EMA on their careers, of political pressures and so on).

Specific researches in the EU's setting (Trondal, 2001), more general studies about national delegated bodies (Thatcher, 2002) and direct interviews with experts confirm that the "nationality" factor is not affecting in a considerable way the "neutrality" of the representatives of the member States and that a perceptible level of "europeanization" of these experts occurs, particularly with reference to those participating to the Scientific Committees' works. For what concerns the national representatives in the Management Board, the change reducing their number from two to one per member State may produce an increase of the closeness of these representatives to the national directives more than to the EMA's vision: further empirical studies are needed in this sense.

Additionally it has to be remembered that also in the case of national representatives not coming from the Health Ministries but from national agencies it might happen that they are closely related in their activities to the Ministries' influence, especially in countries where, for instance Italy, the degree of autonomy of the national and sub-national delegated bodies is rather low. In other countries where the delegated bodies enjoy a higher degree of autonomy or even represent a bureaucracy "parallel" to the ministerial one (i.e., Sweden), the "europeanization" of the representatives may be easier.

### **6.3 Designing an accountability framework**

Assumed that EMA doesn't fit into the standard category of "decentralized agency", because of its peculiar tasks in the communitarian regulatory framework, it is fundamental not to apply to it a conventional hierarchical view of accountability because it might be too restrictive.

When considering EMA's tasks and evaluating the accountability tools necessary to guarantee a good balance between control and effectiveness of its management processes the external pressures and in particular the expectations and preferences set out by the actors involved in the EMA's networked institutional framework have to be considered. At the same time, this assumption has to be conciliated with the standard accountability rules applied to all EU's decentralised bodies.

Metcalf (1999b: 213) argues that the framework of accountability "defines the rules of the game that govern organisational action and defines the terms on which organisations work together, rather than leaving them to respond in an *ad hoc* way to any and all external pressures". Adopting this definition, the "standard" communitarian accountability rules as they stand with reference to EMA are taken into account, in order then to further specify the analysis assessing the peculiar accountability modes designed for EMA.

In chapter 3, five control provisions have been considered: procedural, democratic, external financial, judicial and executive. For what concerns the former four control provisions, nothing differentiates EMA from the other EU's delegated bodies: when assessing the executive control, some peculiarities stand. In EMA's Management Board, both member States and the Commission are represented but also the Parliament and the other stakeholders nominate representatives. This situation demonstrates that, being EMA involved in a networked institutional framework, all

stakeholders can in some ways participate to the management decisions taken inside the agency having the opportunity to get a direct and immediate feedback. To be precise, stakeholders' representatives don't own the vote right: this is comprehensible at the light of the communitarian principles.

EMA, performing actions having (almost) direct consequences on the member States and in general on the public, is organised in such a way that can guarantee both the Commission and the member States an executive control over the agency. At the same time, the stakeholders are directly co-opted in the Management Boards' works but they cannot vote because if they could modify the decisions of the Board, this would be in contrast with the principle of "political" representativeness of this body more than with managerial principles.

The appointment of the Executive Director is another revealing factor of the "executive control": EMA's Director is appointed by the Council; the Council chooses between three names proposed by the Management Board. This is a strong signal of the will of the member States to influence the operational and strategic management of the agency, assumed that the person in charge for defining and controlling EMA's work plan and budgeting has to be chosen directly by them.

For what concerns the financial control it has been shown that a new internal control standard has been adopted in 2004 and an internal body, having an advisory function for integrated quality management at the agency settled up. This body, linked with the European Commission's Internal Audit Service, should guarantee the fairness of EMA's financial performances and indicates the will of EMA's managers to develop modern tools of internal auditing maintaining a strict relationship with the central audit office of the Commission.

#### *Towards an accountability framework*

If the peculiarity of EMA in the communitarian context is considered, it should be built up an accountability framework taking into considerations the complexity of the EMA's organisational network and the necessity to design non-conventional and non-hierarchical tools of control fitting to the un-formal modes of co-ordination of stakeholders' relationships. To develop this accountability framework four general categories of accountability mechanisms are defined:

- administrative;
- political;
- professional;
- client.

The two first categories have already been analysed: for what concerns the administrative accountability it has been shown that conventional staff and financial rules working for the other EU's delegated bodies and, for what concerns the staff regulation, for the whole communitarian staff, are applicable also for EMA; concerning the political accountability, it has been above defined as a sort of "democratic" mode of accountability. Here it should be pointed out the presence of the European Parliament's representatives in EMA's Management Board but also, in more general terms, the fact that the Council, the highest political institution inside EU says the last word in the Executive Director's appointment.

Professional accountability is a dimension "characterising" EMA. EMA, because of its role and of the institutional setting in which it operates, works in close contact with the national regulatory institutions and relies on them for the lists of experts participating to the pharmaceutical products' evaluation process. In addition, representatives of the veterinarians', doctors' and patients' categories seat in the Management Board. This additional measure of public oversight, which might be affected in its effectiveness by the risk of agency capture, is properly restricted by the provision of rights of audience and observer status only.

EMA has been defined as a "professional" agency: the establishment of a regular pattern of peer-group evaluation inside its Scientific Committees (Metcalf, 1999b) distinguishes this agency from the majority of the other communitarian delegated bodies. By means of the contacts between the experts involved in EMA's activities, it operates a continuous process of professional cross-checking process of assessment and discussion. "Professionalism" is a crucial characteristic of EMA because it might prevent the agency from pharmaceutical companies' and from EU's political pressures. The professional reliability of its evaluation prevents EMA from possible Commission's attempt to downgrade EMA's role and in addition, the legitimation of EMA at the eye of its "public" (i.e., doctors and patients) is fundamental for its reputation.

The European Parliament has tried in some cases to secure technical quality by reserving a right of "expert nomination" by itself but this fact has been harshly criticized because there was no reasons supporting the idea that experts appointed by the Parliament could be more "professional" than others and for what concerns EMA, the choice of its Scientific Committees' members is not reserved in any case to the Parliament.

If the relationship between EMA and the Commission is considered, its "professional" nature, in addition to the principal-agent one, seems clear. Being EMA responsible only for risk assessment, it is the Commission to have the power to take the final binding decision and in the case controversial disputes arise, the Council of Ministers may intervene. The relationship between the Commission and EMA is also a "professional" one: the Commission bases its judge on a professional expertise's assessment. It is the Commission to delegate power establishing a hierarchical form of relationship: on one side this relationship follows the traditional principal-agent model, on the other the professional authority of EMA makes this relationship more complicated.

At the other side stays the relationship between EMA and the pharmaceutical companies. In this case, they are the pharmaceutical companies to be "clients" of the evaluations of the new pharmaceutical products. They are the clients to respect the requirements and pay the service, in order to have their products eventually approved for being marketed.

In both this relationships, EMA's professionalism is put into discussion and it stays as one of the most important factors to be preserved from external influence in order to guarantee to EMA an acceptable level of management autonomy.

Also in the relationships with the national regulatory authorities and in general with the European "citizenship", EMA's independence and autonomy have their bases in its professional accountability. Only being accountable as a "professional"

organisation, EMA may play its role of “hub” organisation inside the networked institutional framework in which it operates.

As shown above, “professional” and “client” accountability are strictly connected. Here below the “co-optation” concept is assessed and linked to the professional and client accountability dimensions.

Co-optation of stakeholders’ representatives in EMA’s Management Board operates both on the formal and informal sides. Appointment of stakeholders’ representatives follow formal rules but the rationale behind this mechanism stays in the necessity to build up a set of links with the national regulatory authorities and with the other stakeholders, being them essential for the good functioning of EMA’s regulatory activity. In this context the client-professional relationship and the professionalism of EMA play a fundamental role.

The effectiveness of the network’s performance relies on the relationships between all stakeholders and co-opting them in the EMA’s Management Board, if on one side may arise the “agency capture” risk (it has been shown that it may be limited by the non-voting status of the stakeholders’ representatives), on the other side it gives EMA the possibility to connect itself directly with the national authorities (even if now the weight of the Health Ministries is increased) and so doing, having at its disposal the experts needed to perform its evaluation processes. The direct consequence of this process attains the Scientific Committees’ performances: it is established a professional peer-group recreating an own professional identity and system of values. This eases the process of “professional” consensus to EMA and stays at the base of the double-sided client-professional relationship between Commission, EMA and the pharmaceutical companies.

What said above confirms that the unitary nature of the pharmaceutical regulatory system and of the network’s accountability derives from the management procedures and from the organisational relationships between the bodies involved in the system, which are supported by the “trust” and “reputation” dimensions. EMA is assigned a co-ordinating task and it manages the relationships with the actors involved in the pharmaceuticals’ regulation also by means of non-binding acts aiming to create “spontaneous” forms of co-operation.

The “professional” dimension of EMA supports the good functioning of the relationships with the Commission and the pharmaceutical companies. In this sense, EMA differentiates itself from many other EU’s delegated bodies: the operational tasks of this agency coexist with its “network management” functions and on the “accountability” level it has been shown that in addition to “traditional” accountability tools, common to the whole body of communitarian agencies, additional dimensions have to be added.

EMA’s accountability system cannot be evaluated in a hierarchical framework as usually happens with the “executive” delegated bodies. It should be considered that EMA’s professionalism, if from one point of view is essential for managing in an effective way the networked relationships and in general for controlling and fostering the good management of the regulatory system in which EMA is involved, from another point of view it reverses the straight relationship between the delegating body – the Commission – and the delegated body – EMA – being the first

one in some ways a "beneficiary" of EMA's activities and the second one the service provider, without decision-making power.

It has been here shown how the accountability theme cannot be disjoined by the organisational design of an institution. Accountability here is evaluated as a governance tool, by means of which EMA may perform its primary tasks effectively. The governance framework in which EMA operates and its "professional" nature heavily influences the design of the accountability framework in which it operates. This should be peculiar for each different institution and, if the communitarian context is considered, EMA presents, in addition to the "traditional" accountability tools which are common to all the other delegated bodies, significative peculiarities which affect the parameters of evaluation of its performance and so doing, also the accountability schemes to be applied.

Autonomy and control, the two main dimensions of accountability, in EMA's case are designed in such a way to assure EMA the possibility to manage, autonomously from the Commission, a networked set of relationships being at the same time subjected to controls by the other stakeholders, basing their evaluation primarily on the "professional" services offered by EMA.

## **7. EEA: an organization between information, analysis and policy-making**

The study of EEA (European Environment Agency) and of the European Environment Information and Observation Network (EIONET) represents an interesting occasion to evaluate the performance of what has been defined an "information/coordination" agency inside EU, first at the light of the organizational mode chosen to guarantee EEA the opportunity of engaging its role of observatory and information supplier of environmental information to its stakeholders, and also because of the evolutionary process occurred concerning EEA's real role inside the communitarian system. This second point should be analyzed from two perspectives: first, the "internal" position assumed by EEA's managers to increase the importance of EEA and to "change" its role in order to go behind a merely informative provider function towards a more "political" role by which should be possible to "use" the data collected and, by means of their analysis trying to assume a "policy-making" position inside the communitarian system. Second, it is fundamental to consider the position assumed by the EEA's principal, the Commission, or better to say the DG Environment (formerly DG XI) aiming to circumscribe EEA's responsibilities to a purely informative role.

The case of EEA is particularly revealing of the problems and opportunities linked to the process of establishment and development of an agency in the EU's context: first, because of the complexity in designing an agency dealing with such a sensible issue as the environmental policy, second, because of the pervasive role of the member States in the decisions concerning this issue and the predominance of the Commission in the management of the communitarian environment policy-making. The three main dimensions of analysis will concern:

- the sensitive relationship of EEA with its stakeholders (i.e., the DG Environment, the European Parliament, Eurostat and so on) and its evolution;
- the growth of the tasks assigned to EEA and its "weight" inside the policy-making decisions concerning the EU's environmental policy in the institutional networked framework of EIONET;
- the necessity to design proper accountability tools to assure EEA a proper degree of autonomy, and at the same time assuring to the Commission the possibility to control EEA.

With reference to the last two points, particular attention will be devoted to the role of EEA as "hub" organization dealing with network's management activities, and to the creation and evolution of "soft" instruments of network's co-ordination.

In the end, an attempt to connect the EEA's life stages to different modes of organization models (i.e., "entrepreneurial", "mature" organization) will be done.

## 7.1 Describing EEA

If the timeline of the evolution of the EU's environmental policy is considered, the first time the Commission was called to produce a programme for environmental action was in 1972 (Office for Official Publications of the European Communities, 2005), while in the next year it was produced the first EC environment action programme (1973-76). A first attempt to create a structured network of environmental data gathering was CORINE, in 1985. This network for monitoring the environment in the member states suffered because of the lack of preparation of the member States in collecting and delivering reliable environmental data and of the fragmentation of the system. EIONET has been the natural continuation of CORINE and EEA was intended to be the hub of this decentralised network of national and sub-national agencies. EEA was established with the aim on one side of settling up an organisation in charge with the co-ordination of the information gathering activities and on the other to be the counterpart of the DG Environment, in charge for the management of the environmental policies. In fact, the data limitations, the difficulties to monitor the actions of the member States and to enforce the application of satisfactory environmental actions, added to the lack of a proper scientific and centralised judgement at the EU's level of the member States' data were characterizing the EU's environmental policy before the settlement of EEA.

Stated before this complex situation, it is not surprising that an high degree of uncertainty characterised the definition of the tasks and the design of EEA: its role, formally limited to be of data gathering had been initially interpreted by EEA's management as possibly going towards a more "policy advising" one, even if this was not the intention of EEA's founders. As it will be shown below, this tension still partially exists and follows the change of EEA as an organisation going towards its maturity<sup>40</sup>.

### *EEA's tasks and mission*

The main legal framework for EEA is its establishing Regulation, adopted in 1990 and modified by Regulation 933/1999EC which introduced sustainable development as the context in which the tasks of EEA should be placed, and emphasised the need to co-ordinate activities with parallel organisation including those in third countries. The mission of EEA is to support sustainable development and to help significant and measurable improvement in Europe's environment, through the provision of timely, relevant and reliable information to policy making agents and the public. In addition, EEA should assess the results of the measures taken.

The definition of EEA's mission seems to be pretty clear: EEA's main function is to gather the data available within the member States and to manage the system devoted to monitor the state of the environment in Europe. It should be underlined that, creating EIONET, data gathering is still responsibility of the national institutions, co-ordinated by EEA. But if the size, budget and expertise of EEA are considered, this mission seems too extensive. EEA's potential field of activities might goes, looking to its mission, from information gathering to the analysis and

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<sup>40</sup> See table 11 and 12 at the end of chapter 7 for a detailed chronological resume of EEA's history.

possibly to the assessment of policy's effectiveness. In addition, on a five-yearly base, EEA has to deliver "environment" reports which many experts interviewed suggest to be its most significant output. The same Commission has officially reported that in the first years since EEA's settlement there was "from time to time a divergence of views regarding these priorities and activities, particularly between the Commission and EEA, but now – 2003 – there is a fairly clear common understanding of the respective tasks, although there is still occasional disagreement" (Commission of the European Communities, 2003).

If the tasks of EEA as stated in its Regulation are carefully analysed, it might be pointed out that the main ones are the followings:

- to establish, in co-operation with the member States, a network of national and sub-national organisations gathering information on the state of the environment in Europe and to co-ordinate it;
- to gather, process and analyse data in order to provide the Commission with the objective information needed to identify, prepare and evaluate measures and to draw up more general reports on the state of the environment;
- to ensure that environmental data at European level are comparable, and in case it is necessary to encourage improved harmonization of methods of measurement;
- to stimulate the development of cost-benefit analysis of damage and measures;
- to stimulate the exchange of information on best available technologies;
- to support and assist the Commission in the process of exchange of information on the development of environmental assessment methodologies and best practices and diffusion of relevant information.

If the areas of activity of the agency are considered, art. 3 of the Regulation states that they should "include all elements enabling the agency to gather the information making it possible to describe the present and foreseeable state of the environment from the points of view of the quality, pressures on, and sensitivity of the environment".

On a practical level, the work of the agency is divided in five programme areas:

- topic database maintenance, monitoring and environmental reporting;
- integrated assessment of environmental problems;
- periodical reporting;
- reporting system support, including development of methodology and data tools needed by EEA and EIONET;
- service and network infrastructure, providing IT support and publishing, dissemination and information services.

Recently, EEA has been increasingly asked by the European Parliament, the European Commission, and the member States not only to report and advise on the state of the environment and of the technical issues concerning environmental protection and the sustainable use of natural resources, but also on the effectiveness of key environmental and sectoral policies and their implementation (Office for Official Publications of the European Communities, 2003).



The main beneficiaries of EEA's outputs are those involved in the development, adoption and implementation of environmental policies in Europe: European Commission, European Parliament, European Council and EU's member countries. They are not only in the field of environment but also in economic sectors such as energy and agriculture that impact on the environment. Other key clients are those who influence policy-making: environmental pressure groups, business and industry, media and in more general terms, interested members of the public.

#### *EEA's structure and management*

It is not possible to evaluate the performance of an organisation and the effectiveness of the relationships it manages with its stakeholders, without making an analysis of its organisational design.

The design of EEA during the years has been changed in order to go beyond a classic divisionalised structure: in 1990, EEA was organised in a way reflecting a divisionalised organisation based on separation rather than integration of tasks. The unresolved question concerning EEA's core business was reflected in its structure: the operating core was divided into a "data collection" unit and an "analysis" unit and in addition there was a unit for organising publications, distribution and the technical facilities required to manage EIONET.

The "Monitoring and Database Programme" unit was charged with the task of gathering data and setting up the data collection network. The European Topic Centres (ETCs), which will be analysed below in the text, were the core of the network and for each EEA's work priority an ETC had been appointed. The "Analysis and Integrated Assessment Programmes" unit was responsible for reporting on sectoral topics and for issuing the report on the state of the environment using data from the ETCs, the DG Environment and other sources. The "Operational, Infrastructure, Publications and Information" unit was used to provide technical support to EEA and EIONET.

The reorganizations of 1999 and 2004 created a more complex and decentralised structure based on 6 departments, each of them supervising the activities of other sub-departments. Without going into details, it is worthwhile to point out that a differentiation between what it has been called the "information" unit and the "analysis" unit still exists but the sub-departments devoted to deal with the ETCs are now under the responsibility of the "Environmental Assessment" unit. A "Corporate Affairs" unit, in charge for dealing with EIONET's support and the relationships with the stakeholders and a "Strategic Knowledge and Innovation" unit have been created.

As a first consequence, EEA seems to be moving towards a more decentralised way of working where the decisions tend to be taken more at the level of the professionals and the need is expressed to rely more on horizontal co-ordination (Schout, 1999). In addition, a particular attention has been increasingly devoted to the measurement of EEA's performance: the "Administration and Management" unit has developed an evaluation scheme of the management system based on objectives and measures in four inter-related perspectives.

The EEA's supervision bodies are two: the Management Board and the Scientific Committee.

The Management Board represents the main Community stakeholders of EEA: it meets three times a year and supervises EEA's strategic choices. It is also the control body of the Executive Director. The board members usually are high-level representatives of the member States' administrations and of the Community bodies. From the 1990, the Management Board has increased in size: from 16 voting members (2 of the Commission, 2 experts designed by the European Parliament, 12 of the member States) to 29 (2 of the Commission, 2 experts designed by the European Parliament, 25 of the member States).

The Management Board is the main decision-maker of EEA and it decides on the work programmes and budgets, approves the annual reports and takes the decisions about the ETCs and in general terms on the composition of the *consortia*. The Director and the management team of EEA are present as advisors and also the Chairman of the Scientific Committee is invited as observer.

The Management Board is characterised by the fact that:

- it is fully responsible for the quality of EEA's outputs, assuring that the objectives stated in the work programmes are reached;
- inside the Management Board are represented the national interests and the position of the European Commission;
- the "co-optation" of national members into the board, should assure the representation of the interests of the agency and its network within the member States.

With the growth of EEA's size, the Management Board's agenda became fuller and mainly for this reason and because of the fact that the board only met three times a year, a Bureau was established in 1997 and formalised through the 1999's amendment of the EEA's Regulation. The Bureau consists of 6 members: 1 representative of the Commission, 1 designated by the European Parliament, the chairmen and 3 vice-chairmen of the Board. The chair of the Scientific Committee is observer to both the Management Board and the Bureau.

During the years the Bureau's responsibilities increased and now it can take also some executive decisions (to be ratified) and prepare Board's decisions.

The Scientific Committee's role, which holds three meetings a year and at the moment is made of 20 experts - the maximum number allowed -, is to deliver opinions, either upon request of the Board or the Director or at its own initiative. It is the Board to designate the members for a period of 4 years, renewable once.

The Scientific Committee's main function is advisory and for this reason it is frequently involved in order to give its opinion on EEA's work programme and on ETCs' outputs quality. The Scientific Committee, because its members are in their majority renowned academics from various areas of environmental expertise, represents an important interface between EEA and the academia, and it is supposed to bring to EEA a significative degree of scientific quality control.

The three major tasks of the Scientific Committee may be summarised as follow:

- to deliver an opinion on the EEA's multi-annual and annual work programmes;

- to give an opinion to the Executive Director for the purposes of recruiting EEA's scientific staff;
- to provide advice and/or opinion on any scientific matter concerning the activities in which the Management Board or the Executive Director may be involved in.

One of the main problems concerning the Scientific Committee is, as reported by the Commission (Office for Official Publications of the European Communities, 2003), that there is no clear framework for quality control involving the Scientific Committee in the EEA and the Committee is usually involved on *ad hoc* basis on the evaluation of some products and services, but absent on others.

When originally created, the Committee members were 9, and all of them had a specific field of expertise connected to a specific ETC (in 1990 the ETCs were 9, now they are 5). The attempt to have a broader representation of member States' representatives in order to improve the quality of the network's management and the reorganization of EEA made the number of the members increasing up to 20.

#### *EEA's budget and staff*

From the start of its operations, EEA has grown to 120 staff (2004) and to an annual budget of € 31,1 million (2004). The increase of the EEA's budget has been slow but steady, with the exception of a higher raise during the first years, comparably to the budget's increase of the other EU's delegated bodies.

As pointed out in chapter 3, EEA is mainly funded by Community contributions and another important source of income comes from the membership-contributions of EEA's non-EU member countries. In formal terms the budget of EEA is a budget line under DG Environment and even if this fact shouldn't have formal implications, the possibility for the DG Environment to influence EEA's work programme and the choice of the environmental topics to be analysed has been one of the most delicate points of debate about the mechanisms of control used to influence EEA's operational and strategic choices. To make an example, in 2005, the DG Environment contributes to the EEA's budget with € 27,2 millions, which represents approximately the 80% of the whole EEA's budget and the 10% of the DG Environment's budget.

In order to broaden its financial autonomy, the necessity to get additional funds from external sources has always been claimed by EEA: to make consultancy projects for "clients" others than DG Environment has been considered by the same DG as a potentially dangerous element of diversification of the EEA's activities taking the agency too far from its primary tasks. The debate about the necessity to prevent the need to go "on the market" for getting additional funds and the need for EEA to tie more and more to the general environmental policies of the Commission in an integrated perspective has slightly slowed the increase of the "other funds" percentage in the EEA's budget.

Analysing the evolution of this percentage it may be noted that, excluding the very first years since the settlement of the agency, from 1997 this percentage had an "up-and-down" movement and it had been lower than 10% until 2001. Only in 2003 it became the 13% of the budget and in the next year it was at its highest level (24%). To confirm what said above, in 2005, this percentage has again decreased to the

19,43% of the budget. The 2004-2008 strategy foresees a gradual increase of the core funding at an average of 5% per year, which is in line with the budget's growth assumption of most part of the other EU's delegated bodies.

A substantial share of EEA's expertise is located in the European Topic Centres (ETCs): the ETCs and their staff are mainly funded by the same EEA and in a slower percentage (approximately the 25% of the total) by the host countries. This is a very critical point: the five EEA's ETCs are essential for the good functioning of the process of environmental data gathering and analysis but the amount of funds they withdraw every year from the already limited budget of EEA is extremely high. To make an example, the funds given by EEA to its ETCs, in average in the 2000s have represented the 50% of the total EEA's budget.

Not surprisingly, given the broad mission of EEA and its limited funds, a lot of people interviewed point out that the budget and staff at disposal of EEA haven't been adequate to meet all the demands for support coming from EEA. The same Commission, in its 2003's evaluation of EEA (Office for Official Publications of the European Communities, 2003: 8) recognizes that "the strain on resources has been felt throughout the Agency's existence, but particularly so during the first years, and the gap between the level of ambition and the products and services that could actually be delivered was bigger than present".

As all the other EU's agencies (with the few exceptions underlined above: i.e., EMA, OHIM and CPVO), also EEA follows the principle that agency's activities that fall in the remit of their legal mandate must be financed from the Community subvention in order not to compromise the power of the Budgetary Authorities. In practice, many experts point out that in the case of EEA this principle couldn't be always followed because of the broad range of activities requested to EEA to be performed.

It has been also underlined how in some cases, to follow this principle had been even counterproductive for EEA, because some activities have been contracted out to expertise not at the same level of the EEA's one. In addition, the use of extra funds, others than the Community subsidies, had been essential for developing EIONET in preparation of the enlargement, for the "Environment for Europe" process and for the integration of the environmental theme into other policy sectors. This extra funding was allowed because the principle of using only Community funds can be not followed in the case of structural activities related to the enlargement and of activities especially asked for by the Commission.

## **7.2 EEA and its networked institutional setting**

The evolution of EEA during these years cannot be evaluated without looking to the changes occurred in the relationships between EEA and the Commission and in general with the so called "institutional" network made of the European Parliament, the Commission, and the member States.

EEA may be seen as an organisation created to decentralise responsibilities from the centre to a body operating at arms' length: the focus here is on the necessity to reveal if this centre is the Commission or the member States. When the tasks of EEA are assessed it might be argued that they are limited to collection and procession of data and only recently, and within the budget constrain limit, to the determination of

which kind of information are needed. On one side the authorization to carry out tasks and the policy making decisions rest in the hands of the Commission; on the other side the monitoring of the implementation of environmental policies remain under member States' responsibilities and also data gathering and partially its analysis are delegated to national and sub-national bodies.

The relationships of EEA with the organisations involved in the EU's environmental policy or essential for the good functioning of the same EEA cannot be defined an overall set of links following common organisational patterns: first, a distinction between "internal" and "external" relationships should be done.

The second step is to individuate useful *criteria* to be used in their evaluation. Three kinds of relationships, with reference to the functions performed have been individuated:

- overlapping functions;
- conflict functions;
- collaborative functions.

#### *The "internal" network*

The European Parliament cannot be considered a "client" of EEA and its main duty in the relationship with EEA is to keep EEA informed about the preparation of proposals concerning environmental policies in order to get a scientific feedback: this is one of the main reasons having brought the Parliament to try to increase the "independence" of EEA. Some interviews reveal that "using" EEA, the Parliament might have a tool to influence Commission's decision regarding the environmental policy making.

At the "organizational" level, the presence of the European Parliament inside EEA is rather limited: two experts nominated by the Parliament are members of EEA's Management Board. The Parliament is not involved in the choice of the Director but maintains its discharging power of EEA's budget.

The relationship of EEA with the European Parliament has been varying during the years: recently due to the introduction of the co-decision process, the European Parliament increased its involvement in the environmental policy-making but some experts underline that it stills doesn't use it in a satisfactory way. This can be explained by two objective reasons (Office for Official Publications of the European Communities, 2003: 9):

- EEA cannot meet all the needs of the European Parliament because, for instance it doesn't have at its disposal the expertise and contacts for the work the European Parliament would like to see on the administrative structures for implementation in the member States;
- the Parliament doesn't own a proper mechanism of request's formulation to EEA which might be feasible with EEA's work planning.

The discussions about the new EEA's regulation puts in evidence that the European Parliament tried to broaden the EEA's role emphasising the possibility for the agency to act on its own initiative and underlining the importance of the multi-annual programme and budget, so that the Commission and the member States

couldn't be able to intervene on an annual basis, influencing too much the EEA's operational decisions.

The European Parliament has also pushed for a bigger elasticity of the EEA's budget: the contradiction between the quantity and complexity of EEA's tasks and its budget's constrains is evident. For this reason the European Parliament supported the revision of EEA's Regulation in the sense that EEA now may work for other parties than the Commission, assumed that the marginal costs would be covered. By means of this measure, the possibility for EEA to get additional funds increases but not so much that the European Parliament, and the Commission, lose control over its activities: in addition, as all other EU's agencies, EEA cannot earn profits.

The Commission, and in particular DG Environment is the actor mostly involved in the relationship with EEA. The policy-makers of DG Environment aim EEA to support their activity providing them with data and in particular to give them a reliable description of the state of the environment.

During the years, the officials of DG Environment requested several times EEA to limit its actions to the description of the environment, justifying their requests with the fact that EEA's budget is limited and its Regulation underlines that data gathering is its priority. Instead of this limitation, sometimes EEA, especially in the first stages of its life, has tried to widen its range of action and DG Environment has tried to counteract these "entrepreneurial" activities of EEA.

The relationship between EEA and the Commission is particularly sensible: no one in the Commission is formally responsible for developing the relationships between EEA and the Commission. An official of EEA is located inside DG Environment and one representative of DG Environment seats in the EEA's Management Board. The limitedness of this cross-representation had severe consequences on the evolution of the relationship between EEA and the Commission.

The Commission has on EEA an organisational responsibility: it has been noted that the Commission first, was responsible for ensuring the agency a legal basis, EEA's Regulation, and then acted as a "controller" of the same Regulation taking the measures needed to adjust the Regulation and its organisational elements when needed. The continuous assessment, by means of periodic evaluation of EEA's performance, contributed to the reorganization of EEA but on a concrete plan of action, it couldn't have significative effects for instance on fostering the collaboration between EEA and DG Environment or on EEA tasks' focus.

Only with the increased "maturity" of the organization, experts reveal that EEA found a stable pattern of action and a fruitful collaboration with the DG Environment. In fact, for many years the Commission delegated to the Director of EEA the full responsibility to deal with the organisational issues of EEA, concentrating its supervision more on the outputs than on EEA's design, trying to protect the autonomy of EEA on this issue.

One on side the Commission "controls" EEA's processes using the tools described in chapter 3; on the other side, the Commission in some ways tries to "control" also the quality of EEA's outputs: some experts point out that the periodic evaluations of EEA by the Commission is not enough and to do that it should be directly the DG

Environment. This point is highly controversial and it is linked to the "marketability" of the EEA's products inside the Commission.

Two different views exist about this point: some people say that EEA shouldn't be located under the responsibility of a *super partes* body as for instance the same President of the Commission so that, not being attached to DG Environment and so becoming "neutral"; EEA could foster the collaboration with DGs of other sectors and get more funds. On the contrary, being affiliated to DG Environment, EEA might be more "protected" and maintain its privileged position as main producer of environmental data and analyses for the same DG Environment. The history of the relationship between EEA and DG Environment shows that in many occasions DG Environment's officials have used consultants and bodies others than EEA: this procedure has been justified with the scarce human resources of EEA, the impossibility to "control" EEA's outputs (in particular with reference to the fact that EEA has always wanted to make public its reports, sometimes in contrast to the will of DG Environment and of the member States), the need for EEA to work itself with external consultants.

The opposition of DG Environment to be the "marketer" of EEA's outputs can also be explained by the fact that in the case EEA might "sell" its products to other DGs, DG Environment might lose its influence on EEA and also its independency and become in some ways "dependent" from EEA in the sense that EEA would become the main actor in the communitarian environmental field. In this case, the DG Environment might run the risk to gradually delegating its policy-making functions, or at least to "practically" delegating those functions to EEA. This is of course not acceptable for the officials of DG Environment and also the Commission in general would never accept an agency to be so powerful and "out of control".

During the last years some changes occurred. The role of EEA seems to be clearer inside the communitarian system and the relationships with the DG Environment more collaborative. This evolution is due, as many experts argue to three causes:

- the Commission has more and more integrated EEA in the environmental policy-making process, both fostering the collaboration with DG Environment and allowing EEA to get new projects (and extra-funds in particular with reference to the EU's enlargement process);
- the officials of DG Environment are increasingly considering the importance of EEA's outputs allowing EEA's representative inside DG Environment not only to transmit information about environmental trend but also to develop a successful collaboration on other tasks as information analysis and partially considering EEA also as an input provider inside the policy-making process: the role of the DG Environment's representative inside EEA's Management Board is also changing in this sense. He/she is not anymore only a controller of EEA's decisions but acts as a "collaboration" chain between the two bodies;
- EEA, after one phase of growth in which an "aggressive" behavior was conducted to create an its own "space" inside the communitarian system, has started to be more integrated in it and its role has become more important and respected, also at the light of the increased quality of its reports and

human skills. A better strategic and operational management has also permitted EEA to focus more on the quality of its network (internal and external) relationships' management than only on its "technical" skills' development.

The tasks of EEA are in some cases possibly overlapping the ones of Eurostat and Joint Research Centre in Ispra (JRC). Of particular relevance is the relationship between EEA and Eurostat: both these organisations gather data from the member States and for this reason they both have to rely on a network of national and sub-national organisations, focussing the attention on the harmonization of the methodology used and of the data issued. Eurostat is organisationally located inside the Commission and cannot be considered a "delegated" body as EEA. Even if both these organisations provide data to the Commission, some differences between them are evident.

Many officials report that when EEA had been settled up there was a diffuse complain about the overlapping tasks of these organisations and a sort of "competition" between them was a natural consequence of a "defensive" strategy of Eurostat to defend its role and of an "aggressive" strategy of EEA to establish its position inside the communitarian system. Even if Eurostat is more "reporting" oriented and EEA is more "analysis" oriented, some overlaps have been documented.

Schout (1999) points out that EEA goes beyond data gathering and it "works on information for the public" and that Eurostat's main task is strictly connected to data gathering and statistic analysis while EEA has, or at least tries to have a more "policy-oriented" role.

In some cases Eurostat provides data to be processed to EEA but in other cases comparable analyses on the same topics have been conducted by these two organisations without a satisfactory degree of collaboration between them.

The first stages of EEA's life witnessed a more "entrepreneurial" attitude of EEA towards creating an own operative space inside the Commission: now it seems that the "maturation" of EEA reduced the potential conflicts with the other EU's bodies, and this is true also in the case of Eurostat. Even if cases of overlaps and missing collaboration still exist, interviews reveal that EEA is getting more and more integrated inside the communitarian system and also its relationship with Eurostat is clearer.

What is still debated is the absence of a "binding" legal framework regulating the relationship between EEA and Eurostat: the controversies are solved when coming out, delegating the solution to practical bargaining processes more than to a formal dispute to be solved by the Commission or other EU's bodies.

The relationship of EEA with the member States is rather strict: all member States are represented in the Management Board and it is the same Management Board to nominate the experts of the Scientific Committee. Given the limited power of EEA in deciding the policy guidelines to be followed, even if the main influence of the member States is on the work programme, in many cases it has been noted that more than trying to change EEA's work programme in order to defend the national



interests, member States have usually followed the decisions of the Commission, and in particular of DG Environment without considerably influencing them.

The importance of the member States is fundamental also at the "external level", in the data gathering, information providing and monitoring activities. The risk of the National Focal Points to be "captured" or the politicization of the European Topic Centres is evident and it will be analysed below. Here it is useful to underline that on the member States relies the most part of the work programme's implementation and for this reason it is interest of the Commission to develop a work programme that might be feasible for the member States.

The member States cannot be forced to give information and they only "shall, as appropriate, co-operate" with EEA. There is no legal requirement for the member States to provide data to EEA and the national differences are pretty evident in this field. The different national traditions concerning the "importance" of the environmental policies and in general the "sensitiveness" of the environmental theme may affect the quality of the data gathered and more in general the attention of the national and sub-national bureaucracy to collaborate in an effective way with EEA. The effectiveness of EEA's activities in the field almost completely depends from the member States: for this reason the uniformity in this context should be the priority. To complicate this aim are three main factors:

- the national competences in monitoring the environment;
- the value attached to the environment issue;
- the administrative structure devoted to deal with these topics.

Again, the controversial on the importance of EEA as "data gatherer" or "data analyst" reflects two opposite vision of policy-making: on one side the policy processes strictly confined to the relationship between the Council and the Commission, on the other the possibility to make "regulation by information", and so doing adding to the environmental reports a "public" value influencing the same EU's policy.

For instance, if it is defined as a *continuum*, it can be underlined that at one side there are the northern European countries, in particular the Scandinavian ones, where there is a long tradition of environment monitoring. The environment issue is considered as a priority at political level and the environment agencies are generally detached from the political structures and in some cases represent a parallel administration possibly conflicting with the governmental positions. On the opposite side stay the southern European countries where the environment protection as a priority is a rather new values and for this reason the monitoring and implementing tools have been developed only recently. In some cases the environmental topics are delegated to agencies strictly connected to the Ministries (i.e., in Italy) or are the same Ministries to be in charged for this issue (i.e., in France).

There are three main consequences:

- the possibility that in the EEA's Management Board are nominated national representatives coming from the political *apparatus* and they might lack an adequate level of independence from their member States;
- the scarce autonomy and technical competencies of the national and sub-national bodies belonging to EIONET (i.e., in Italy the network of regional

and provincial institutions with environmental functions, previously reporting to the Ministry, have been transformed into a network of formally independent institutions reporting directly to a centralised technical agency, strictly linked to the Ministry for the Environment);

- the possibility that environmental information considered too “delicate” from the Governments could be hidden if the environmental monitoring bodies are too dependent from the ministerial bureaucracy.

Stated against what said above, it is not surprising that the most debated topic at the Management Board’s level, where the member States are involved, is the one concerning decisions about the ETCs, i.e., where to locate them, which amount of budget providing them, which national organisations to involve in the ETCs’ activities. The ETCs are mainly funded by EEA: the interviews reveal that the money aspect and the crucial role the ETCs have in the data gathering and analysis have pushed the member States to heavily politicise the ETCs’ topic.

#### *The “external” network*

EEA operates through a network of other organisations, by means of which the data gathering duty is primarily on national and sub-national organisations belonging to the network (EIONET). The direct consequence of this mode of governance is that the most significant task of EEA is to monitor the quality of the outputs coming from the networked organisations and not to directly operate “on the field”. For this reason, one of the most significant points is the necessity to hire staff with good management skills more than purely technical ones. During the years the change in the profiles of the staff acquired by EEA confirms this impression.

EEA carries out its mission by drawing on the resources of the EIONET group, which consists of almost 300 institutions in 31 countries: it is made of the National Focal Points (NFPs), ETC managers, representatives of the European Commission and relevant EEA’s staff and meets three times a year with around 70-80 participants (EEA, 2005a). The results of these discussions are fed into EEA’s Management Board meetings and in this way provide support to the decision-making process at the policy level.

EIONET comprises:

European Topic Centres (ETCs): these are centres of expertise formed by international *consortia* of specialist organisations to assist EEA in carrying out its work programme. They are under 3-year contracts with EEA and they usually work together with some National Reference Centres (NRCs) in a *consortium*. There are currently 5 ETCs working in the following topic areas:

- air and climate change;
- water;
- nature protection;
- waste and material flows;
- terrestrial environment.

Each ETC regularly invites the relevant NRC to EIONET’s workshops where they present the results of their activities and discuss and agree the way forward with the

country representatives: by means of these meetings are maintained and strengthened the contacts between the ETCs and the NRCs and also between the countries themselves. EEA is responsible for the work programme and quality of the ETCs and the ETCs are mainly funded by the same EEA. The member States support the ETCs with some funding, with the national expertise and institutions (EEA, 2005b).

It has to be underlined that the direct responsibility of EEA on the ETCs gives to these organisations a very special position in the network because the other organisations are connected to the network only on a voluntary basis or invited to join with a consultancy role.

Before the new Regulation was approved, it was needed the unanimity to take the decision to change the topics to be dealt with or the organisation of the ETCs: a long debate about the exaggerate number of ETCs and the scarcity of funds to be allocated to them took a long time to be solved. Only under the new Regulation it has been possible to reduce the number of the ETCs from 9 to 5<sup>41</sup>.

EEA's responsibility implies also the task to monitor ETCs' outputs and their quality. EEA's experts, Scientific Committee's and Management Board's members visit ETCs on a three-yearly base: in addition to this periodical evaluation there is a continuous assessment of the products of the ETCs and of the correspondence between EEA's annual and multi-annual work plan' objectives and the ETCs' activities (EIONET, 2005a). In the past the members of the Scientific Committee were coming from a specific field, corresponding to one ETC and they were expected to follow the activities of "their" ETC: it has been shown that now the association ETC-Scientific Committee's expert has been relaxed.

National Focal Points (NFPs): they are environmental organisations and experts appointed by EEA's member countries at the national level as primary links/contacts between EEA and the national EIONET's partners in order to support the implementation of EEA's work programme and coordinate the environmental information exchange. NFPs are the main contact points for the charge of cooperation with EEA and the ETCs and organise national coordination of activities related to EEA's strategy.

Because of the significative differences between the national environmental agencies and the degree of dependency from the national ministries, also their working methods might differ. Some NFPs are collocated inside the national agencies (i.e., Sweden), some in the national Ministries (i.e., France), some others in the national agencies but nominated by the Environmental Ministry (i.e., Italy). This differentiation might create serious problems of uniformity of methodologies and political approaches to the environmental theme.

In accordance with EEA's Regulation, every member State has appointed its NFP. NFPs' main task is to maintain and develop the national network, facilitate and coordinate contacts, requests and deliveries between national and EU's level: they also act as advisers to their EEA's Management Board members and develop contacts to other relevant networks such as Eurostat. NFPs have also to continuously

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<sup>41</sup> It now requests a two-third majority.

assure that the financial requests connected to the data provided are taken care of: the organisation paying for the service may be the same EEA, the national environment or another sectoral Ministry, or a national environmental agency.

One of the main controversial points when discussing NFPs' tasks concerns its "two-way communication" task (Schout, 1999). On one side the NFP has to defend the work of EEA "at home" but at the same time it has to communicate the national interests at the meetings of NFPs at EEA. NFPs don't enjoy independence from the national Governments as the Scientific Committee's members: for this reason they may play a very significant role in connecting EEA's requests to the home governments' pressures. In addition, many experts underline that being the NFPs usually only one person, they don't have enough power to counteract the influence of the Ministries or in general of the governmental bureaucracy. In some cases, another element reducing their independence is due to the fact that they may be nominated by the same Environment Minister as it happens in Italy.

National Reference Centres (NRCs): they are groups of experts in national environment organisations nominated and funded by the country to work with EEA and relevant European Topic Centres in specific environmental areas related to EEA's work programme. NRCs usually belong to organisations which are regular collectors or suppliers of environmental data at the national level and/or possess relevant knowledge regarding various environmental issues, monitoring or modelling. NRCs are established in specific areas of environmental activity, usually corresponding to ETC's areas (EIONET, 2005b). The structure of the NRCs may change in accordance with the requirements and priorities of the EEA's strategy.

Main Component Elements: they are the specialised bodies within the member States and act as collectors, interpreters and suppliers of environmental data and have expertise in environmental science, monitoring or modelling. Approximately a quarter of them are NRCs.

EIONET is a crucial infrastructure in the decentralised mode of governance of EEA: it is not only the main channel of primary data for EEA but it also brings in the expertise from across the member States and it represents a forum where discussing EEA's activities and work plan's priorities. EEA plays an active role in managing and improving EIONET: it basically develops formal and informal co-ordination tools to improve the quality and consistency of the inputs delivered by the NFPs and ETCs.

The main problems pointed out in the interviews concerning EIONET consists in the substantial variation in the organisation and quality of the national networks constituting it; in addition, the connection between EEA's Management Board and the NFPs is sometimes imperfect and it makes difficult for the NFPs to get essential policy information and, on the opposite site it may make the Management Board missing technical information coming from the NFPs.

The recent European Commission's evaluation of EIONET (Office for Official Publications of the European Communities, 2003: 14) underlines some weaknesses of the system, in particular with reference to the ETCs, which can be summarised as follows:

- to concentrate the “topical expertise” of EEA in the ETCs weakens the central capacities of the agency;
- the creation of the ETCs adds an extra layer of bureaucracy between EEA and its users, rendering communication unnecessarily complicated;
- being ETCs’ staff at a distance of EEA and being them less policy-oriented, it makes difficult to steer the ETCs and in addition, there is little staff, with few specific competencies, to assess the ETCs outputs.

EIONET’s bodies may be identified in different ways: by the Community legislation, by an agreement between the European agency and the national governments and so on. This “polycentric” nature of EIONET is increased by the co-operation with external administrations as Eurostat and with third-country administrations. Which kind of tools might be used to co-ordinate this network? It has been underlined the importance of developing “voluntary” relations by means of “non-hierarchical” tools of control, when a complex mode of governance as a network is to be managed.

The role of EEA in EIONET may be defined as the one of promoting the administrative integration but the resource dependency of the ETCs on EEA or the possibility for EEA to give its binding opinion in the choice of some EIONET’s members, may not improve the effectiveness of EIONET: the positive effect, leading to the real integration of the organisations involved in the network, consists in developing operative relationships fostering the interdependence of the bodies and their functional complementarities.

Main feature of the relationships is that they cannot be predefined in the founding regulations and are consequence of structural or procedural forms of voluntary co-operation among the various components of the administrative system (Chiti, 2003). As seen above, the difficulties of EEA to have the same specific competencies of the topic centres, the reluctance to create extra-bureaucracy, the different “vision” of EEA, more policy-oriented and of the EIONET components, usually more “operative” oriented, and in general the “distance” in terms of competences, work philosophy (and, some experts argue, the scarcity of effective control mechanisms) might affect the good functioning of EIONET. For this reason, it has to be underlined that only the use of “soft-law” instruments fostering “spontaneous” co-operation, may be the tools to manage this network.

This “spontaneous” stability may be the result of the relationships between the various bodies involved in the network and it may develop a non formal way of order: the main point is here to understand how this order may come to existence and if the situation actually responds to this “normative” assumption.

The interviews reveal four elements fostering this spontaneous collaboration:

- non binding communitarian measures;
- professionalism;
- europeanization processes;
- identity and reputation issues.

There is in EU a trend towards developing networked administrative structures in which national and European-level institutions create closer cooperative

arrangements (Graver, 2002). The European Commission has intensified its work on alternative and non-legal instruments for improving implementation and in this specific case data gathering and technical collaboration by developing a wider repertoire of organisational instruments involving national and sub-national administrations (Sverdrup, 2003).

For what concerns the first point addressed by people interviewed, it seems clear to almost everybody that EEA is not an "equal" member into EIONET: it has certain resources that make it something more than an equal partner; first its "legal" position and then, money. The network operates to a large extent through projects defined by EEA having EEA as its main contributor, and through the funding EEA influences which projects are realized (Martens, 2005). EEA acts not only as an actor with certain knowledge and expertise, which might be less specific than the ones needed for a certain project, but also as facilitator and coordinator of the network. In some ways, EEA steers the direction of the network's projects not only by its funding, but also through its expertise and knowledge and its role as coordinator. Even if its competences are more "policy" oriented than the ones of the EIONET's components, by means of constant evaluation and projects' assessment, it influences EIONET components' participation to the network: in this case the "authority" of EEA is clear and it is used to maintain control on the network while fostering the development of common work methodologies and objectives.

If the "professionalism" issue is addressed, it should be put in evidence that national and sub-national experts have more contacts between each other than with EEA: for this reason it is possible to argue that the common professional background and the high degree of contacts between the experts create a sort of common identity deeper than the companionship with the institutions at the European level, in this case with EEA. This common identity may foster the development of common work methods and may make the experts spreading shared visions and values.

This "europeanization" process might be more evident when organisations relatively independent from national Ministries are taken into consideration: in these cases the experts and in a wider sense the same organisations may be well placed to collaborate with actors at the Community level and to take part in networked structures across level of governance, promoting an effective and voluntary collaboration on one side among the same organisations and on the other with EEA.

The last element underlined by some experts is the necessity to maintain a positive image and as a consequence a good reputation by the organisations involved in EIONET. This point is strictly connected to the "professionalism" one. Organizational identity constitutes part of the shared meanings held by the members of an organization: it influences not only how members define themselves, but also their interpretation of issues and roles, responses to problems, and feelings and outcomes (Dutton & Dukerich, 1991). Organisational identity might be influenced by the stakeholders (Scott & Lane, 2000) or by the membership to a "group" (Adler & Adler, 1998).

People interviewed see in the identity and reputation issue a really significant element pushing for the creation of effective relationships of collaboration and state that these relationships are based on the maintenance of a good reputation linked to a

properly defined organisation's identity. Being their relationship with EEA based on the success of the projects in which they are involved, to lose their reputation because of technical inefficiencies might mean to lose the possibility to receive projects and money in the next future. Because of the constant evaluation of EEA and of the fact that the staff of the EIONET's members own as a primary skill their technical competence, they have to work for maintaining unchanged, or modify it when it is the case, the identity of the organisations they are working for, fostering the good reputation of the same organisation.

This last point in some ways integrate all the previous points: the non binding communitarian measures press on fostering the good reputation of the organisations involved in the EIONET's network; their reputation is mainly based on the "professional" skill of their members and the degree of "europeanization" of their members mainly depend on the degree of independence the organisations join from the ministerial structures. The situation changes from country to country and depends on many factors (i.e., bureaucratic tradition, importance of the "environment" topic in the political agenda and so on) and this fact should be considered into the analysis, in order to understand if and in which way a "spontaneous" collaboration inside EIONET really exists.

### **7.3 Designing an accountability framework**

To assess the accountability framework of a delegated body is always a sensible issue: in the case of EEA this topic is even more complicated given its position of "executive" agency with reference to the Commission and its "hub" role with reference to the network on which it relies to perform its activities. For this reason an analysis taking into consideration only "internal" accountability tools wouldn't be complete: insights about the mechanisms designed to check the activities of the national and sub-national bodies performing data gathering and analysis in support of EEA's activities is equally important.

#### *The "internal" accountability framework*

EEA's history is characterized by a problematic relationship with the DG Environment and informal mechanisms have been, especially in the past, frequently made by the DG Environment's officials to side down the role of EEA. As the other EU's delegated bodies, EEA's processes are under control provisions of different legal nature (i.e., procedural, financial, judicial and so on). Given the fact that the main components of these control procedures are the same for EEA and the other EU's agencies, here the attention is concentrated first on what have been above called the "executive" and "democratic" controls performed by the Commission, the European Parliament and the member States.

The Commission has two representatives in the EEA's Management Board; the Parliament doesn't have direct representatives but maintains the power to nominate two "experts". The reason behind this difference is quite clear. The role of the Commission's representatives is double: on one side they are the "decision-making" chain between the Commission, and in particular the DG Environment, and EEA and on the other side they act as "defender" of the Commission's interests in the Management Board. Given the fact that it is the Management Board the place where

the decisions regarding strategic and operational management of EEA are taken, the presence of two Commission's representatives is fundamental. The role of the Commission is important also for the appointment of the EEA's Director: it is the Commission to propose the Director and the influence of the Commission on the approval by the Management Board of the Director comes clearly out in the interviews performed.

The direct representation of the European Parliament in the Management Board of an EU's delegated bodies is not common (with little exception): the European Parliament's role is neither to intervene in the day-to-day activities of the agencies nor to directly influence their strategic vision. The Parliament should *ex-post* ensure that the agencies fulfil their obligations and check on the good use of the budget (and on Council's recommendation, the Parliament discharges the budget).

The presence of experts nominated by the Parliament on one side allows the Parliament to exert supervision on EEA's activities. More significative is the fact that the Parliament nominates experts in order to assure an adequate level of expertise inside the Board: this approach has been heavily criticised because there is no reason why these experts should have an adequate level of professional skills and in the recent years in almost no new agencies settled up there is the presence of Parliament's representatives, not even as external experts.

The member States own one representative each inside the Management Board and even if the members of the Scientific Committee are nominated directly by the Management Board, they may in some ways influence the names to be proposed, not only by means of their representatives in the Management Board but also because the experts frequently come from national and sub-nationals institutions heavily linked to the ministerial structure.

If the attention is concentrated on the executive control, it is clear that it is performed by the Commission (and in part also by the Council) in many ways others than the direct representation in the Management Board. First of all the resource dependency of EEA from the Commission and the Council (the two institutions defining the quantity of the Commission's budget to be conferred to EEA) is legally predefined. Second, EEA's activities are periodically evaluated by the Commission (and in some cases also by the Parliament) and on the basis of the Commission's report the Council reviews the progress of, and the tasks undertaken by EEA in relation to the Community's overall policy on environment. Aim of these reports is also to formulate recommendations concerning EEA and its main stakeholders and partners. The fact that in the end it is the Council to review EEA's activities makes clear that these reports don't have only a "contingent" and "operative" nature but they directly call the member States for the evaluation of EEA's progresses and in the case it is needed for eventually modifying EEA's Regulation.

Different nature has the relationship with DG Environment: it doesn't exist an accountability tool DG Environment may use in order to check the activities of EEA and the quality and nature of its outputs. The EEA-Dg Environment's relationship is based on a consuetudinary relationship in which DG Environment uses, or should use, EEA as environmental data gatherer for its policy analysis. DG Environment can exert its direct "executive" control over EEA by means of its representative



inside EEA's Management Board and can make pressures on the EEA's official located inside the same DG Environment.

What comes out from the interviews is the ambiguity of this relationship, especially in the past, in terms of setting up and steering EEA: the institutionalisation of EEA has been slow not only because of the necessity to create a new agency but also because of the problematic relationship between the political and operational will of DG Environment and the quality and nature of the outputs coming from EEA. In this sense the lack of collaboration of DG Environment in linking EEA to the Commission and in marketing EEA's projects inside the Commission has been interpreted as a reaction to the impossibility to directly influence EEA's tasks and philosophy of work, that is in the lack for DG Environment of effective steering tools. Only with the changes occurred in EEA, its more secure and "institutionalised" position, and in the suggestions coming from the Commission (and the new consideration of EEA by the same DG Environment), the relationship between EEA and DG Environment, paradoxically based most on a "voluntary" collaboration, has become stricter and more successful in the recent years.

#### *The "network" accountability framework*

The "hub" role of EEA implies that EEA has the responsibility to monitor the quality of the ETC's outputs. This quality control consists in a regular review, usually every three years, by a committee of EEA (made of Management Board's and Scientific Committee's members and additional consultants). In addition there is an on going review of the products of the ETCs by EEA's experts.

The first type of control has consequences on the work plans of the ETCs and also on the same numbers and structures of the ETCs; the second one may provoke a "fine tuning" of the operational management and work objectives of the ETCs.

EEA owns an extraordinary accountability tool when checking the quality of ETCs' activities: the resource dependency of the ETCs from the same EEA. In the case a performance of an ETC is not satisfactory, EEA may not pay the output and in the long run it may happen that in the EEA's Management Board meetings are proposed cuts to the annual budget of the poor performing ETC.

This might be the extreme consequence of the control procedure against an ETC: the poor performances of some ETCs during the first years since the EEA's settlement provoked radical changes in the network structure.

Internally to EEA, before its re-organization, there were 9 ETCs, each of them corresponding to an expert inside EEA informally responsible for controlling an ETC. This extremely disaggregated structure and the difficulty, on one side for one person to control the quality of a delegated organisation and on the other side for the same EEA to co-ordinate all ETCs' activities pushed for a more streamlined organisational chart of EEA with a new "Management and Network Support" unit dealing with co-ordination management issues and four units dealing each with a different topics, partially mirroring the topics dealt by the now 5 existing ETCs, but depending from a centralised unit called "Environmental Assessment" unit.

The role of the member States is extremely important in relation to the process of control and evaluation of the ETCs because they might heavily influence EEA's decision in this regard. Member States support ETCs' funding them and providing

them with logistical facilities: in addition, the ETCs usually rely on national and sub-national organisations frequently strictly linked to the Environment Ministries. The decisions concerning the location and the possible cuts of existing ETCs are taken into the EEA's Management Board, where the member States are all represented. Many experts point out that it is extremely difficult to understand where decisions about ETCs are taken following technical or political reasons.

Schout (1999: 146) on the contrary argues that "the strong involvement of member States in determining the focus of the ETCs and the division of tasks between them has hampered their effectiveness and the reputation of the agency": this position refers to the first stage of life of the ETCs but if it is assessed how the situation has changed during the last years, it might be noticed that the comments are extremely positive about ETCs' network management. The problems of flexibility of the ETCs' work plans and the lack of adequate expertise inside EEA seems to be almost totally solved and even if the role of the member States inside the ETCs has slightly increased (also from the financial point of view), the decision to reorganize EEA and the same ETCs have been fully supported by the member States.

The management of EEA's network is not limited to the relationships with the ETCs but refers also to the relationship EEA stipulates with the approximately 300 bodies of EIONET. EEA doesn't own an adequate expertise and budget to control the whole EIONET system and it would be absurd for an agency as EEA to perform this activity because it would drawn from its core business an extremely large amount of resources. The collaboration with the member States and a severe control of the quality of the EIONET bodies' outputs are the main tools in the hand of EEA. The quality check performed by EEA with reference to the data gathered by the national and sub-national bodies involved in EIONET has been already assessed. Here the attention is concentrated on the relationship with the member States: the most important critique done to the member States regards the frequent politicisation of the NFPs and the *criteria* used to settle up the *consortia* working for EIONET. The strict relationship between some NFPs and the national members of the Management Board might bias the independence and autonomy of the NFPs' decisions and this distortion may have serious consequences also on the organizations linked to the NFPs.

The reality on the contrary seems slightly different: the quality of the outputs of EIONET is of good level and it exists an acceptable degree of collaboration between the experts and scientific bodies participating to EIONET's activities.

The periodical evaluation of EEA reveals that only seldom there has been the necessity to directly intervene on EIONET bodies' management but the cut of some bodies happened in the past makes clear that to make the system tighter and streamlined has been possible so that the political interference had been probably not so invasive.

It might have happen on the contrary that the strong involvement of the member States into EIONET pushed them to intervene on the quality of the national and sub-national centres chosen to "represent" the State into the network, pressing them to increase the quality of their outputs: a process of "professional cross-check", the necessity not lose the communitarian funds supporting the activities of the member

States' bodies and also the "control" role of EEA made possible to develop a reliable system of "network accountability" based on non binding legal measures and in general on a "soft law" approach.

Date	Event	Notes
1972	I programme for environmental action: definition	For the first time the Commission is called to deal with environmental policy-making
1973-76	I EC environment action programme	The programme becomes operative
1985	CORINE	First attempt to structure environmental data gathering
1990	EEA's Regulation	Settlement of a task force to create EEA
1990	Multiannual work plan	Definition of the phases of settlement of EEA
1994	Building up of EEA	EEA officially starts its activities
1995	First European Environment Report	For the first time a report on the overall condition of the environment is issued by a communitarian body
1999	New EEA's Regulation	EEA's tasks and organisation are redefined
1999	I EEA's reorganisation	EEA's structure is streamlined and made less divisionalised. EIONET is re-organised
2003	Commission's Report on EEA	Commission evaluates EEA's activities and suggests improvements for the future
2004	II EEA's reorganisation	EEA's structure is made more co-ordinated. EEA is better integrated in the EU's environmental policy-making process

**Table 11: EU's environmental policy: chronological resume**

	EEA's nature	Features
1994-1999	Settlement and growth: EEA may be defined "entrepreneurial"	Divisionalised structure; problematic relationships with DG XI; difficulties in managing EIONET; confusion between "information" and "analysis" tasks
1999-2004	Institutionalisation: EEA increases its "managerial" skills	More relaxed relationships with DG XI; improved quality of EIONET's outputs; better reputation of EEA's Environment Report; institutionalisation of EEA's role
2004-present	Maturation: EEA is becoming a "professional" organisation	EEA's structure is more co-ordinated and decentralised; EIONET's structure is reorganised and becomes more streamlined and coherent; European Parliament and Commission fully recognizes EEA's role

**Table 12: EEA's evolution**

## 8. Conclusions

In this dissertation it has been tried to escape the dichotomy intergovernmentalism/functionalism and to find a scientific way to analyse delegated modes of governance as implemented in a communitarian setting, assessing this organisational evolutionary process as an "institutional *phenomenon*" through the conceptual lenses of public management.

European agencies can be defined "administrative integration" agents: they indeed may represent an extraordinary element of impulse to the re-organisation of communitarian structures and procedures. In this last chapter, first the "structural disaggregation" and the "performance contracting" dimensions of analysis will be assessed, relying on the findings of the study of overall communitarian "agency" system and of two case studies. A specific further evaluation of the case studies and a final discussion on the research will complement the conclusions.

### 8.1 Discussing structural disaggregation and performance contracting

#### *Overall findings*

The increasing number of delegated bodies inside EU can be seen as a rising fragmentation of the EU's structure: as a consequence, task disaggregation and specialisation cannot remain unchanged. Assumed that the structures and in general, the overall characteristics of the EU's delegated bodies embrace a wide range of organizational models it is clear that having increased the responsibilities and as a consequence the functions of EU, it has followed an increase of the differentiation and specialisation of the delegated bodies of the communitarian system, demanding to each institution different objectives (clearly stated in the different founding statutes) and so doing, different tasks.

It cannot be fully argued that the introduction of delegated bodies inside the communitarian model of governance might have always taken out from the Commission functions already being on charge of the Commission itself. This has happened: at the same time, the creation of delegated bodies has been also an answer to the demand of "new" services, with an increasing importance devoted to the introduction of new "regulatory" tasks. For this reason, it is important to recognize that an increased task disaggregation and specialisation of the communitarian system is evident, but it is also possible to speak of "introduction" of delegated bodies organizationally disaggregated from the Commission and performing specialised tasks, not always directly linked to one specific DG.

The policy/implementation division of labour between the Commission and the agencies is rather manifest: some agencies have been created on the model of, and in order to replace, the comitology system; some to supplant a procedural mechanism within EP and the Commission; some to replace programmes already active inside the Community. In other cases the creation of agencies has been the effect of transference of functions from the intergovernmental level to the communitarian one. In two cases, the emergence of an agency was the consequence of the decision to establish a new Community regime: this was the case of CPVO (plant variety) and OHIM (trademark). The specification of tasks is usually done in the Founding Statutes and it is constantly monitored by means of continuous and compulsory

communications specified in documents as the Annual Reports. The distinctive split between the policy maker (the Commission and partially the other EU's bodies) and the policy implementers (the agencies) is evident. EU' agencies have been classified in "co-ordination/information" and "authorization" ones, especially when no decision-making powers are attached them, as with EMA and ECA. CdT is the more manifest case of "provider of services" on request of EU's bodies; EAR, which has been defined also a "management" agency, has as a primary task to realize reconstruction projects on behalf of the Commission.

The presence of Commission's representatives in the Management Boards of almost all agencies complicates the analysis: if on one side this presence is fundamental for assuring an adequate degree of policy specification and actuation, influence upon the agency's management decision, and link between the Commission's and agency's policy orientation, on the other one, the clear distinction between policy-making body (the Commission) and service provider (the agency) is less clear.

Analysing the accountability set of laws regulating the management functions of those bodies, it has been shown that all of them are regulated by a unique financial regulation amendable only with the approval of the Commission. In this sense, having been imposed a uniformity of regulations, it should be guaranteed a better control by the Commission and the other communitarian bodies – and also by the member States and the "public" in general – on the agencies' activities. In this sense, the increasing differentiation of the accountability rules, as usually occurring when the structural disaggregation increases, didn't happen.

Audit is guaranteed, both internally and externally, by plain and general rules: if on one side the external audit is always carried out by the Court of Auditors, the internal auditor may be appointed by the Management Board of the agency but also by the Commission: in all agencies, the Internal Auditor has to report to the Management Board and to the Director and to submit to the EU's bodies an annual internal report. From the auditing point of view, a homogeneous application of the communitarian regulations, involving almost all EU's bodies, guarantees an acceptable level of unit performance's audit; not increasing at the same time the level of fragmentation of the audit rules.

For what concerns the flexibility of the personnel and organisational modes, conclusions are different. Even though the establishment plan of the delegated bodies has to be approved together with the budget by other communitarian bodies, this fact doesn't mean uniformity in personnel policies. The same considerations have to be done for what concerns the organisational flexibility: it is not particularly relevant, in the sense that almost all agencies have the same internal management structure consisting in a Management Board, Advisory Forums and Scientific Committees (when needed). The presence of "quasi-judicial" bodies in two agencies (CPVO and OHIM) is a natural consequence of their "authorization" nature. What changes more is the composition and appointment rules of the Management Board: these differences reveal that the rational behind this heterogeneity should be found in the role of the agency and in the relevance of its actions on the member States' influence and, in general, in the ownership or lack of decision-making power.

When using the term of “performance contracting” in the communitarian context a researcher should be very careful: to use the term “contract” to describe relationships between the Commission and the agencies is probably too provocative. Leaving aside the term “contract”, it might be noted that all agencies are required to follow budgetary processes with defined documents, produced at defined times. This process includes written communication of objectives and performance requirements as well as follow-up procedures mainly involving the Commission and the Court of Auditors but also, and increasingly, the European Parliament and the Council.

The resource dependency of the delegated bodies from the Commission is usually quite high. Only in few cases, the possibility to raise funds charging fees reduces the degree of this dependency. It should be stressed the fact that when fixing fees, EU's agencies are not autonomous and they depend on a procedure defined in their Founding Statute, in which both the Commission and the member States have a fundamental role. Here again the conclusions should be carefully drawn: resource dependency from stakeholders others than the Commission might provoke a “capturing” *phenomenon* that might lessen the possibility for the Commission to maintain under control the management of the delegated bodies.

Performance reporting is compulsory and involves primarily the Commission and the European Parliament; it is of Court of Auditors' competence to evaluate how well the agency has applied the principles of sound financial management – economy, efficiency and effectiveness – to the management of EU's funds. All agencies are subjected to a continuous and predominantly identical form of assessment of their performances.

EU's delegated bodies don't operate in a *vacuum* but on the contrary their objectives and the actions taken for reaching them are constantly kept under control. Policy-making power is usually in the hands of EU's bodies others than the agency, with few significative exceptions. It doesn't mean that EU's agencies don't own any power in stating the guidelines of their actions and their objectives, both in quantitative and qualitative terms. It is the Director to be responsible for the implementation of the Annual and Multi-annual work plans of the agency, as defined by the Management Board and the relevance given to the objectives of the agencies as stated in their Founding Statutes is always considerable. Agency's managers are required to deliver work plans' documents: aim of this procedure is to give the possibility to the Commission, and in general to the other EU's institutions to “control” the effectiveness of the agency's performance and to verify that the activities of the agencies are in line with the tasks and objectives stated in their Founding Statutes.

Jointly with the development of performance management monitoring systems, financial indicators and time measures have been identified by many agencies. In some cases, target audience, objectives/methods and performance indicators are included in the Annual Reports of the agency and their effectiveness is evaluated by the Court of Auditors. In general terms, evaluation quality standards include ways to assess the quality of the outcomes of the tasks carried out in all areas and at all levels of the organisation, whether in quantitative or qualitative terms, according to the nature of the outcomes.

What seems to be evident from the analysis of the performance management monitoring systems put in essence by some EU's agencies, is that they don't represent a homogeneous picture. Many EU's agencies have developed modern and complex system of evaluations of their performances; some others have also settled up internal audit committees or delegated to consultancy firms an assessment of their managerial processes. The most relevant point is that, from the "performance contracting" point of view, these systems of evaluations are not used by the "central" organisation (i.e., the Commission) to assess the decentralized agency's performance. Internally to the communitarian system, a precise body of rules concerning internal and external auditing has been developed: a constant link between the agencies and the other EU's bodies has been established and the managerial performance of the agencies is constantly evaluated. The mechanisms of performance management monitoring analysed here should be on the contrary identified as an internal tool of governance evaluation, designed to improve the managerial efficiency of the agency.

The use of categories of analysis taken directly from the public management literature should be evaluated at the light of the peculiar setting in which the bodies under study operate. For instance, what said about the concrete possibility that the creation of those bodies doesn't answer to efficiency needs but to power or "diplomatic" struggles might affect the possibility to easily give an unequivocal judge on their "performances". From this piece of analysis, some kinds of "purchaser-provider" split can be observed: a policy/implementation division is in some way clear especially with reference to "informative" agencies and to some "regulatory" agencies but this topic is still highly debated and sometimes controversial<sup>42</sup>. Less easy is to confirm that disaggregation should tend to raise expertise (even if in some cases, the introduction in the communitarian system of national experts as in the case of EMA can be a confirmation of this hypothesis) or that a "contractual relation" should embed a result-oriented focus also at the communitarian level.

#### *Evaluating the findings in the field*

EMA's and EEA's cases have provided many insights for an assessment of the structural disaggregation and performance contracting dimensions of analysis. Given the differences of those agencies concerning their operative tasks, relationship with the Commission and network management responsibilities, the cases will be dealt separately but when useful a comparison *per item* will be proposed.

In the case of EMA, its co-ordination task and its institutional setting makes problematic to apply categories of analysis developed in national and sub-national public frameworks: the relationship between Commission and EMA cannot be fully evaluated as a "policy/operations" relationship but still the structural disaggregation occurring because of the delegation of functions from DG Enterprise and Industry to EMA is useful for assessing EMA's management processes. In fact, even if it cannot be argued that the Commission's role is to impose policy guidelines and the EMA's

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<sup>42</sup> For instance, consider the "will" of EEA to affirm its own "political" role.



role is to realize these policy guidelines it may be noticed that the "consequences" of this disaggregation have been realized.

A raise of expertise, quality and efficiency in the pharmaceuticals' regulation occurred: before the settlement of EMA, the communitarian pharmaceutical policy was poorly regulated at the central level and the role of the member States was prominent. At the Commission's level, DG III (the former DG Enterprise and Industry) was the main actor involved in the pharmaceuticals' regulation but the policy-making phase was still "hidden" in the comitology process and some experts reveal that the number and quality of the expertise involved was not satisfactory.

By means of EMA, the centralized procedure of authorization had started to become more "reliable" and the creation of lists of experts to be used in the technical evaluation increased the value of the scientific assessment.

Task specification is extremely clear: EMA has been established to perform the centralized procedure of pharmaceuticals' authorization, to intervene in the disputes coming out from the decentralized procedures and, in more general terms, to operate as a "controller" of the communitarian pharmaceutical policy as applied in the member States. By creating a network with the national agencies, EMA has been provided with an adequate expertise coming from the member States. Not owning an adequate staff internally, the agency had to rely on an external support, developing strict relationships, of professional natures, with those organisations.

If the unit accountability rules of EMA are the same of all other communitarian delegated bodies, the peculiar relationship with the Commission and with the pharmaceutical companies introduces a further accountability dimension potentially more important, at the practical level, than the formal ones stated by the communitarian regulations. EMA owns an acceptable level of financial autonomy because it can "sell" its service but it is subjected to the same personnel and organisational flexibility limitations than the other EU's delegated bodies. If its financial autonomy is specifically considered, it is true that EMA has the possibility to raise its budget because of its relationship with the pharmaceutical companies, but at the same time this fact shouldn't be overemphasised.

EMA cannot take loans and the potential budget's surpluses go into the next general Commission's budget. EMA's budget is part of the Commission's budget and the rules for its approval are the same of the other EU's delegated bodies.

Because of the structural disaggregation between Commission and EMA, the transparency of the pharmaceutical regulation processes has increased: now a well defined set of rules stays at the base of the pharmaceutical products' authorization process and the intervention of the Commission is strictly limited to some specific cases. Two factors support this analysis: first, the very small amount of EMA's decisions rejected by the Commission and second and more important, the increase of the number of centralised procedures from 1995. This fact witnesses the increased trust of the pharmaceutical companies with regard to EMA, and in general to the EU's pharmaceutical regulation and the convenience to go for a centralised authorization instead of a decentralised one.

To speak of "contractual relation" concerning EMA is also a very delicate issue: it has been argued that the relationship existing between EMA and the Commission on

one side and between EMA and the pharmaceutical companies on the other is based on a "professional" set of values. For what concerns the resource dependency, EMA gets its funds both from the Commission and the pharmaceutical companies: in both cases EMA receives funds for performing a technical evaluation and again the "price" is paid in return for receiving a well defined service. But on the Commission's side, the funds are given to EMA in return for receiving not only the technical evaluations but also for managing the regulatory and pharmaco-vigilance network.

The Founding Statute defines the mission of the agency but it cannot be referred to as a "contract" between the agency and the Commission. If the Annual Reports of EMA and the objectives stated in its strategic and operational plans are analysed, the concept of "contract" may be carefully and only partially used. It is the Management Board to design the Annual and Multi-annual plan of actions of the agency: in these plans both general aims and more specific performance objectives, often detailed in budget's, quantity's and time's objectives are stated.

If the composition of the Management Board is considered, it may be noticed that Commission's and Parliament's representatives participate to the report's designing process: this is peculiar of the communitarian agencies and reveals that even if the term "contract" cannot be used when analysing the relationship Commission-EMA it should be considered that to define the strategic and policy-making processes is a Management Body including representatives which are expression of the principal – the Commission – but also of the Parliament, that is expression, in general terms, of the citizenship.

More than "result-oriented" focus in a "contractual" relationship between EMA and its principal, this might be defined a "professional" relationship, not only between EMA and the Commission but also between EMA and the pharmaceutical companies (see next sub-chapter for details). In this respect, only the "professional" accountability of EMA might guarantee EMA's independence and autonomy, which are fundamental for EMA to play its role of "hub" organisation inside the networked pharmaceutical regulatory framework. In addition, when speaking of "professional-oriented" relation instead of "result-oriented" focus, the dimensions of trust and reputation become essential for the good functioning of the network.

Also in the case of EEA, it is not easy to apply the "structural disaggregation" and "performance contracting" analytical categories to the evolution of the relationship with the Commission but it might be useful to make an attempt in order to assess if delegating tasks in the field under analysis – environmental monitoring – has brought to an improvement of the EU's policy-making and of its implementation.

When those categories for the assessment of EEA's processes are used, first it should be considered the controversial definition of EEA's tasks and the never ending debate about its "information", "analysis" and "policy-making" role. Also EEA's settlement Regulation reflected the unclarity of the tasks delegated to EEA and as a consequence stating definitive conclusions might be difficult.

While in the case of EMA, the relationship with the Commission on one side and the pharmaceutical industry on the other, based on the "professional" nature of EMA, made difficult to clearly distinguish the true nature of the delegation, in the case of

EEA, its formal "information" role should ease the analysis. This is not totally true: the change of Regulation and the evolution of the relationships between EEA and DG Environment and the existence of a network of organisations involved in the data gathering activity makes the analysis equally difficult.

"Structural disaggregation" between EEA and DG Environment is formally clear: "policy" is on DG Environment; "operations" are on EEA. In this case it is not possible to speak of implementation of the environmental policies because they are still under member States' responsibilities.

The functional specialisation of EEA has been stated from the beginning: EEA has to provide the Commission with reliable information on the state of the environment. If the institutional evolution of EEA is not considered, it seems clear that this division of labour has been defined in a very effective way. Before the settlement of EEA, the environmental policy was mainly conducted in the obscure "comitology" sessions and, more important, the data about the state of the environment were coming directly from the member States. This process of data gathering presented several problems: there was no methodological uniformity in the process of data gathering and some member States were reluctant to provide "sensible" data about the state of the environment.

The settlement of EEA gradually solved those problems: even if the member States were still the main actors in the process of data gathering, EEA had been assigned the role of network's "hub": its task in this sense is to organize the network and to verify the scientific reliability of the data gathered. The history of EIONET hasn't been always successful: the multiplicity of bureaucratic new structures, the politicization of many national and sub-national organisations and the difficulties to manage such complexity have characterized for many years the activities of EIONET. After fifteen years the situation has improved and the reliability of EEA's environmental reports is better than the environmental data collected before its settlement.

The expertise, quality and efficiency of data gathering has improved and the role of EEA is now clear in this sense: the periodical evaluation of the ETCs and of EIONET as a whole pushed the member States to improve the quality of the bodies involved in EIONET, also for financial and political reasons.

The "environment" issue has risen in importance: the concept of "regulation by information" became one of the most debated topics on the political agenda. Also the transparency of the data collection process has increased and in general terms the quality of the management devoted to deal with the environmental monitoring is considered better than before the disaggregation between EU's policy maker and EU's collectors of data came into existence.

EEA cannot be considered as the executive body of DG Environment: on the contrary EEA might be defined a provider of inputs – environmental data – for the "output's" – environmental policies – provider, DG Environment. This "reversed" relationship reminds to the relationship between DG Enterprise and Industry and EMA: also in that case it was EMA to provide inputs – evaluations of pharmaceuticals – to DG Enterprise and Industry so that this DG could take the final binding decision on pharmaceuticals' marketability.

In the case of EEA, to complicate the analysis there is the difficulty to clearly identify EEA's role in the sense that it is not evident to which degree EEA should stop the level of analysis of the data gathered. It is here fundamental to put in evidence the importance of disaggregating the data gathering function from the policy-making one in order to get an improvement of the quality and reliability of both those functions: this is one of the reasons supporting the firm position of the Commission not to give up with its role in the environmental field.

If the relationship between EEA and the Commission is defined as a "contractual" one, it might be expected that this relationship embeds a "result-oriented" focus where the results are specified in terms of outputs: "translating" this definition in "communitarian" words, this specification of the EEA-Commission relationship makes partially sense.

EEA has the duty to report to the DG Environment on the state of the environment: a system of performance reporting exists into EEA and it is based on a performance measurement using objectives and measures in financial, client, business and learning, and growth perspectives. Even if it is an internal performance management system, it goes in the direction of the system used by DG Environment where issue framing, policy measure identification, policy measure development, policy measure implementation, policy measure effectiveness are interconnected, as it happens inside EEA, in an annual and multi-annual framework.

EEA depends on DG Environment for what concerns its resources: even if it is not only DG Environment to decide about EEA's budget (the Commission and the Council are involved), formally EEA's resources are part of its budget.

DG Environment cannot modify the resources of EEA because of shortcomings in EEA's management activity but it may politically influence the allocation of these funds: for this reason, even if there is not a direct relation between "performance" and "budget", a poor quality of the data gathered might have brought to a substantial cut of the budget. This was not the case of EEA: its budget has steadily, even if slowly, increased during the years. On the other side, the dependency of the ETCs from EEA presents the same peculiarities: even if ETCs may ask for the member States' contribution, their funding dependency from EEA has given EEA an effective accountability tool to maintain the quality of their outputs under control.

As it happens with EMA, also here it is possible to speak of "professional" oriented contract: it is not the amount of output but primarily its quality to be discussed. To complicate the assessment of the quality of the EEA's outputs is the fact that EEA and DG Environment have different competences and tasks and for this reason complains of DG Environment about EEA's outputs regarded not only its quality but the fact that they were not limited to the "state" of the environment but they have been sometimes aimed to "analyse" the environmental trend when not to "regulate by information". Then, as it happens with EMA, it is useful to refer to the EEA's Annual and Multi-Annual plans to assess the agency's performance in terms of budget's, output's and time's objectives.

Also in the case of EEA, Commission's delegates (and experts appointed by the Parliament) participate to the activities of the body – the Management Board – designing the plans. For this reason, out of the founding Regulation, it is problematic

to refer to these plans as “contracts” between the agency and the principal (the Commission), being delegates of the Commission participating to their drawing up.

## **8.2 Evaluating the empirical evidence**

The analysis of the organisational and management design of EMA, first of its tasks and procedures but also of its structure and management rules tries to take into account the process of institutional change occurring in this period to EMA and to link EMA’s operational and strategic management with the accountability tools designed to give EMA an acceptable level of autonomy maintaining EMA under control, with the peculiar “professional” nature of this delegated body. The relationships with its stakeholders, essential for the good functioning on the networked regulatory framework of which EMA is the “hub”, and the consequences they have on EMA’s performance have also been taken into account.

Before analysing the uniqueness of EMA in the communitarian context, some findings came out from the interviews performed are now underlined. Notwithstanding the institutional change occurring in this period, there are still many controversial aspects about EMA and in general about the communitarian pharmaceutical products’ regulation system.

The institutional location of EMA is sometimes criticized: the direct link with the DG Enterprise and Industry is seen as one of the main problems. First, it is underlined that at the national level the health regulatory agencies are linked to the Health Ministries and, second, this institutional position reveals the attitude of the Commission to include in the regulation of the European pharmaceutical industry elements of industrial policy as proposed for the first time already in 1993 (Commission of the European Communities, 1993).

The financial support EMA has increasingly received from the pharmaceutical companies may confirm on one side the “maturity” of the agency, having it reduced its dependency from the Commission. On the other side it may confirm the possibility that EMA might be affected in its independency and judge’s objectivity. For this reason some experts suggest that a possible solution might be to follow the example of some national health agencies, i.e., the British one, which have started to sell their services, in addition to the pharmaceutical companies, also to the public health agencies. A direct link with DG Health, in spite of the one with the DG Enterprise and Industry, has been proposed because one of the most common critiques to the EU’s pharmaceutical policy is that it doesn’t mention a customer approach or public health promotion.

Another point is the feeling many have that neither the Commission nor the member States co-ordinate enough the activities of EMA: as a consequence EMA is put in the condition to demand too much to the pharmaceutical companies. It has been shown that the co-ordination mechanisms developed inside EU and the accountability tools aiming to keep under control EMA, in condition of operational autonomy, are well developed. On the contrary, the perception some interviews reveal, is that EMA doesn’t receive enough support, both from the political and the funding points of view. Some argue that “if the member States and the Commission would give more money and would “believe” more in EMA, it would be possible to

make centralized. "vigilance" (and effective pharmaco-vigilance) and scientific evaluation in addition to the evaluation and data diffusion activities".

A decision about a higher "support" to EMA's activities and in particular concerning EMA's institutional allocation inside the communitarian system and the link of the agency with DG Health, pertains to the European Parliament: a widely concerted political will is needed and some experts see in this fact, in addition to the possible pressures of the Commission, one of the main factors counteracting the opportunity to assist to a change in the philosophy of work and in the institutional position of EMA.

After ten years from the settlement of EMA there has been a good "recover" of authorizations at the central level from the national one and this is undoubtedly a positive signal of the increased recognition of the importance of EMA by the pharmaceutical industry and of the goodness of the centralized procedure of evaluation. The pharmaceutical companies are increasingly referring to EMA for the centralized procedure, even if it costs them approximately 400.000 €, also when they are not obliged, because of the security of the protection assured when the pharmaceutical are marketed.

Some positive comments are also directed, in opposition to the majority of the opinions, to the new membership of the Management Board: the fact that now they are appointed by Health Ministries (or in few cases by the National agencies) and not by both of them as it happened when the national members where two instead of one is considered as an improvement for the co-optation mechanism and the network management, even though almost nobody neglects the possibility of facing problems of independency from the national Ministries .

Stated against this background, the uniqueness of EMA sounds pretty interesting.

If the relationship with the Commission and in general the communitarian rules EMA follows are evaluated, it is evident that the accountability, personnel and audit processes of EMA are not different from the ones characterising the other EU's delegated bodies. On the contrary, EMA's peculiarities suggest to carefully arguing that EMA is a "typical" EU's agency. The co-ordination tasks of EMA and its "hub" role, in addition to its resource "dependency" from the pharmaceutical companies are the main points people interviewed took into considerations as the crucial and sensible elements to be evaluated when giving a judge about EMA's performance. If EMA is not a purely operational agency it is not possible to evaluate its performance relying only on the goodness and the speediness by which it processes the authorization requests. The first point the experts interviewed consider is the need to limit the influence of the member States on EMA: if from one point of view the co-optation may ease the relationship with the national health ministries, on the other side it can reveal an extraordinary degree of interference by them on EMA's management.

For this reason some critique this dependency and would propose a closer link with the national agencies and some even propose to appoint only "technical" representatives coming from the national agencies to guarantee the "independence" of the Management Board. It follows from this proposal that the funding should be guaranteed by the same Commission.

The analysis of EEA's case reveals significant insights: if the EU's Treaty is considered, it is interesting to note that one of its goals is to integrate the environmental concern into the general policy-making of EU.

For the first time in the history of EU, a delegated body had been created owning a legal basis different from the former Art. 235 of the Rome Treaty (referring to the "great utility provision" principle): EEA owns its legal basis on Art. 130S (now Art. 175) and for this reason some experts consider this agency as a "constitutional-type" agency (Everson, 1995) created to foster the realization of a principle included in the founding principles of EU. This founding base doesn't give EEA greater power or independence than the other EU's agencies and, especially in the past, EEA couldn't be engaged in activities other than information and collation.

At the light of the analysis performed above does this restriction still make sense?

Noticed that the design and aims of EEA have been unclear since its settlement, it has been clarified that this controversy has lasted for the whole EEA's life and a satisfactory integration of EEA with the communitarian system, and a recognition of its role out of the field of the purely information collation, has happened only recently. The compatibility between producing data for the policy-makers and the provision of "politically" sensible information to the public and of "policy relevant information" to the policy-makers has been widely questioned.

The concern of the Commission and of some member States to restrict EEA's activities to data gathering has been already documented: what is interesting is now trying to understand whether the will of some other member States and in some ways of the same EEA to make "soft-law" regulation through information has been converted in reality and which possible consequences it had on the organisational design of EEA and on its network management activity.

The institutionalisation of EEA inside the communitarian system was mainly influenced by three factors:

- the role the Commission;
- the starting design of EEA;
- the strategic and operational vision of EEA's management.

EEA was first designed as a divisionalised organisation with little attention to the "professional" nature of the organisation, on the possible internal horizontal co-ordination and on the network's management skills needed. The focus initially was on the attempt to "institutionalise" EEA inside the communitarian system: the first consequence was a negative reaction of DG Environment (at that time DG XI) which tried to downgrade the role of EEA and didn't collaborate in "marketing" EEA's products inside the Commission. Internally, EEA presented a low degree of co-ordination between its units. The management of the network was unclear and the aim of the first management staff was to get a strong credibility inside EU more than organising effectively the relationships with the organizations participating to the EIONET's network. As a consequence, member States could easily influence the composition of the *consortia* and increase the number of the organisations participating to the network.

The expectations of the Commission and the outputs issued by EEA had been, and sometimes still are, different: the independence of the Management Board, given

first the little attention devoted by the member States, is one of the most scaring factor for the Commission because EEA is independent not only in carrying out its tasks but also in formulating its work programme. Given the fact that the new Regulation didn't introduce new supervision tools, the improvement of the relationship between the Commission and EEA had been the consequence of two main elements:

- the will of the Commission to integrate EEA in its environmental policy-making activities;
- the new strategic and operational attitudes of EEA.

The organisational capacities of EEA have been gradually improved and the same DG Environment has been getting more and more involved in building up an effective collaboration between the Commission and EEA. The same new Regulation of EEA issued by the Commission answers to the need to modernize EEA in respect of its "new" position inside the communitarian system. Even though the role of EEA remains a "data gathering" one, its integration into the EU's environmental policy-making has increased.

EEA has issued prestigious reports which have been recognized as important steps forwards in the environmental monitoring; the sensibility about the environment has increased during these two decades and the importance of EEA at the eyes of the public has reached levels unimaginable when the agency has been settled up.

The European Parliament pushed for an increased autonomy of EEA in choosing its work purposes and has increasingly asked to EEA for independent reports on the state of the environment in Europe and for a stronger collaboration with non-EU countries. Even if the new Regulation didn't introduce new elements of organisational autonomy for EEA, it is now almost universally accepted, inside the Commission, that EEA is not playing only a subsidiary role of DG Environment but it is the main player when environmental information are requested and scientific insights about environmental policy making decisions are needed. The recent call of the Commission for a stronger integration of EEA's activities in the EU's environmental policy (EEA, 2004) confirms this new attitude.

The re-organization of EEA responds also to the need to better manage the EIONET's network: to manage EIONET a strict contact with the member States is needed. For this reason, the political pressures have influenced many decisions about ETCs: first at the central level – Management Board – where the decisions about where to locate the ETCs are taken but also at the local level – ETCs and other EIONET's bodies – where the decisions about the organisations to be involved in EIONET are taken and where operatively the data are gathered. Researches in the past (e.g., Schout, 1999) put in evidence that the three main concerns about ETCs have been their number, the focus of these centres and their quality.

Now the number of ETCs and of the bodies involved into EIONET has been reduced and EEA has re-shaped its internal structure so that no direct relationship between internal topic units and a specific ETC exists. The divisionalised structure of EEA has been changed in a more co-ordinated structure. In addition, the increased "professionalism" of EEA has improved the quality of the ETCs' outputs monitoring. The increase of number of the Scientific Committee's members,



consequence of the EU's enlargement but also of an organisational choice, breaks the direct link between the single experts of EEA and specific ETCs and adds a "collegial" dimension to EEA's outputs.

The constant monitoring of ETCs' activities and their reorganization have had as a direct consequence the greater attention of the member States for improving the quality of the ETCs' outputs, in order to maintain high their reputation and not to lose the communitarian funds: the scarce critiques to the outputs coming out from EIONET's activities in the recent years confirm the improvement of the network's scientific reliability.

In the end, is it possible to definitely affirm that EEA has found its way between information, analysis and policy-making? The "institutionalisation" process may happen also in the absence of a formal transformation: EEA's role is now changed, its autonomy in deciding its work plan has increased and its position in respect of DG Environment has changed.

EEA has modified its operational and strategic objectives and at the same time the attitude of the Commission towards EEA has become more flexible and open. The reputation of EEA and the quality of its outputs, in condition of budget and human resources' constrains has given EEA the possibility to gain an uncontroversial position inside the EU's environmental policy-making. This is an interesting example of "maturation" of an organization which has been successful in changing its internal design in order to face operational and "political" problems: the feedback action of the Commission and its new attitude towards EEA puts in evidence how the communitarian institutional setting is based on a delicate – turbulent – compromise between management and policy needs in a systemic framework where the performance of a delegated organisation is linked to the action of its principal with the additional element of a networked institutional framework influencing this dynamic by means of member States' intervention.

#### *Discussion*

Delegation in EMA's case is characterised by a four-sided relationship with its stakeholders. "Stakeholder" is meant an actor directly involved in a relationship with EMA and not necessarily as an actor "depending" from EMA: four different kinds of stakeholder relationships characterise the institutional framework in which EMA operates.

The principal-agent relationship *dilemma* is how to get the agent to act in the best interests of the principal when an information advantage for the agent exists (Sappington, 1991). Control theory suggests that when consequences of agent's actions are homogeneous and therefore easily-monitored, an after-the-fact control is preferred to a before-the-fact control, which should be chosen when consequences are unique and hard to monitor (Thompson, 1998). It has been underlined that traditional budgeting and regulation are at the base of the principal-agent relationship between Commission and EMA. Is it possible to argue that Commission-EMA relationship is regulated only by traditional principal-agent control mechanisms?

When the case study has been analysed, it has been stated that "professional" elements stay at the base of this relationship: now it should be added that agency

theory coexists with elements of exchange theory. The Commission cannot be considered a pure "customer" of EMA in the sense that exchange theory provides a reciprocal process in which the customer gives money in return for goods and the customer normally has a choice among a number of competing suppliers (Alford, 2002). EMA depends from the Commission, in the sense that it is the Commission (the principal) to delegate EMA (the agent) the execution of the pharmaceuticals' evaluation process. What is peculiar of this relationship is the fact that the "contract" between those two actors is not based only on outcome performance standards but both on formal mechanisms of control typical of a delegation relationship and on "professional" mechanisms of reliance.

The Commission is a "beneficiary" of EMA's services (Lamb, 1987) in the sense that it receives a service or benefit but gives no money directly to the organisation in return for the service. This kind of exchange is also characterised by the formal check of EMA's outputs by the same DG Enterprise and Industry: this *ex-post* monitoring process doesn't attain the quality of EMA's outputs but mainly their formal coherence.

On the other side, the relationship with the pharmaceutical companies cannot be considered only a "client" interaction. It is out of the aim of this dissertation to enter in the debate over the validity of the "customer" concept in the public sector (see for instance Frederickson, 1997 and Moe, 1994). Here it is important to underline that elements of professionalism and compulsion have to be added to the definition of the EMA-pharmaceutical companies' relationship.

A company may demand EMA to have its products evaluated in cases where it is not obliged to do that; in other cases this request is a duty for the company. In the first case, the company is pushed to ask for a centralised authorization first because of the net gain it has on the market, and as a second point because the reputation of EMA guarantees the fairness of the evaluation process.

Pharmaceutical companies are at the same time "paying customers" and "obligates": they are paying customers when they can choose between competing substitutes (EMA and the national authorities); they are obligates because they have to choose the central authorization to get some of their products marketed in the entire communitarian market. In addition, pharmaceutical companies should provide information, compliance and co-operation to EMA in the context of the pharmacovigilance.

The most important peculiarity of this relationship is represented by the resource dependency of EMA from the fees paid by the pharmaceutical companies: resource dependency theory emphasizes that when elements in the environment have power over an organisations, it is logical to assume that the organisation will try to pursue activities that contribute to making the environment more friendly (Pfeffer, 1972). Co-optation is the natural consequence. Again the picture in this case is more complicated. Pharmaceutical companies' representatives are not co-opted in EMA's Management Board and even if many experts argue that friendly informal relationships exist between EMA and the companies and that EMA's policy is biased towards industry competition's defence more than health protection, other opinions go in the direction of recognizing an acceptable level of independence of judge of EMA. To bridge the gap between those two positions is the "professional"

reliability of EMA: if EMA provides scientifically justified authorization (both in the case the evaluations are “requested” or “mandatory”) the resource dependency from the pharmaceutical companies might be considered only a direct product of the “exchange” relationship existing between EMA – the provider of the service – and the pharmaceutical companies – the obligates or clients of the service.

The third side of the stakeholder relationship regards the link between EMA and the national health agencies. EMA bases its “professionalism” on the experts assigned to it on a temporary basis by the national agencies. This point is crucial: the non-binding tools put in essence to manage this network have been already analysed; here it is interesting to underline that without this collaboration with those national stakeholders the effectiveness of the relationships of EMA with the Commission and the pharmaceutical companies would be dramatically affected.

National agencies “delegate” EMA to perform centrally what they perform at the decentralised level. This form of delegation doesn’t take the form of a principal-agent relation because it is consequence of a political decision of the Commissions (or better to say, of the member States) to centralise some processes of pharmaceutical authorization at the communitarian level. The national agencies don’t “control” EMA but are requested to support its activities providing the needed expertise to EMA. On the opposite side, EMA becomes a “forum of exchange” where experts coming from different national backgrounds share their competences, experiences and professional values.

If in the Management Board, member States’ representatives operate in some cases on behalf of their “principal” – the national Health Ministries – in the Scientific Committees they usually operate as “professionals”. One of the direct consequences of this process is EMA’s “reputation building”: this process has positive consequences both on the Commission-EMA-pharmaceutical companies’ relationship, and on fostering the creation of “soft” tools for managing the networked institutional setting in which EMA operates.

Veterinarians, doctors and patients represent the last side of EMA’s four-sided relationship with its stakeholders. They indirectly consume value produced by EMA (pharmaceuticals’ authorization) but they receive “public” value, while pharmaceutical companies receive a sort of “private” value (and this is the reason why they directly pay for it). Exchange theory doesn’t account for these kinds of relationship: the concept of “social exchange” should be inserted in the analysis. The concept of social exchange offers a more structured way of comprehending them than merely seeing them as “stakeholders” (Moore, 1995) and it provides a variety of contributions from them, such as co-operation, compliance or, in the case of pharmaco-vigilance also co-production. The public benefit they receive from the relationship with EMA is not consequence of a “direct exchange” but of a wider type of “generalised exchange”: the public organisation, in this case EMA, provides public value to these actors in the very act of providing private value to its “clients” (Alford, 2002).

These actors cannot be compared to the “citizenry” which operates in the traditional social exchange with the Government because they cannot vote for representatives actively operating at the public level (they have representatives in EMA’s

Management Board but these representatives cannot vote) but in some ways they represent all the possible "public" of EMA's decisions<sup>43</sup>: those who prescribe medicines and those who use medicines.

In this sense, the public agency – EMA – acknowledging that the community it serves is engaged in an exchange process involving complex set of values and parties, may find it in its same interest to "serve" them as well as possible, especially in the case it relies on them for "active" services as the pharmaco-vigilance one.

Both EMA and EEA cases present the problem of "efficiency measurement". If the problem is addressed by means of the conceptual lenses of public management, one of the first questions coming out from the analysis is how to measure the impact of collaborative relationships on the efficiency of the "command-control" chain between principal and agent. From this question it follows the necessity to evaluate the impact on policy-making and on the internal efficiency of the agency.

Above, it has been showed that the four-sided relationship EMA has developed with its "stakeholders" had a significative impact on the reputation of EMA and on the institutionalisation of its role inside the EU's setting. Even if no quantitative indicators have been used, the improvement of EMA's management efficiency, and on a "policy" level, the creation of a more reliable communitarian system of pharmaceuticals' regulation seems evident.

If now the attention is focussed on EEA's case, to perform this analysis from a different perspective might be useful. Here the main dimensions to be evaluated are the institutional evolutionary process of EEA and the definition of the effects of overlapping, conflict and collaborative functions developed with the communitarian and not communitarian bodies on its management efficiency.

In chapter 7 and 8, the institutional evolution of EEA has been already noticed: the effectiveness of EEA as a provider of reliable and high quality information has increased and also its role inside the communitarian system has been clarified. The interviews reveal that the problems between EEA and its main reference in the Commission, DG Environment, have gradually disappeared also at the light of the increased expectations the Commission and the European Parliament have on EEA's performance. To have recognized that *ex-ante* and *ex-post* evaluations of policy implementation are becoming important features for the European environmental policy-making and that EEA might play a significative role in these fields, means that on one side the Commission is increasingly recognizing in EEA the most fitting organization to deal with environmental topics inside EU and on the other side it is the consequence of the change occurred inside the same EEA with reference to its management – from "entrepreneurial" to "professional" – and to its strategy – to be more policy-oriented.

Of course this process has been slow and gradual and still it can be noticed that in the same Commission there is a certain reluctance to "decentralize" policy tasks. Commission's officials recognize the importance for EEA to be more and more

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<sup>43</sup> To be more precise it might be argued that they are subjected to consequences of DG Environment and Enterprise's decisions because EMA lacks of decision-making power. When stated against the analysis performed in chapter 6, it should be clear what is meant in this context.

integrated in the communitarian environmental policy-making process but at the same time underline that "prioritisation continues to be necessary". The need to better coordinate EEA's activities with the other "internal" stakeholders, i.e., with Eurostat, is still a sensible issue. Additional tasks cannot be disjoined from additional funding: being EEA still imposed no to get external funds in a significative amount, there is the constriction to undertake additional activities only if appropriate funding is obtained by the Commission or from third parties but only when "EEA's independence is not endangered".

In this context it has to be read the conclusions of the evaluation report on EEA of the Commission (Office for Official Publications of the European Communities, 2003: 20). Even if it is recognized that EEA should enter into fields different from establishing the state and trends in the environment and reporting information, and entering into other stages of the policy cycle, it is recommended that "it should avoid putting its reputation at stake by becoming a player rather than an independent source of information". The diversification of EEA's products is evident: EEA is not anymore only a "report producer" but it "offers" a wide range of products and services which are possibly influencing the policy-making phase. The fear of the Commission and in particular of the DG Environment is in this sense justified.

Overlapping, collaborative and conflicting functions characterise the relationships of EEA with its "stakeholders": the descriptive analysis performed in chapter 7 denoted the main features of those relationships. Here it is useful to apply the scheme of analysis used in the case of EMA to find similarities and differences with the EEA's one and to define a theoretical framework to explain the findings.

Between Commission and EEA, traditional budgeting and regulation are at the base of their principal-agent relationship: the "disturbing" elements characterising the EMA's case are not recognizable in the EEA's one.

What is evident here concerns the attempt of EEA to increase the importance of its role inside the Community at expenses of its relationship with its principal. It has been underlined that the resource dependency of EEA from DG Environment and the *ex-post* monitoring of DG Environment on EEA's outputs follow the pattern of the relationship between a principal involved in the decision-making phase and an agent performing executive tasks.

EEA doesn't own regulatory or authorization tasks: the crisis factors have been individuated in the unclarity in defining EEA's tasks and in the attempt of EEA to "market" its role inside the Community. The conflicting relationship with Eurostat and DG Environment are consequences of those two factors: only the evolution of EEA as an organisation and the improvement of its reputation have partially solved the problems attached to those relationships.

The process of EEA's "reputation building" had consequences also on its relationships with EIONET's components and the public in general. The "public good" issued by EEA is not directly used by the citizens as in the case of the pharmaceutical products authorized to be marketed by EEA. In the case of the environmental policies, the role of EEA is more indirect.

EEA acts as information provider for the Commission and the member States: EIONET is the tool by means of which data are collected and analysed. Into EIONET, EEA performs a co-ordinating role. In the case of EMA, national health agencies provide the expertise needed for performing scientific assessment at the central level. In the case of EEA, decentralisation of functions and responsibilities occurs.

The collaborative relationships existing between EEA and EIONET's components are only partially consequences of the particular principal-agent relationship between EEA and the ETCs but mainly of soft instruments of collaboration between all bodies involved into EIONET.

Description of those relationships and of the tools used to maximise the collaborative advantage coming out from those interactions has already been done: here it is interesting to interpret them at the light of the model developed in the research. Elements of principal-agent relation might be found between EEA and ETCs: after-the-fact controls have been developed. ETCs are resource dependent from EEA and a constant *post*-evaluation of their outcomes is performed.

Even more than in the case of EMA, assumptions of asymmetric information and conflicting stake between the executive managers (agents) and the residual claimant (principal) have to be done and it has been shown that management manoeuvres to avoid control mechanisms. But agency theory considers organisational processes as a "black box" and cannot explain the processes surrounding such opportunism and information asymmetry (Huse & Eide, 1996).

The analysis here should take into account the networked setting in which this relationship occurs and the disturbing factors coming from external "political" influence. ETCs cannot be considered merely executive agencies acting on behalf of EEA: they have a certain degree of organisational and decisional autonomy. *Ex-post* monitoring sanctions may be imposed on them but the decision to close an ETC depends not only on technical reasons but it involves a political dimension in which member States' influence is predominant. Collaboration within EIONET's components on the contrary is not solely competence of EEA: national organisations are involved and the role of EEA is sometimes extremely limited.

The double-sided relationship having EEA at the centre, in between Commission and EIONET's components, is what characterises this case. Elements of principal-agent theory co-exist with network management mechanisms based on "soft" law regulation. Behavioural forms of monitoring co-exist with traditional budgeting and regulative tools.

In addition, the definition of "information" as a public good adds another dimension of analysis: EEA provides the public<sup>44</sup> with environmental reports and in this sense the citizenry is a "beneficiary" of EEA's outputs. At the upper level, it is the Commission to utilize EEA's "products"; at the lower level it is the European public

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<sup>44</sup> Public is meant not only the member States. The follow-out of EEA's environmental reports concerns also the citizenry: in this sense information might assume a political value and they might be used as an instrument of pressure on the same member States' decision-making processes.

to enjoy the results of EEA's activity: member States' policies in the environmental fields may be influenced by the Communitarian pressure to change.

From a scientific point of view, the co-existence of principal-agent theory, collaborative relationship's management and public goods' delivery, represents an extraordinary interesting case of study and the confirmation that European agencies don't completely fit in the traditional categories of analysis developed by public management to assess delegated modes of governance.

### **8.3 Towards a revisited EU's agency model?**

The chronological evolution of the agency model inside EU has witnessed an increased importance of the delegated bodies inside the EU's institutional architecture: the last "wave" of communitarian agencification demonstrates that the role of the agencies has profoundly changed: they don't anymore represent "residual" organisations devoted to perform purely executive tasks but are between the main agents of change of the European regulatory system. Where the Commission cannot influence the role of the member States and don't own enough competences to autonomously develop "new" regulatory systems in fields before entirely managed by national and sub-national administrations and to evaluate and control these networks of bodies, several times this duty has been delegated to an EU's agency.

In this dissertation different accountability modes have been defined: in brief it is possible to distinguish between "political" and "administrative" accountability tools. Many authors, when analysing the EU's institutional setting, focus on understanding the way to render more "democratic" the decision-making processes more than on the best manners to control the delegated bodies. In this research it has been demonstrated that EU is not an unaccountable administrative system but in addition to the "technical" accountability tools, direct and indirect mechanisms of democratic accountability have been developed. The main problem in this sense concerns the unclear distinction between legislative and executive authority inside EU and as a consequence, the problematic designation of the body in charge for the management of the accountability tools.

The EU's setting generally makes difficult to define a clear chain of delegation and it might be more useful to consider EU as a system of multiple interlinked principals delegating to single or multiple agents. In the dissertation the attention has been devoted to consider the Commission as the main principal. In this sense, Curtin's definition (2005) is appropriate: the Commission can be considered a "putative" principal in the chain of delegation at the EU's level, having been appointed by those who are directly (European Parliament) or indirectly (the European Council) elected. Following this approach, the Commission is itself a principal because it may use its authority to establish "non-majoritarian" institutions through a public act of delegation, delegating its powers and tasks to those non-majoritarian institutions. The agents are those who govern by exercising delegated powers: the Community agencies.

The first step of the analysis has been to find the points of contact between the agencification processes occurred at the communitarian and at the national levels. A

relevant convergence has been found: to the increase in number and functions of the EU's delegated bodies has not corresponded a parallel attention of the legislators for their regulation. The unclear legal position of the European agencies has been one of the main problems for a proper development of this mode of governance inside EU and its legitimation. Recent legislations go on the contrary towards this direction but the absence of an omni-comprehensive set of law regulating the state of being of the EU's agencies is still felt. The communitarian system has been increasingly going towards the definition of an "EU's agency model" and of a properly institutionalised system of checks and balances building up an accountability framework to control the delegated bodies. At the same time, even if the Commission delegates specific tasks of implementation and administration, because of the strict limitations imposed by the Meroni doctrine, it is the same Commission to retain control over the operational performance of these tasks.

If the communitarian framework is considered, it seems clear that delegated bodies are subjected to accountability mechanisms which make them reliable to the Parliament, the Council and to the Commission. The relationship with the other European institutions is guaranteed by a financial regulation which is the basis for each delegated body. The relationship with the Parliament and with the Council is also strong and the Commission plays the role of main (executive) "controller" of the agencies' activities. The relation between the "political" level (Parliament and Council), the "policy-making" level (Commission) and the "operational" level (delegated bodies) is also accurately regulated.

Delegated bodies are indeed subjected to a limitation of their autonomy by other measures: for instance, the resource dependency from the Commission, the limited possibility of playing a significative "decision-making" role, the "packing" of their Management Bodies with representatives of the European institutions and of the member States. To these mechanisms, the external financial control and the judicial control have to be also added.

To define an EU's agency, an analysis of the features "commonly" characterising the communitarian delegated bodies, from the organisational point of view should be done. In chapter 4 it has been shown that every EU's agency owns an appreciable level of specialisation identified in its founding statute; it has legal personality and operates following the rules of administrative transparency.

Other elements characterising most part of the EU's agencies are represented by the parity of the executives (in the agency's Management Board, the member States are always represented) and by the high representation of Commission's officials and in some crucial cases of stakeholders' representatives. The "non-representation" of the European Parliament is peculiar in the vast majority of the agency's Management Boards. It also exists a direct democratic accountability performed by the European Parliament and the Council and an external audit by the European Court of Auditor.

In the recent years new agencies dealing with regulatory tasks have been established. In those cases, even if general conditions governing their settlement, management and accountability are precisely defined, an organisational and functional autonomy from the Commission is more evident. These agencies have been considered products of an "administrative integration" process where a europeanization of tasks



formerly performed by the member States are not given to the Commission as such but are managed through a network relying on the contributions of member States' institutions to a "hub" institution – the EU's agency. The implementation of these tasks is so shared between communitarian institutions and public or private national and sub-national institutions.

A risk run by these agencies is to be "captured" by its stakeholders: this is a risk run also from the national regulatory agencies but at the communitarian level the "co-optation" of stakeholders' representatives in the Management Boards might be seen more as an opportunity than as a problem. It has been underlined on the contrary that it might become a problematic situation in the case an agency is dependent from non-communitarian resources, as in the case of EMA .

The analysis of the two case studies and in general, the evidence coming out from the assessment of the whole agencies' system inside EU, puts in evidence that it is not only the Commission but also the Council to delegate executive and operational tasks, in many cases previously belonging to the member States, to European level agencies. The development of participatory procedures for the stakeholders in the decision-making phase in EMA and in most part of the newly established agencies confirms this attitude.

To evaluate the performance of decentralised modes of governance inside EU, and interpret their functioning through organisational conceptual lenses of analysis gives the opportunity to underline that more than concentrating on the procedure to "constitutionalise" the community administration and developing vertical forms of accountability based on mechanisms taken from the "representative democracy" it would be better, because of the characteristics of the EU's political system, to go towards the definition of proper horizontal accountability modes in a coherent framework recognizing at the same time the peculiarity of each "agency". The recognition of the importance of delegated modes of governance inside EU as an "accepted" mode of delivering communitarian services and managing selected policies has increased jointly with the definition of a common communitarian procedure to be followed in the settlement of the agencies.

The conceptual lenses of public management used to develop the dissertation influenced the analysis towards the definition of a proper model of delegated body inside the communitarian system. The analysis has followed three main dimensions:

- the assessment of the relationships between the EU's agencies and their main principals;
- the definition of the organisational and strategic processes of the agencies;
- the evaluation of the networked relationships between the agencies and their stakeholders.

For what concerns the first point, it has been pointed out that, at the light of the new Financial Regulation, the relationship between the most part of the agencies and the other EU's bodies follows a common pattern. Procedures of democratic and executive accountability, audit procedures, involvement of Commission's representatives in the agency's Management Board are common features of almost all the relationships agency-EU's bodies. The importance of individuating a

univocal structure eases the management of the “controllers” on the “controlled” delegated bodies.

The analysis of the organisational and strategic processes of the EU’s delegated processes puts in evidence the specialisation, autonomy and transparency features of the agencies. Also with reference to this issue, the Executive Director’s and Management Board’s appointment and responsibility follow patterns establishing common rules for the majority of the agencies. In the case studies taken into consideration - the “institutionalisation” processes of EMA and EEA – it has been noticed that the operational and strategic choices of the agencies may heavily influence the growth of the organisation and its role inside the communitarian system. The controversial story of those two agencies suggests that, from one point of view the existence of accepted communitarian rules may avoid the Commission loosing control over the agencies and, from another point of view, that it exists a “free” space that the agency’s management may use to “institutionalise” its organisation. In particular, the story of EEA teaches how much is important a proper definition of the organisational structure and tasks of a delegated body, in order to grant legitimation in its institutional setting.

The relationships of the EU’s agencies with their stakeholders have been widely debated above: here it is worthwhile to underline that a model of “hub” agency is becoming more and more essential for the good functioning of many communitarian policy areas. If a “model” of modern EU’s agency is to be defined, it is necessary to consider the regulatory agencies operating in a networked institutional framework. The analysis, on one hand of the participation of stakeholders’ representatives to the Management Board’s and Scientific Committees’ activities and on the other hand, of the importance of national and sub-national, public and private bodies for the management of many agencies’ tasks (i.e., EEA) is evident. Contrary to what shown in the case of the relationship Commission-agency, here the rules are less codified and even if the representation of stakeholders’ representatives is strictly regulated, the management of the network of organisations linked to a specific agency is based more on “spontaneous” and “voluntary” forms of collaboration.

At the light of what said above, does it still make sense to try defining an EU’s agency model? This dissertation has tried to give an answer to this question, investigating not only the organisational mode of delegated governance as it stands but inserting it into the peculiar setting of the European Union.

“Traditional” frameworks of analysis developed by public management scholars have revealed their limitedness when used to describe and interpret delegations of executive and regulatory tasks from the Commission (and the Council) to the EU’s agencies because of the environmental peculiarities characterising an institutional system where the democratic deficit makes difficult to apply the concept of “vertical” delegation and the lack of decision-making power of the delegated bodies affects the possibility to develop an efficient form of “horizontal” delegation.

To solve this controversy it might be useful to consider a “revisited” EU’s agency model in the sense that the delegated bodies actually existing into the communitarian system are organisations established first because of political reasons and only recently as the consequence of an evident operational deficit. To outrun the

limitations imposed by the Meroni doctrine to the establishment of delegated bodies inside EU it might be useful to evidence the necessity to settle up organisations operating as administrative tools dealing with matters the member States don't want to leave to the Commission's responsibilities and the same Commission cannot assume as its own operational priorities.

From an administrative point of view, the reorganization of the rules defining EU's agencies financial, staff and operational processes tries to develop an efficient and unequivocal internal framework for checking and controlling the activities of the delegated bodies. From the institutional point of view, it seems evident that EU's agency model goes towards the settlement of regulatory organisations having as main objective the management of different policy regimes in collaboration with the same member States. The "turbulence" of such a networked institutional setting obliges to be careful about stating definitive conclusions because if the relationship between Commission and agency operates following well defined conventions, only further researches will clarify if the collaboration with national and sub-national organisations, which can be only partially confined into a predefined set of conditions, might really work effectively.

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