**Master Thesis**

# European Agencies in Technocratic Governance:

## Influence of agencies on policy-making

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## Abstract

Regulatory policies are highly technical, requiring a high level of expertise and scientific information from experts rather than political discussions from politicians. This is a central feature of technocracy and the current form of EU governance. Due to the need of expertise for policy-making, the Commission has increasingly relied on European agencies for their policy inputs. Accordingly, the establishment of agencies has boomed, resulting in 36 agencies at present and more to come in the near future. Delegation to European agencies brings important benefits to the EU: yet, it also causes the legitimacy deficit argument since democratically elected politicians and ordinary citizens cannot meaningfully participate in policy-making without expertise.

Amid the well-known phenomenon of agencification, this thesis seeks to find out the conditions that formally and informally affect influence of agencies on policy-making. In this thesis, 'influence' is understood as persuasion among seven forms of influence suggested by Dahl and Stinebrickner (2003). Persuasion is influence through information, argumentation, or explanation that leads others to do or think in a way that the influence-holder wants.

Keeping this in mind, I suggest three indicators that determine agencies' influence. They are resources, environment and motivations. 'Resources' mean the information that European agencies process and produce based on their expertise and scientific knowledge. This indicator looks at the characteristics and structurability of information. The second indicator is 'Environment'. It is the institutional setting in which agencies use their resources and decision-making takes place. The level of coupling of agencies and the level of formal restrictions imposed on decision-makers are considered. 'Motivations', lastly, mean reasons of European agencies to network with stakeholders. The frequency of agencies' contact with stakeholders and the type of activities organized by agencies for stakeholders are looked at.

The hypothesis is that European agencies can exert high *de facto* influence on policy-making if all three indicators in agencies are focused on enhancing the production and usage of information. In order to test this hypothesis through the empirical analysis, the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) are chosen for the case studies. While all indicators in EMA are positively related to high influence, in EFSA, the characteristics of information, formal restrictions and motivations are negatively related to influence. Among these, I argue that EFSA's motivations informally but mainly cause its low *de facto* influence.

The EMA case proves that effectiveness – the goal of technocratic governance – and participation of stakeholders – input legitimacy – can mutually reinforce each other by utilizing participation in the production and usage of scientific outputs. It has indeed resulted in EMA's high *de facto* influence, and the hypothesis was supported.

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# 1. INTRODUCTION

Since the first day of the European Coal and Steel Community, the European Union (EU) has gradually expanded its role. A large number of functions that were traditionally performed by nation states has been transferred to the European level, and free markets, privatization and liberalization have become the main concept of the political economy of the EU. However, it does not mean that rules have disappeared (deregulation); rather, there have been wide-ranging regulatory reforms with new rules at the European level (re-regulation) (see Majone, 1990). This has induced a structural shift from the 'positive' to the 'regulatory' state (Gilardi, 2008; Majone, 1996). Accordingly, the European Commission, as a policy initiator, has expanded its competence mainly in regulatory policy-making. Since regulatory issues are technical, knowledge, instead of politics, becomes the critical resource, and experts, instead of politicians, come to the center stage of public policy-making. It stems from the belief that reliance upon qualities such as expertise, policy consistency, fairness or independence of judgment is more important and efficient than reliance upon direct political accountability (Majone, 1996; Gilardi, 2002). This is a central feature of technocracy and the current form of EU governance.

However, it is widely understood that the Commission lacks both expertise and resources for policy-making in the technocratic mode of governance. Furthermore, legislative processes are generally too slow to keep up with the rapid pace of change in highly technical policy areas. Then, how are European policies drafted and decided? Since the Commission has a genuine need to seek external expertise for regulatory policy-making, it has established and increasingly utilized European agencies that perform specific tasks with their expertise. Indeed, European agencies are viable actors in technocratic governance, and European Commission Vice-President, Margot Wallström, said "[a]gencies have a significant role to play in the EU and have made a valuable contribution to the EU over the years" (CEC, 2009). Moreover, the number of agencies has increased fast in the last decade. Currently, there are over 30 European agencies, and they cover diverse policy areas ranging from environment and fundamental rights to medicines and fisheries. 'Agencification' is now an important phenomenon in the European institutional landscape, and there is no sign that the agencification process is likely to slow down soon.

Since European agencies became a vital actor in policy-making, scholars have given increasing attention to the role of agencies in the public policy-making procedure in the EU.

Most research focuses on a legal understanding of the institutional design, independence, functions, and autonomy of agencies (see, for example, Kelemen, 2002; Krapohl, 2004; Eberlein and Grande, 2005; Geradin et al., 2005; Gehring and Krapohl, 2007; Groenleer, 2009; Wonka and Rittberger, 2010). There is also a considerable number of literature about the conditions for the establishment of delegation to the European agencies based on the legal perspective or the principal-agent framework (see, for example, Permanand and Mossialos, 2005; Dehousse, 2008; Gilardi, 2008). The issues of agencies' accountability or legitimacy have also received academic attention (see, for example, Curtin, 2005; Vos, 2005; Borras, 2006; Busuioc, 2010a). Moreover, scholars have extended their research into the cross-national comparative analyses of agencies at the domestic level (see, for example, Thatcher, 2002; Christensen and Lægreid, 2006; Trondal, 2011).

However, while the volume of literature on European agencies is growing, far less attention has been devoted to agencies' real-life influence considering both formal and informal mechanisms in the European policy-making process. This is problematic because analyzing policy-making only through a formal or a legal perspective tells us no more than one side of the story. For example, some scholars suggest that agencies with the main task of information gathering do not exert as much influence as regulatory agencies do on policy-making. However, by analyzing informal resources and informal institutionalization processes after the formal creation of agencies, Martens (2010, p.898) argues that the European Environment Agency (EEA), a typical information gathering agency, "has gradually learned to play and enjoy the insider role, and developed into an important and viable institution in the EU administrative system". Therefore, I stress that understanding the formal functioning of a European agency is the first step, but the next step should focus on the actual capacity and ability of the agency based on informal arrangements.

### 1.1 Introducing research questions

For regulatory policy-making, the Commission relies increasingly on European agencies. This directly implies that gaining insight into both formal and informal arrangements of agencies' influence is crucial if the aim is to understand how policy-making progresses in practice. Accordingly, the main research question in this thesis is: *what are the conditions that formally and informally affect influence of European agencies on European policy-*

*making?* In other words, the research question aims to find out the conditions that affect '*de facto* influence' of European agencies on policy-making.

This question reflects the need to develop common ideas of agencies' roles, purposes and influence not only based on legal descriptions but also based on what is really happening in practice. While recognizing the academic gap and the empirical weakness particularly on agencies' informal mechanism of influence, it also requires more empirical considerations on the role of European agencies and their expertise in the policy-making process. The need to understand real-life influence of agencies in European policy-making has never been greater since agencies are allocated with more resources than ever before, and the establishment of agencies is not likely to stop anytime soon. Especially, the issue is significant when evaluating the current pattern of EU governance that increasingly utilize European agencies, and also when thinking about likely implications on the future of EU governance. In fact, European agencies are considered to be "the next mode of growth of the Union, perhaps they could become an opportune vehicle for enhancing transparency and participation in Union affairs" (Shapiro, 1997, p. 291).

When considering the research question in the context of the theoretical framework of technocracy versus politics, in addition, it is related to the normative discussion of technocratic governance and its social relevance. Since technocratic governance gives more attention to actual problem-solving in an efficient and effective manner, rather than strong redistributive policies, a political debate among the Member States is neglected. Moreover, as EU policies are technical and relatively opaque (Radaelli, 1999), the voice of the ordinary citizens and their representatives are hardly heard during the policy-making process. While expertise plays a bigger role than politics, the EU is faced with criticism of a democratic deficit. What is generally concerned is 'exclusion' of citizens and politicians and lack of legitimacy, accountability and transparency. However, in the theoretical framework, I will explain that the concept of legitimacy in relation to democracy is different from what is considered as legitimate in technocratic governance. Moreover, through the empirical analysis of agencies' informal networking with actors such as industry representatives and civil society organizations, which I will present below, I suggest that the democratic means of 'inclusion' is also accommodated.

Given the fact that agencies are proliferating – and also becoming "a new paradigm of European governance" (Geradin et al., 2005) – and that the reliance on them is growing, it is

crucial to gain a better understanding of how agencies, based on their formal and informal influence, affect the shape and the outcome of public policies in practice.

### 1.2 Analytical framework

The aim of this thesis is to gain empirical insight into formal and informal influence of European agencies in order to explain how European policy-making is done in practice. It will also contribute to providing a better understanding of technocratic governance of the EU and its policy-making patterns. In order to achieve this aim, it is important to find a right balance between the theoretical background and the empirical analysis. The latter is done through an in-depth case study of two agencies – the European Medicines Agency (EMA) on European pharmaceutical policy-making and the European Food Safety Authority (EFSA) on safety regulation of genetically modified organisms. As for the theoretical background, the main features of technocratic governance, its concerns compared to the traditional concept of politics, and conceptualization of influence are provided in this thesis.

There are two reasons to focus on both the theoretical and empirical aspects: first, a better understanding of relevant theory and clear ideas about the concepts and operationalization of variables can be contributed as a strong foundation when conducting the empirical step of this research; and second, there is no clear definition of the concept of 'influence', and also there is a severe lack of research on the subject of *de facto* influence of agencies using systematic indicators that can measure influence. In short, it is precisely the aim of this exploratory research to present the empirical findings of agencies' influence, on the basis of the conceptualization and operationalization of influence, at the formal level, as well as in practice, in connection with the technocratic mode of governance.

The EU policy process can be conceptualized as consisting of three distinct phases: first, the agenda-setting or pre-proposal stage; second, the decision making stage; and, third, the policy-implementation stage (Christiansen and Larsson, 2007). Although there are European agencies operating in each of the three phases, most of them are designed to function in the pre-proposal stage. They provide technical opinions and other necessary scientific inputs to the EU institutions, and on the basis of this information, the Commission draws up proposals and takes decisions. However, as it will be explained in detail in Chapter 4, 'Concept and indicators of influence', there are mechanisms that enable agencies to go beyond the agenda-

setting stage and influence in the decision making level. Therefore, in this thesis, the focus is given to the role and activities of agencies in the first two phases of the EU policy process.

I argue that there are three factors that formally and informally affect the level of influence of European agencies on policy-making, and they are briefly mentioned here (see Chapter 4 for the detailed explanation and operationalization). '*Resources'* is the first indicator of influence and closely related to the theoretical framework of technocratic governance. Considering the fact that European agencies are the vital actors in technocratic governance based on their specialized expertise, the policy areas where technocracy can be best applied are also the areas where agencies can utilize their expertise in a most effective and efficient way. According to Radaelli (1999), technocratic governance works most effectively in policy areas where political salience is low and uncertainty is high. Consequently, agencies are likely to exert high influence if they provide technical information as policy input that is characterized with low political salience and high uncertainty. In this sense, it is important to look at political salience and uncertainty as the characteristics of information, which determine influence of agencies.

When policy issues have high uncertainty, politicians and ordinary citizens puzzle over their interests because the issues are too complex for them to discuss without expertise. Since uncertainty is often, "implicitly or explicitly, perceived as something which can be eradicated or at least reduced by research or monitoring" (van Asselt and Vos, 2006, p.316)[1], politicians and citizens turn to experts in order to reduce uncertainty pertaining to policy issues. Experts are capable of explaining what is important with regard to the issues and providing solutions. In addition, high political salience is decided by high economic, scientific, political or normative stakes involved in the policy issue. When there is high salience, conflict may arise among groups within a society and/or among nations at the international level because they pursue different interests in the policy areas. For instance, environmental issues are typically associated with high political salience because strict regulations of environment can cause a negative impact on productivity growth of vital industries in some countries. By contrast, if an issue is not politically salient, politicians and citizens neglect the issue since it does not directly concern their interests.

[1] It implies that uncertainty is equated with the absence of scientific knowledge; yet, some scholars argue that sometimes more knowledge can also increase uncertainty (see van Asselt and Vos, 2006; 2008).

Furthermore, resources are the information that European agencies process and produce based on their expertise and scientific knowledge on a certain policy area. If one seeks to examine how an agency processes and produces information, structurability of information in the agency should be considered. Structurability in information processing is the availability of well established cognitive strategies and problem solving routines which are able to structure, more or less easily, the incoming data into meaningful configurations, extract their relevant informational content and almost automatically suggest an appropriate reaction or course of action (Blom et al., 2008).

'*Environment'* is the second indicator, and it means the institutional setting in which European agencies perform their obligations and other relevant activities. What should be considered here is loose or strict coupling of agencies in the policy-making process and the formal restrictions imposed on the decision making bodies. A social system (an organization, an institution, etc.) may be called 'strictly coupled' if the behavior of one of its units has direct and relatively fixed consequences for the behavior of other units (Blom et al. 2008). Within the framework of an analysis of political systems, strict coupling implies the competence of an actor (or ensemble of actors) to fix the premises of the future decisions of other actors (Blom et al. 2008). As for the formal restrictions, in addition, depending on the existence of the restrictions, decision-makers may be free to ignore or deviate from opinions of European agencies. Such restrictions imposed on the decision making bodies about ignoring or deviating from the agencies' opinions show that the decision-makers are acting properly and adequately, so that their conduct is above question (Meyer and Rowan, 1977).

'Motivations' as the last indicator of agencies' influence are linked to the reasons why European agencies network with stakeholders. This has been, in fact, overlooked in the relevant literature of European agencies. To be more precise in the context of this research, networks, as informal activities, are personal relations among multi-lateral actors and structures of such relations in European policy-making. Since informal activities of networking are not the agencies' main responsibilities or obligations, there must be valid reasons to do so. The starting point for analyzing this indicator is that based on motivations for networking which can add value to the role of European agencies in the policy-making process, agencies' influence can go beyond formal rules, and enhance overall influence of agencies further. The frequency of contact between agencies and each actor involved in European policy-making on the one hand, and the frequency of consultations and forums that

agencies organize on the other hand can tell us to whom agencies mostly focus on to create the network, and it reveals the main reasons to network with that particular actor.

The hypothesis of this research is that in technocratic governance of the EU, European agencies can exert high *de facto* influence on policy-making, which may go beyond their *de jure* influence, if all three indicators – resources, environment and motivations – in agencies are focused on enhancing the production and usage of information. The level of European agencies' *de facto* influence on European public policy-making is the dependent variable, and the three indicators, as the mechanisms both formally and informally determining influence of agencies, are independent variables. Since the concept of *de facto* influence is not a tangible object, how is the dependent variable understood and measured?

High *de facto* influence of agencies, which goes further than *de jure* influence, means that the Commission not only draws up draft proposals but also takes decisions solely based on agencies' input. The forms of agencies' input do not matter. They can be recommendations, opinions, reports and so on. But the point is that agencies' input is taken seriously and reflected without any disagreement on its contents both in the agenda-setting and decision making process. By contrast, low *de facto* influence of agencies, which may be the same as or lower than *de jure* influence, means that either Commission's draft proposals or the outcome of decisions (or both of them) are usually deviated from agencies' opinions. It may result from disagreement on the contents of agencies' input or simply because agencies' input is not considered when policy proposals are drafted.

One way to operationalize whether or not the Commission's proposals and decisions are solely based on agencies' input is to look at the numbers of quotations of an agency's opinions in Commission policy proposals. This information is found in agencies' annual reports and periodic evaluation reports of agencies. For example, the '2008 Annual Report' of the European Foundation for the Improvement of Living and Working Conditions (Eurofound) states that "the use of Eurofound expertise by the European Commission remains stable (with an annual average of 45 quotations of Eurofound work in its policy papers since 2006)". Moreover, the Commission is responsible for deciding on whether or not to grant marketing authorizations for certain products (e.g. genetically modified food, medicinal products for rare diseases). In this case, the Commission has to receive agencies' evaluations on applications of these products. Thus the contents of Commission proposals and decisions, rather than the numbers of quotations, are analyzed to check whether they are

in line with agencies' opinions. These documents are publicly accessible on the websites of agencies and the Commission.

Furthermore, one of the signs that a person or an organization has high *de facto* influence is that it generally receives support from other actors involved in the system or the procedure. It stems from the concept of 'output legitimacy' that "the goals are ones you endorse or at least that they are arrived at through processes you accept" (Christiansen et al., 2003, p.13). Thus, if a European agency has high *de facto* influence, it implies that other actors involved in the policy-process phases, such as stakeholders, will support agency's work. The level of stakeholders' support can be found in evaluation reports of agencies which are published based on the survey and interview results.

Table 1: *De facto* influence of an agency and operationalization

| ***De facto* influence:** | **Operationalization:** | **Data collection:** |
|---|---|---|
| Commission proposals and decisions based on agency opinions | - Numbers of quotations of an agency opinions in Commission's policy proposals<br>- Contents of Commission proposals and decisions that are in line with agency opinions | - Annual reports<br>- Policy documents from the agency and the Commission websites |
| Support of stakeholders on agency's work | - Survey results of the level of support on agency's work | - Evaluation reports of an agency |

Source: Author's compilation

The structure of the thesis is as follows. The next chapter introduces the main actors of this thesis; European agencies. It describes the agencification phenomenon and the reasons why competences are delegated to agencies at the supranational level. In the third chapter, I explain the main features of technocratic governance in the EU, as well as the concerns accompanied in technocracy. Then, in the fourth chapter, the term influence is conceptualized in detail with the analysis of the indicators that can measure influence of agencies. This chapter also explains the methodological framework with the introduction of two agencies – European Medicines Agency (EMA) and European Food Safety Authority (EFSA) – that are selected for the case studies. The following three chapters are dedicated to the analyses of the indicators in the context of EMA and EFSA specifically. Lastly, the conclusion of this thesis

reflects upon theoretical implications on the issue of democracy and legitimacy in the technocratic mode of governance and the empirical results. It concludes that for agencies to exert influence on policy-making in the EU, they should focus not only on providing accurate and timely information but also on utilizing participation of stakeholders in a way that can enhance agencies' scientific outputs.

# 2. AGENCIFICATION IN THE EU

EU agencies are no longer 'residual' organizations: they are a significant component of the functioning of the EU system and policy networks (Barbieri and Ongaro, 2008). European agencies have been set up in various policy areas, such as environment, railway, aviation, fisheries, chemicals, food safety, medicines and so on. The "EU's appetite for creating new agencies seems limitless" (Geradin and Petit, 2004, p.4), and it is unknown how many European agencies will be established more in the future. In this section, a well-known phenomenon of 'agencificaiton' is presented with the definition of a European agency. Then, the rationale behind setting up agencies at the European level is explained.

## 2.1 Agencification: what is a European agency?

According to Egeberg and Trondal (2011), 'agencification' at the national level is a phenomenon that has signified a transfer of government activities to agency-type organizations that are vertically specialized outside ministerial departments. This phenomenon at the European level means a transfer of competences that are traditionally performed by the Member States to supranational agencies which operate outside the main EU institutions (such as the Commission, the Parliament and the Council). What is a European agency and what role does it play in the EU?

In the EU, it is hard to find such an unambiguous and specific definition of an 'agency'. As a result, there exists some confusion as to what exactly makes a certain organizational entity an 'agency' and not a 'body', 'organ', 'office' or 'committee' of the EC/EU (van Ooik, 2005). Before the Treaty of Lisbon came into force, the EU had the three-pillar structure, and Community agencies which fell into the first pillar were defined on the EU website that:

> "a body governed by European public law; it is distinct from the Community Institutions (Council, Parliament, Commission, etc.); it has its own legal personality; and it is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task" (http://europa.eu/agencies/index, accessed on 24 October, 2010).

Recently, the term of 'Community agencies' is changed to 'Policy agencies' on the EU website, reflecting the changes from the Treaty of Lisbon, while remaining the same

definition of agencies mentioned above. Various scholars have proposed different definitions of agencies. Some explain that European agencies are "EU level public authorities with a legal personality and a certain degree of organizational and financial autonomy that are created by acts of secondary legislation in order to perform clearly specified tasks" (Kelemen, 2005, p.175; Wonka and Rittberger, 2010, p.733). Others generally define an agency as "an administrative organization with a distinct, formal identity, an internal hierarchy, functional capacities and at least one principal" (Levi-Faur, 2010, p. 6; Christensen and Lægreid, 2006). Not all European agencies have the name 'Agency'. Some are called as 'Authority', 'Office', 'Foundation' or 'Centre'. They are not located in Brussels, but spread in all over the EU.

Since the focus of this thesis is given to the policy agencies and their influence in the policy-making procedure, European agencies hereafter will refer to the policy agencies. The process of agencification of the total 23 policy agencies can be characterized with the three major waves. 1975 was the year when the first two European agencies were established. They are the European Centre for the Development of Vocational Training (Cedefop) and the European Foundation for the Improvement of Living and Working Conditions (EUROFOUND). After more than a decade, the second wave was emerged in the 1990s. Total ten European agencies were established, but two of them do not exist anymore. The European Monitoring Centre for Racism and Xenophobia has been integrated into the European Union Agency for Fundamental Rights (FRA), and the European Agency for Reconstruction (EAR) was closed in 2008. Agencification is now in the third wave which began in the beginning of the 2000s. Total 13 agencies have been established in a decade, and the last one established is the Agency for the Cooperation of Energy Regulators (ACER). Its founding legislation was adopted in 2009, and the ACER took up operation in March 2011.

Table 2: List of policy agencies

| **Agencification process** | **No.** | **Agency Name** | **Established Year**[2] |
|---|---|---|---|
| **1st wave** | 1 | European Centre for the Development of Vocational Training (Cedefop) | 1975 |
| | 2 | European Foundation for the Improvement of Living and Working Conditions (EUROFOUND) | 1975 |
| **2nd Wave** | 3 | European Environment Agency (EEA) | 1990 |
| | 4 | European Training Foundation (ETF) | 1990 |

[2] It is the year when the legislation establishing the agency was adopted as the basic institutional design was decided. The actual set-up and operation of an agency is on average 1 or 2 years postponed.

| | | | |
|---|---|---|---|
| | 5 | European Medicines Agency (EMA) | 1993 |
| | 6 | European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) | 1993 |
| | 7 | Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM) | 1993 |
| | 8 | Community Plant Variety Office (CPVO) | 1994 |
| | 9 | European Agency for Safety and Health at Work (EU-OSHA) | 1994 |
| | 10 | Translation Centre for the Bodies of the European Union (CdT) | 1994 |
| | (*[3]) | European Monitoring Centre on Racism and Xenophobia (EUMC) | 1997 |
| | (*[4]) | European Agency for Reconstruction (EAR) | 2000 |
| **3rd Wave** | 11 | European Aviation Safety Agency (EASA) | 2002 |
| | 12 | European Food Safety Authority (EFSA) | 2002 |
| | 13 | European Maritime Safety Agency (EMSA) | 2002 |
| | 14 | European Agency for the Management of Operational Cooperation at the External Borders (FRONTEX) | 2004 |
| | 15 | European Centre for Disease Prevention and Control (ECDC) | 2004 |
| | 16 | European Network and Information Security Agency (ENISA) | 2004 |
| | 17 | European Railway Agency (ERA) | 2004 |
| | 18 | The European GNSS Supervisory Authority (GSA) | 2004 |
| | 19 | Community Fisheries Control Agency (CFCA) | 2005 |
| | 20 | European Chemicals Agency (ECHA) | 2006 |
| | 21 | European Institute for Gender Equality (EIGE) | 2006 |
| | 22 | European Union Agency for Fundamental Rights (FRA) | 2007 |
| | 23 | Agency for the Cooperation of Energy Regulators (at planning stage) (ACER) | 2009 |

Source: Author's compilation based on http://europa.eu/agencies/index_en.htm

Similar to defining European agencies, categorizing them is also ambiguous. There is no clear categorization of European agencies, thus they have been categorized in various ways by the Commission and scholars. The Commission (2008), for example, proposed that there are two broad types of agencies: one is "regulatory" or "traditional" agencies which are set up

[3] It is not numbered because it was integrated into the Fundamental Rights Agency in 2007.
[4] It is not numbered because it does not exist anymore.

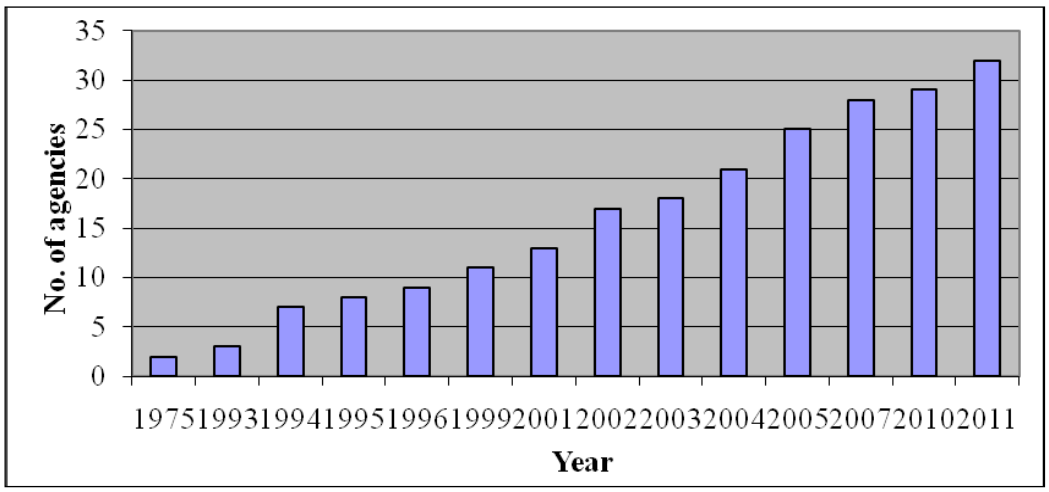
in their own legal basis with a variety of specific roles, and the other is "executive" agencies which are set up under a Council regulation adopted in 2002 with the much more narrowly defined tasks of helping to manage Community programs for a fixed period. The category of regulatory agencies is again divided into three different sub-types. They are 'Policy agencies' which currently have 23 agencies; 'Common Security and Defence Policy agencies' which currently have 3 agencies that carry out very specific technical, scientific and management tasks within the framework of EU's security and defence policies; and 'Police and judicial cooperation in criminal matters agencies' which currently have 3 agencies that aim to create co-operation among the EU Member States in the fight against organized international crime. Besides the broad types of regulatory and executive agencies, there is one more category: 'EURATOM agencies'. They are created to support the aims of the European Atomic Energy Community Treaty (EURATOM).

Table 3: Categorization of EU level agencies by the Commission

| **Type of agencies** | | **No. of agencies** |
|---|---|---|
| **1) Regulatory agencies** | 1.1) Policy agencies | 23 |
| | 1.2) Common Security and Defence Policy agencies | 3 |
| | 1.3) Police and judicial cooperation in criminal matters agencies | 3 |
| **2) EURATOM agencies** | | 1 |
| **3) Executive agencies** | | 6 |
| **Total** | | 36 |

Source: Author's compilation based on http://europa.eu/agencies/index_en.htm

Figure 1: Numbers of EU level agencies, 1975-2011




Source: Author's compilation

Although the Commission does not further categorize sub-groups within the group of policy agencies, scholars have identified several sub-groups depending on the main functions that agencies perform. For instance, Geradin and Petit (2004) identify three sub-categories: firstly, the executive agencies – which are not the same as '3) Executive agencies' in Table 3 – are responsible for purely managerial tasks, observatory roles or missions of cooperation; secondly, the decision making agencies have the power to enact legal instruments binding on third parties; and lastly, the true "regulatory" agencies[5] enjoy the types of powers enjoyed by the national regulatory agencies, including a discretionary power to translate broad legislation guidelines into concrete instruments.

Furthermore, Eberlein and Grande (2005) categorize the policy agencies into four groups: a first group of agencies serves the development of common standards in the internal market (e.g. European Medicines Agency); a second group lies in collecting information and acts as co-ordinators for transnational networks (e.g. European Environment Agency); a third group, alongside gathering information and networking, promotes the 'social dialogue' between employers and unions (e.g. European Centre for the Development of Vocational Training); and a fourth group carries out specialized programs (e.g. European Agency for Reconstruction).

Regardless of different categorizations and various policy areas that agencies belong to, most European agencies perform one of the following functions as their primary task: information gathering (or fact finding); standard setting by issuing opinions or recommendations to the EU institutions; or monitoring and enforcing EU legislations. Agencies with the information gathering task collect and analyze objective, reliable and comparable data on a specific policy area. They formulate advice based on this information, and disseminate to the EU institutions and the general public. In addition, Eberlein and Grande (2005) explain that the standard setting task corresponds fully with the concentration of European regulation in particular policy areas such as labour, health and consumer protection. European agencies with this task, they argue, set not just low standards, at the level of a 'lowest common denominator'; but indeed, very high regulatory levels are often reached (Eberlein and Grande, 2005). By recognizing the compliance problem with the EU *acquis* in the Member States, moreover, the EU has established a few agencies that carry out the implementation task. Groenleer et al. (2010, p.1226) argue that "officially, independent regulatory agencies such as the European

[5] True regulatory agencies do not exist yet, but the authors are in favor of this evolution (see Geradin and Petit (2004) for further details).

Maritime Safety Agency (EMSA) and the European Aviation Safety Agency (EASA) were created because member states do not always comply with their obligations with regard to implementation of EU law, and the European Commission is not in the position to ensure the efficient and flexible implementation itself".

The responsibilities of European agencies are not limited only to their primary tasks listed above. Although agencies devote the majority of their time and resources to carry out the primary task, they also perform other functions as a secondary task. When we consider both the primary and secondary tasks of European agencies, some common features are quickly emerged. Firstly, European agencies would have no decision making power, and all relevant decisions are taken by the European Commission (Geradin and Petit, 2004). There are only a few agencies that are excluded from this feature by having formal decision making power (e.g. the OHIM, the CVPO, EASA). Secondly, European agencies have been typically assigned information and technical tasks (Egeberg et al., 2009). For example, while the primary task of the European Chemicals Agency (ECHA) is to set a standard of chemical safety by managing the registration, evaluation, authorization and restriction processes for chemical substances, it also gathers information on chemicals and their safe use and makes them publically accessible.

Since agencies focus on accumulating technical expertise and producing policy inputs in their specialized policy areas, it is expected that the need for the Commission to rely on them will not likely decrease. As demonstrated in Table 3, 36 EU level agencies are in operation at present. No fewer than 6,857 administrative posts are assigned to European agencies in 2010, representing a significant and growing share of the EU administrative space (Levi-Faur, 2010; see also Dehousse, 2008; Wonka and Rittberger, 2010). Moreover, Figure 1 shows that the number of EU level agencies has increased fast and steadily, especially since the end of 1990s. There is no single legal framework governing the establishment of European agencies, and agencies have been created on a case by case basis through various mixes of political pressure (Ramboll Management et al., 2009a). It implies that the agencification process has not ended yet. Discussion on other European agencies is going on, such as in the field of inland waterways and air traffic management (Schout 2008). Having explained the increasing numbers of European agencies, it is time to ask why the EU Member States and the EU institutions decide to delegate such functions to agencies.

### 2.2 Agencification: why delegate to European agencies?

Although there are certain policy areas where national governments would not like to hand over their competences to a supranational body, scholars explain that there are many reasons why politicians in the Member States agree to delegate certain functions to European agencies. The most popular view to explain the idea of delegation to independent authorities is the principal-agent approach. Pollack (2007, p.3) explicates this approach by stating that:

> "the [principal-agent] approach draws from rational-choice theories of domestic and international politics, arguing that instrumentally rational actors (voters or legislators at the domestic level, states at the international level) delegate powers to executive and judicial agents systematically in order to lower the transaction costs of policy-making, and that in doing so they tailor the discretion of their agents, again systematically, as a function of several factors including the demand for credible commitments, the demand for policy-relevant information, and the expected gap between the preferences of the principals and the agents"

Put simply, a principal decides to delegate a given task to an agent because the agent can get the job done more efficiently. If a principal delegates, it also chooses the formal institutional form (notably the power delegated and controls imposed) that minimises 'agency losses' arising from 'shirking' (divergence of the preferences of an agent and its principal) or 'slippage' (institutional design causing an agent decisions to differ from those desired by its principal) (Thatcher, 2002, p.130). Therefore, it is argued that principals tend to choose agents that are as similar to them as possible in terms of preferences, and tend to control the behaviour of the agent in sophisticated ways (Gilardi, 2008).

While the principal-agent approach provides some basic insights into why and how delegation happens in general, this theory does not fully explain the creation of European agencies. Most notably, European agencies and their principals – whether they are one or more of the EU institutions and/or the Member States – do not necessarily share same preferences. When the creation of the EEA was being discussed in the EU, for instance, the coalition of the Commission and the Member States with high environmental standards that supported the creation of the agency had to secure the approval of the Member States in the Council that were those opposed to strict environment regulation (Kelemen, 2002). The latter did not want the EEA to have extensive regulatory authority to force high standards of environment regulation on them.

Besides the principal-agent approach, a wide variety of motives for establishing European agencies has been identified. Groenleer (2009, p.18), for instance, explains that:

> "agencies are created in order to lessen political interference, achieve higher efficiency, put public services closer to citizens, enhance scientific or technical expertise, improve flexibility, facilitate partnerships with other public or private bodies, or demonstrate credible commitment. In addition, agencies are set up to pay-off political allies, create a power base for some group or faction, hive off unpopular activities or complex tasks, avoid political responsibility, or manipulate civil service numbers (i.e. to make it look like budget cuts are made or government personnel is reduced)."

Likewise, by publishing a series of papers, the Commission affirms that "the creation of agencies is a useful way of ensuring [the Commission] focuses resources on core tasks" (CEC, 2001) and that "the main advantage of using the agencies is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations" (CEC, 2002b). Moreover, since European agencies make it possible to devolve certain operational functions to outside the Commission (CEC, 2008), the Commission can focus on its core tasks and at the same time, also expand the Community's governing capacity. Agencies, furthermore, support the decision making process by pooling the technical or specialist expertise available at the European and the national level, and the spread of agencies through the EU adds to the visibility of the Union (CEC, 2008).

Like other non-majoritarian institutions, agencies are generally expected to fulfil regulatory goals in the public interest better than central government institutions because they are isolated from the direct scrutiny of voters, changes in government and the influence of powerful pressure groups (Majone, 2000, Majone, 2005). These explanations are particularly related to the argument of the credible commitment problem and political uncertainty. As for the credible commitment problem, it derives from the fact that decisions of public policy may change over time, thus they are not implemented in a coherent and consistent manner. This time inconsistency has three main causes: first, new and unforeseen contingencies in the policy-making context may lead decision-makers to revise their policy when it no longer fits the situation; second, economic actors anticipate the inability of policy-makers to stick to their commitments, and thus generate pressures for them to change course of action; and third, actors do not discount the future exponentially but hyperbolically, which cause temporary

preference reversal (Gilardi, 2008, pp.30-46). Since credibility is a valuable asset for policy-makers, it is natural for them to find ways to strengthen it. Establishing an independent authority, such as an agency, is one way. Equally, Thatcher (2002, p.130) argues that the most important function of agencies is to enhance credible commitment.

While the credibility argument partly results from the economic aspect of reducing the transaction costs, the issue of political uncertainty is based on a democratic system. All nations and/or institutions that are operated under democracy reallocate political property rights on a regular basis. Generally through elections, political actors either gain or lose authority over policy-making. Therefore, political actors are not only interested in making and implementing policies efficiently, but also are concerned firstly with securing their political property rights when they have the opportunity to do so (Gilardi, 2008, p.46-53). This is the main reason why policy-makers establish and delegate powers to independent authorities. In independent authorities, current policy-makers as well as future policy-makers have limited political control, thus once policy is adopted, it will stay insulated from politics in a long term. This situation may be particularly attractive to politicians who are not likely to be re-elected in an upcoming election.

Credible commitments and political uncertainty are related concepts, and it is hard to distinguish whether newly established agencies come to exist due to the credible problem or political uncertainty. Moreover, Majone (1997, p.145) stresses that "it is difficult for elected politicians to be credible, notably because they have a very short time horizon, namely the next election". It implies that political uncertainty can affect credible commitment. Although the two problems cannot be fully separated from each other, Gilardi (2008) suggests that the main difference is that credibility problems do not necessarily emerge out of the democratic process, while political uncertainty would not exist without elections.

In addition, there are other functional reasons for delegation. One is that independent authorities allow policy-makers to shift blame for policy decisions that are necessary and desired but unpopular to voters. It is true especially when it comes to economic or commercial policy, such as tariff increases, that may be perceived as burdens to voters. Moreover, when new and complex issues emerge and when the issues require very high levels of scientific knowledge, delegating tasks to independent agencies that are equipped with specialized expertise can be beneficial to elected politicians and voters. This was precisely the reason why the EU established the EMSA to ensure a high, uniform and

effective level of maritime safety after the *Erika* tanker ran aground in 1999 and caused the pollution of large parts of the French coast (see Groenleer et al., 2010).

Notwithstanding a number of positive contributions generated from delegation to European agencies, there are some obstacles to the establishment of new agencies and expansions of their authority. Kelemen (2002) suggests that delegation to European agencies requires the agreement of several veto players. Veto players are actors whose consent is necessary to move away from the status quo. When creating a new European agency, the Commission, the Council and the Parliament have to agree with the formal institutional design and its mandate. To put it differently, each of them can block both the creation of a new agency and the delegation of authority to agencies. In the mid-1990s, a debate emerged over whether a European telecom agency should be established to regulate the liberalized European telecom market, but it was opposed by some powerful Member States in the Council because they were concerned that delegating powers to the new agency would threaten the existence of national bureaucracies (Kelemen, 2002). Eventually, the proposal was killed.

As for the European Parliament, it became a veto player under the co-decision procedure which has been applied since the third wave of agency creation. Additionally, the Parliament has the ultimate weapon at its disposal vis-à-vis European agencies: it can rewrite or even terminate the mandate of its agencies in the event of underperformance (Busuioc, 2010b, p.107). Although the Commission certainly is a beneficiary of the creation of agencies as mentioned above, it is likely to be reluctant to delegate to agencies in policy areas where it has already accumulated far-reaching competences. The area of competition policy can be an example here. In fact, the Commission has consistently opposed the German proposal for the creation of an independent European Competition Agency and has refused to submit a proposal for the creation of such an agency (Kelemen, 2002; see also van Miert, 1996).

Having explained the agencification phenomenon in the EU and the reasons to delegate to European agencies, the next chapter explains how agencies became the important actors in regulatory policy-making in technocratic governance.

# 3. THEORETICAL FRAMEWORK: TECHNOCRATIC GOVERNANCE

This chapter provides detailed explanations on the main features and concerns of technocratic governance in the context of the EU policy-making process. Technocratic governance is explained in comparison to decisionist governance and in relation to a four-fold typology suggested by Radaelli (1999). Then, the legitimacy deficit argument as the major concern is mentioned.

## 3.1 Features of technocratic governance

The *sui generis* EU polity has been described as a 'regulatory state' and specialized in economic, social and legal regulatory policies (Majone 1996; Radaelli 1999). Unlike in some welfare states, the EU's main focus is not given to the development of the distributive and re-distributive policies. These policies require a large amount of financial resources, and Harcourt and Radaelli (1999, pp.108-109) explain that they are hard to pursue "due to the lack of a full-fledged European public finance, based upon genuine extractive capacities of EU institutions, and due to the limited dimension of the Community budget (no more than 1.5 percent of the EU GDP)". Regulatory policy, however, does not depend on how much money the EU has at its disposal. Rather, scientific knowledge and expertise are required as the necessary resources. Any substantial costs arising from regulations are borne by those who are regulated, such as industries and/or individuals. This 'science-based regulation' is, it is argued, the driving force of the EU policies and technocratic governance.

What exactly is technocratic governance? Who are technocrats and what is their role in policy-making? Meynaud (1969) defines technocratic governance in classical political terms. To him, it is a system of governance in which technically trained experts rule by virtue of their specialized knowledge and position in dominant political and economic institutions. Frank Fischer (1990, p.18) develops further from the 'rule by experts' and defines that:

> "Technocracy is more than expertise per se. Expertise can be organized to serve a variety of social functions and interests. Technocracy, in this respect, refers to the adaptation of expertise to the tasks of governance. It gives rise to a theory of governmental decision making designed to promote technical solutions to political problems."

In the same way, Robert Fischer (2008) explains that the technocratic mode of governance makes politics more rational and efficient by relying on experts who are capable of assessing the underlying complex issues, and subsequently are capable of developing adequate solutions.

Overall, Radaelli (1999, p.7) provides several reasons for looking at the EU from the angle of technocratic governance:

> "The institutional structure of the EU presents (a) a bureaucracy (the European Commission) endowed with a pivotal position in policy formation; (b) the lack of a democratically elected government with a legislative program; (c) a party system still in consolidation, hence comparatively weak; (d) the proliferation of non-majoritarian institutions (that is, institutions which are not accountable to the political system, for example the European Central Bank)."

The emphasis on scientific expertise that stays away from the political debate in technocratic governance stems from the fact that politicians and in the context of the EU, the Commission officials who draft legislative proposals do not understand all issues that contain a significant amount of scientific background and specific technologies. With regard to technical issues such as the risks of nanotechnology or the safety of genetically modified organisms on human and animal health, politicians have neither expertise to design policies in detail nor the capacity to adapt them to changing conditions or particular circumstances (Majone, 1997). Moreover, the growth of scientific knowledge and technological development are faster than the legislative process and political debates. As a consequence, politics is increasingly reduced to the technically oriented task of "keeping the machine running" (Fischer, 1990, p.16).

A wide range of professions is considered as technocrats in the literature of technocracy. It includes engineers, managers, scientists and scholars working in governments or think tanks. In general, what is common among them is that they are experts in a certain field of policy areas. They are believed to have specialized knowledge and expertise in that field. These experts are neither subject to general elections by citizens nor under political control. However, in technocratic governance, the best available scientific knowledge is applied during the decision making procedure and therefore, in practice, the decision making power is given to the experts who are chosen among the most excellent scientists. In other words, politicians become fully dependent on experts, and only formally sign what the experts have

decided (due to democratic rules) or, in a more "sophisticated" way, the politicians pretend to do exactly what the experts have decided (Fischer, 2008, p.5). In fact, the Commission's White Paper on Governance states that:

> "It is often unclear who is actually deciding – experts or those with political authority. At the same time, a better informed public increasingly questions the content and independence of the expert advice that is given" (CEC, 2001, p.19).

In technocratic governance, technically trained experts are the dominant actors in policy-making, and it implies that access to scientific knowledge and expertise is the key to be involved in the policy-making process. On the contrary, it is the lack of access to such knowledge that prevent politicians as well as ordinary citizens from actively and meaningfully participate in the political decision making processes. This sheds light on the important issue of the relationship between expertise and politics from the perspective of political science. To put it pointedly, Fischer argues that technocrats see "politics as a *problem* rather than a *solution*" (1990, p.22, italics in original). For expertise to become the main resources, political decision making must be perceived as slow, corrupt, and ultimately irrational (Radaelli, 1999).

By contrast, some may argue that it is not possible to totally neglect politics even in the technocratic mode of governance. Political decisions always reflect normative reasoning and value considerations and thus, opinions based purely on expertise cannot be sufficient to make decisions about public policies. This is the central idea of decisionist governance, which is the counter concept of technocratic governance. While there is a strict separation between experts and leaders, politicians have authority to make final judgment considering non-scientific elements. Since value-based judgment by politicians and/or citizens is vital in decisionist governance, Fisher (2008) explains that decisionist governance asks for the primacy of politics. Politicians must make decisions in relation to different or even contending values and goals. In this mode, politicians will seek expert opinions and advice only when they want, and expert advice is only one of several alternative options in policy-making. As a result, it is not necessary to explicitly communicate the expert advice to the public, seeing that the politicians may ignore the advice the experts have given at any time and without giving reasons (Fisher, 2008). In short, political decisions dominate the recommendations and analyses of experts in decisionist governance.

The distinction between technocratic and decisionist governance is made based on the 'tracking' of how decisions are made, by whom, and on what basis. Besides, technocratic governance can be characterized in a four-fold typology based upon two dimensions – uncertainty and political salience – which is presented in Figure 2. As explained before, technocratic governance refers to policy domains with high uncertainty and low political salience. Politics is replace by scientific expertise here. If a policy issue becomes salient while remaining highly uncertain, Radaelli (1999) argues that epistemic communities are expected to play a political role of resolving conflict among actors since conflict tends to arise around salient issues. Epistemic communities are the networks of experts, but the difference compared to the ones in technocracy is that epistemic communities have "a shared set of normative and principled beliefs which provide a value-based rationale for the social action" to deal with politically salient issues (Haas, 1992, p.3).

Figure 2: The prevailing logic in the policy process when uncertainty and salience vary

| | | **Uncertainty** | |
|---|---|---|---|
| | | Low | High |
| **Political Salience** | Low | Bureaucratic politics | Technocratic logic |
| | High | Political decision making (politicization) | Epistemic communities |

Source: Radaelli, 1999, p. 48

When uncertainty becomes low while political salience remains high, expertise is not a relevant aspect in policy-making. Since issues are politicized and values need to be considered to make policies, this is the area where decisionist governance dominates. Moreover, when policy issues have both low salience and low uncertainty, politicians neglect the issues while organizations compete to gain more control over the issues. Expertise remains significant, but more importantly still, bureaucracies will fight for expanding their competences in a classic turf battle (Radaelli, 1999).

These various modes of governance are ideal types and in reality, they do not appear as in their pure forms. Moreover, there is no clear line that divides technocratic governance from its similar type of epistemic communities in many policy issues. Nevertheless, the central feature of technocratic governance still remains evident: objective expertise prevails

subjective values. When the EU gives more attention to the role of expertise, what becomes major concern to the public in the EU and what are likely implications on democracy?

### 3.2. Concerns of technocratic governance

First and foremost, it has been recognized that effective policy-making in technocratic governance and legitimate governing seem to be in tension for some time in the EU (see Majone 1996; Beetham and Lord, 1998; Skogstad, 2003; Borras, 2006). Before moving to a detailed discussion of the legitimacy concern, it is worth clarifying what legitimacy means. Generally, legitimacy is related to public support and trust and also to how and why political authority is justifiable and accepted. Scholars have specified legitimacy into input and output legitimacy or procedural and substantive legitimacy. Input legitimacy, according to Scharf (1997, p.7), "relies on the rhetoric of participation and of consensus" to improve the acceptability of EU policy outcomes by involving citizens and stakeholders in policy formulation. Procedural legitimacy, particularly in terms of regulatory policy-making, implies that the regulators are appointed by elected officials; that regulatory decision making follows formal rules, which often require public participation; that decisions must be justified; and especially that they are open to judicial review, and are adequately monitored by the political principals (Majone 1996, 1998). Both input and procedural legitimacy pay attention to the importance of public participation and involvement of different interests in policy-making.

Output legitimacy, on the other hand, is about efficiency and effectiveness of the final policy outcomes in the EU. Efficiency, more specifically, is "the accomplishment of tasks without undue wastage in terms of time and resources" (Heard-Laureote, 2010, p.24), and effectiveness is the achievement of problem-solving capacity. Substantive legitimacy is also related to the features of the regulatory process as policy consistency, the expertise and problem-solving capacity of the regulators, their ability to protect diffuse interests and a rational selection of regulatory priorities (Majone 1996, 1998).

During the first few decades of the EU's existence, Heard-Laureote (2010, p.28) explains that the issue of input legitimacy was not concerned at all because it was assumed that "the European integration project would be popularly accepted and thus assured of legitimacy on solely instrumental or technocratic grounds". Legitimacy in the technocratic mode is focused on governmental performance – output legitimacy – and on the claim that the public good is

better realized through having professionals in charge, who are not subject to the vagaries, biases and distortions of democratic and especially electoral politics (Beetham and Lord, 1998).

In fact, Majone (1996) believes that in the EU as a regulatory state, any democratic deficit is not a serious problem as long as European regulatory policies serve their goals efficiently and effectively. Similarly, Scharpf (1999) suggests that legitimacy based on performance and expert authority has historically been an acceptable substitute in policy domains, like consumer safety and environmental protection, where good policy outcomes depend upon expertise. Moreover, to some extent, it was considered that there was no room for the direct involvement of uninformed publics in such technocratic administrative affairs (Lord, 2000). It appears that in technocratic governance, output legitimacy was taken more seriously than input legitimacy.

However, input legitimacy could and should not be disregarded eventually. According to Majone (1996), the most persistent and fundamental criticisms of statutory regulation and policy-making by expertise have been concerned less with such technical problems than with the normative issues of public accountability and democratic legitimacy. It is because the operation of technocrats and experts are not subject to elections by the people, and decision making takes place in the form of exclusion rather than inclusion of the people. In fact, most of the time, the operation of agencies go unnoticed by the public (Groenleer, 2009). In this regard, input legitimacy is closely related to what is believed as the element of democracy, and technocratic governance and its consideration of output legitimacy contradict to the traditional principle of democracy. Dahl (1994) explains that democracy has usually been conceived as a system in which "rule by the people" makes it more likely that the "people" will get what they want, or what they believe is best, rather than alternative systems in which an elite determines what is best. It implies that in order to ensure public supports for policies and to achieve output legitimacy, citizens or their elected representatives should be involved in decision making – input legitimacy should be taken into consideration.

In addition, there is the tendency to equate democracy with majority rule. From this perspective, the Commission’s dependency on non-majoritarian institutions in policy-making and the apparent phenomenon of agencification itself can be perceived as undemocratic. Therefore, from the view of democracy, questions on technocratic governance – for example, by whom decision making by technocrats is authorized, to whom technocrats are accountable

and in what sense they are representative – contribute to the 'input legitimacy' deficit argument. In technocratic governance, in other words, it is undeniable that a deficiency in the normative credentials of democracy and input legitimacy is the prevalent concern.

It seems like the logic of the concerns in technocratic governance follows in this way: "scientific information = technical expertise outside of politics = technocracy = a non-democratic legitimacy" and therefore, "technocracy is, these days, not perceived by the public as legitimate" (Shapiro, 1997, p.287). As a result, enhancing input legitimacy has been the Commission's priority for a long time, and the Commission has published various papers that illustrate the importance of public participation in policy-making. Heard-Laureote (2010) argues that it was 1997 when the Commission began a participation discourse whereby citizen membership of CSOs [civil society organizations] and their participation in its activities constitute a complement to conventional sources of democracy. In the White Paper on Governance in 2001, moreover, the Commission implies the shift of its focus from output to input legitimacy:

> "The quality, relevance and effectiveness of EU policies depend on ensuring wide participation throughout the policy chain – from conception to implementation. Improved participation is likely create more confidence in the end result and in the Institutions which deliver policies. […] It will no longer be judged solely by its ability to remove barriers to trade or to complete an internal market; its legitimacy today depends on involvement and participation" (CEC, 2001, p.10-11).

In order to reinforce consultation and dialogue with representatives of regional and local authorities as well as CSOs and interest groups, the Commission published another paper a year later. It states that:

> "Wide consultation is not a new phenomenon. In fact, the Commission has a long tradition of consulting interested parties from outside when formulating its policies. It incorporates external consultation into the development of almost all its policy areas. Thus, the benefits of being open to outside input are already recognized" (CEC, 2002a, p.3)

More recently, the Commission recognized that communication has remained too much of a 'Brussels affairs' that has focused on telling people what the EU has decided rather than listening people's view during the policy formulation stage (CEC, 2006a). While

emphasizing communication as essential to democracy, the Commission proposes plans to increase citizens' involvement. What has been a clear pattern in the legitimacy deficit argument in the EU is that the Commission tends to believe that through citizen involvement in policy-making it can escape from criticisms of the increasing legitimacy deficit.

At this point, it is important to remember that what is crucial in regulatory policy-making is the principle of Pareto optimality and its efficiency and effectiveness. From this perspective, introducing more transparency and participation in the political system may lead to the loss of effective and efficient decision making as it consumes more time and resources. The complete exclusion of participation cannot be realized in a democratic society. In the same way, the ideal type of technocratic governance – public policy is purely based on scientific knowledge and expertise; nonetheless, it is accepted and supported by the people – can be neither achievable nor justified in the current situation of the EU as well as elsewhere. Therefore, finding the right balance between effectiveness of outcomes and the degree of participation may be vital in order to move forward in technocratic governance.

Amid the growing concern of the legitimacy deficit, it is important to analyze how European agencies influence policy-making. It is because while the Commission calls for more input legitimacy, agencies are established and operate around exerts, to whom possessing expertise, rather than listening ordinary citizens' voice, is essential. By analyzing factors that determine agencies' influence in policy-making, it will become clear whether technocratic governance evolves more into the ideal type or adapt itself to the new demand in the EU.

# 4. CONCEPT AND INDICATORS OF INFLUENCE

In order to test the hypothesis that in technocratic governance of the EU, *de facto* influence of European agencies on policy-making can be higher than their *de jure* influence, it is important to clearly specify what it is meant by influence. In addition, before moving to the empirical part of this thesis, the indicators of influence should be explained and operationalized. The specific nature of technocratic practices at the operational level of decision making is not always easy to identify, thus making it difficult to study the actual workings of technocratic power and influence (Fischer, 1990). However, this section will demonstrate the definition of influence and the indicators to measure influence by reviewing the existing literature and developing further from it.

## 4.1 The concept of influence

What does 'influence' mean in the context of policy-making in the EU? Many people would have a hard time if they try to define it with words although they know what it is. It is because influence is an elusive matter. Since it is considered that normal people understand the meaning of influence with their common sense, some scholars have thought that it is not necessary to elaborate on the definition. Unfortunately, up to now, in neither ordinary language nor political analysis is there agreement on the definition and usage of what might be called "influence terms" (Dahl and Stinebrickner, 2003).

Among the scholars who have tried to give certain definitions of influence, however, what is immediately noticeable is that unlike political theories, the term of influence has not evolved over time on the basis of the core meaning of it. Rather, there is wide disagreement over the core meaning of influence, and the term of influence is interchangeably and synonymously used with other terms – most notably with the term of power. Therefore, "influence" is used in some literature, and "power" is used in other literature to describe the same or similar phenomena. It all depends on what definition and which word the authors decide to use or their decision about not to provide any specific definition. It would be theoretically easy and neat if we could agree that there is one concept of power or influence (Goverde et al. 2000). But in fact, "power" and "influence" seem to suffer from the same defects as the concept of "illness": we all know what we mean when we use the word, and yet it seems to be impossible to define it in a satisfactory way (Rothschild, 1971, p.15).

In general, when we talk about influence or power, the terms describe relationships that involve one person or many people as a group affecting actions or decisions of another person or groups. These relationships and each involved actor's action to the other actors can be explained as types of causation (see Nagel, 1975). Influence and causation can be further identified with positive and negative influence. An instance of influence is positive if the influence-wielder gets someone to do something positive or favorable from the perspective of the influence-wielder; by contrast, it is negative if the influence-wielder brings about the opposite of favorable or positive consequences (Dahl and Stinebrickner, 2003). For example, during an election campaign, a candidate A explains her position on an important issue. Her speech on the position will make a voter B decide to vote for her or against her. A exercises positive influence over the voter B if B decides to vote for her (A) after listening to her speech. However, if B decides to vote against her, it is opposite to her favorable outcome. Then it is negative influence of A over B.

Since the aim of this thesis is to find out European agencies' influence on policy-making in practice – more precisely, how agencies' expertise and opinions determine the main contents of European policies in a way that agencies favor and propose – the term of influence used in this thesis will always refer to positive influence. Analyzing negative influence may be necessary for certain purposes; yet, "in political analysis what ordinarily interests us is positive influence" (Dahl and Stinebrickner, 2003, p.14). Giving more attention to positive influence in most political analysis is reflected in a number of definitions. Mokken and Stokman (1989) explain that power and influence are usually introduced as the capacity to determine the actions of others in accordance with the will or the purposes of the holder of power or influence. Max Weber (1978), moreover, understands power (and influence as well since these two terms are used indiscriminately) as the carrying out of one's will in a social relationship, something which can also be accomplished through violence.

In the context of positive influence, the next step is to make the concepts of power and influence clear. There are some scholars who have attempted to do this. Hoogerwerf (1972), for instance, argues that power and influence are different concepts. He defines power as the possibility to influence the behavior of others in accordance with the actor's own purposes, and also explains that influence occurs wherever behavior leads to change in behavior (Hoogerwerf, 1972, cited in Mokken and Stokman, 1989). To him, power means potential influence, but the concept of influence is not so clear to be directly applied for empirical studies. Dahl and Stinebrickner provide more specific definition of influence. By adopting

and paraphrasing Nagel's definition of power, they suggest that influence can be defined as "a relation among human actors such that the wants, desires, preferences, or intentions of one or more actors affect the actions, or predispositions to act, of one or more actors in a direction consistent with – and not contrary to – the wants, preferences, or intentions of the influence-wielder(s)" (2003, p.17).

What is worth noting, in my view, is Dahl and Stinebrickner's suggestion of seven different forms of influence, which also include power as one form of influence. By distinguishing among various *hows* and *whys* of influence, they explain that these seven forms are inducement, power, force, coercion, persuasion, manipulation and authority. It implies that influence is the general concept and power is a special case. Although power is the one that is the most synonymously used term in confusion of the meaning of influence, the definitions of all these seven forms are explained in order to conceptualize in detail the term of influence and to clarify in what sense it is used in this thesis.

Table 4: Seven forms of influence

| **Form of influence** | **Occasion when it occurs** |
|---|---|
| Inducement | When A offers B something B values in return for doing what A wants |
| Power | When B does what A wants because A will deprive B of something B values unless B complies with A's wishes |
| Force | When A makes B do something by using physical means (lifting, carrying, pushing, shooting) |
| Coercion | When B does A's bidding because A has credibly threatened to use force if B does not comply |
| Persuasion | When A conveys to B information, argumentation, or explanation that leads B to do or think something different from what B otherwise would have done or thought |
| Manipulation | When A influences B by communication in which A intentionally distorts, falsifies, or misleadingly omits aspects of truth known to A that, if communicated to B, would affect B's thinking or acting |
| Authority | When B tends to do A's bidding automatically, unthinkingly, unreflectively as an automatic pattern of obedience |

Source: Author's compilation based on Dahl and Stinebrickner (2003)

Inducement and power have two opposite aspects when being exercised. Inducement occurs when A offers B something B values in return for doing what A wants; by contrast, power occurs when B does what A wants because A will deprive B of something B values unless B complies with A's wishes (Dahl and Stinebrickner, 2003). What makes power different is the prospect of severe sanctions for noncompliance. Similarly, Weber also implies a situation of noncompliance when defining power. He states that "power is the probability that one actor within a social relationship will be in a position to carry out his own will despite resistance, regardless of the basis on which this probability rests" (Weber, 1978, p.53).

Force and coercion are very closely related and often confused with one another. But the main difference is the existence or absence of physical engagement. We can say that force is at work when A makes B do something by using physical means (lifting, carrying, pushing, shooting); and coercion is the form of influence that results when B does A's bidding because A has credibly threatened to use force if B does not comply (Dahl and Stinebrickner, 2003). If two sons are fighting, for example, and if their mother physically pulls them apart, force is applied. But without physically pulling them apart, the mother can also tell the two sons that if they do not stop fighting, she would pull them apart. This is the use of coercion. Dahl and Stinebrickner (2003) explicate that coercion can be understood as an extreme variant of power since power is influence based on the threat of deprivation while coercion is influence based on the threat of force.

Persuasion and manipulation are the forms of influence that have two opposite sides of being truthful or untruthful. When A influences B using persuasion, A conveys to B information, argumentation, or explanation that leads B to do or think something different from what B otherwise would have done or thought; by contrast, manipulation occurs when A influences B by communication in which A intentionally distorts, falsifies, or misleadingly omits aspects of truth known to A that, if communicated to B, would affect B's thinking or acting (Dahl and Stinebrickner, 2003).

The last form of influence is authority, which is different from other forms of influence in a way that B follows A's wishes *automatically*. For other forms of influence, the reason why B does what A wishes for is because of expected benefit (inducement), application of physical means (force), the threat of force (coercion), deprivation (power), or based on communications of convincing truth (persuasion) or of distortion of truth (manipulation).

However, when authority is at work, B tends to do A's bidding automatically, unthinkingly, unreflectively (Dahl and Stinebrickner, 2003). Since there is an automatic pattern of obedience to the influence-wielder(s), some scholars may consider authority as the most desirable form of influence. The question is: what makes B to obey? One may guess that it is based on perception of B that it is appropriate and even morally right to obey, but the source of automatic obedience is not clear.

Since all seven forms of influence are explained, it is now time to connect the meaning of influence to the context of European policy-making and influence of European agencies in the policy-making process. As mentioned in Section II, the core role of European agencies is to gather information and provide their expertise in their specific policy area to the Commission as well as the other EU institutions and the Member States if necessary. Agencies' expertise can be served as important input when the Commission develops policy proposals for the EU, which should be eventually agreed and adopted by the Commission, the Council or the European Parliament depending on the type of policy. This process outlines that European agencies function – and therefore may exert influence – in the agenda-setting stage among the EU policy-process phases, and they are not the actors who decide in the decision making stage.

A good image of the meaning of decision making is of a person pausing at a fork in the road, and then choosing one path – to reach a desired goal or to avid an unpleasant outcome (Hastie and Dawes, 2010). The action of decision making involves a set of alternatives, and among these alternatives, a choice or a decision is made by the decision maker(s) to choose one option among many alternatives which will affect other actors in the situation. The decision is made and imposed despite resistance and regardless of the will of actors being affected. This implies what is meant by power that it is associated with the restriction of freedom of non-decision-makers. Therefore, power-holders are the decision-makers, and European agencies cannot be the power-holders unless they are given the competence to make legally binding decisions. Yet, as mentioned in Chapter 2, there are only a few European agencies with power to make legally binding decisions in the EU.

How European agencies influence European policies is not through exercising power but through persuasion. One of the most crucial background to explain persuasion as the form of agencies' influence is the fact that in most of the cases, the Commission is not obliged to follow opinions, recommendations and/or reports from European agencies when it formulates

policy proposals. Then, it is understandable that agencies cannot interfere with and restrict the degrees of freedom of the Commission through such means of force or coercion. By definition, however, persuasion applies the accurate communication of truthful information as the only means affecting others. Armed with knowledge acquired through rational communication, the decision maker(s) may now choose the better rather than the worse alternative – or, at the least, accept the inevitable (Dahl and Stinebrickner, 2003). Expertise and the ability to persuade or to supply information are characteristic sources of influence for European agencies in the policy-making process.

### 4.2 Indicators of influence

Influence and power are concepts that cannot often be observed clearly because they are rarely manifested in the form of clearly recognizable 'influence' or 'power' behavior (Mokken and Stokman, 1989). Then, when we try to measure whether someone (a person, group of persons, an institution or a system) has influence, what can be used as the indicators of influence? Dahl and Stinebrickner (2003, p.34) explain that in general, there are three fundamental factors that affect differences in the amount of influence that persons or organizations exercise:

a. Resources: differences in the distribution of relevant resources. A relevant resource is a means by which one person can influence the behavior of other persons. Such resources include money, information, food, the ability to make credible threats, jobs, friendship, social standing, the ability to make and enforce laws, votes, and a great variety of other things.
b. Skills: variations in the skill or efficiency with which individuals use their relevant resources. Differences in such skill or efficiency stem in turn from differences in endowments, opportunities, and incentives to learn and practice such skills.
c. Motivations: variations in the extent to which individuals use their potentially relevant resources for political purposes. […] These variations are themselves traceable to differences in motivation that arise out of variations in endowments and experiences

Based on the factors mentioned above, I suggest more specific indicators that can be used in this thesis to measure influence of European agencies on European policy-making. The indicators are:

a. *Resources*: the information that European agencies process and produce based on their expertise and scientific knowledge
   - Characteristics of information
   - Structurability of information
b. *Environment*: the institutional setting in which European agencies use their resources and decision making of policies takes place
   - Loose/strict coupling of agencies in the policy-making process
   - Formal restrictions imposed on decision-makers
c. *Motivations*: reasons for European agencies to network with stakeholders
   - Frequency of agencies' contact with stakeholders
   - Type of activities organized by agencies for stakeholders

Policy-making itself is a complex procedure and especially at the European level, it is very dynamic as it involves a wide variety of multi-level actors who are not easily recognized at times. Nevertheless, focusing on European agencies as the main actors, each indicator is analyzed in detail in order to explain how to measure influence of agencies on policy-making.

Table 5: Summary of indicators and operationalization

| **Indicators:** | | **Operationalization:** | **Data collection:** |
|---|---|---|---|
| ***a. R*** | Characteristics of information | - Uncertainty: background of members in Scientific Committees of an agency<br>- Salience: presence of consultations with the Member States or agency's opinions addressing Member States' concerns | - The scientific profile of members from the agency website<br>- Agency's documents from the agency website addressing Member States' concerns |
| | Structurability of information | - Presence of guidance documents for information processing and producing<br>- Number of opinions adopted by an agency within time limits under the standardized procedure, in comparison to the number of opinions requested to | - Guidance documents from the agency website<br>- Annual reports |

| | | | |
|---|---|---|---|
| | | an agency | |
| ***b. E*** | Coupling | - Presence of formal procedure in the founding regulation requiring mandatory involvement of an agency when the Commission drafts policy proposals | - Agency's founding regulation |
| | Restrictions on decision-makers | - Presence of time constraints and the written procedure for taking decisions | - Agency's founding regulation |
| ***c.M*** | Freq. of contact with stakeholders | - Number of contact between an agency and stakeholders in a given period | - Annual reports<br>- Evaluation reports<br>- Annual activity report<br>- Interviews |
| | Type of activities | - Type of activities organized by agencies for stakeholders | - Annual reports<br>- Evaluation reports<br>- Annual activity report<br>- Interviews |

Source: Author's compilation

*a. Resources*

Technocratic politics changes the nature of power in that knowledge becomes the terrain of politics (Fischer, 1990; Radaelli, 1999). In this sense, resources are directly linked to the information that European agencies process and produce on the basis of their expertise and scientific knowledge. Chiti (2000) argues that even if agencies do not enjoy the power to control the compliance of private action with the EC regime's requirements, and cannot take decisions directly and individually affecting private actors, their production of technical information can be used either as a means of control and persuasion or as the direct foundation of certain administrative measures.

What is important to look at in this context are the characteristics of information. Before, it is explained that technocratic governance works most effectively in policy areas where political salience is low and uncertainty is high (Radaelli, 1999). Accordingly, agencies operating in these areas can best utilize their information, and are likely to exert high influence, compared to agencies operating in other policy areas in Figure 1. Uncertainty and political salience are

the key elements that characterize agencies' information which determines influence. Then, when can we confidently say uncertainty and political salience are high or low?

In order to check whether an agency operates in a policy area that has high uncertainty, it is useful to see firstly if the agency has Scientific Committees. Since uncertainty is perceived as the lack of scientific knowledge as explained earlier, an agency that does not have Scientific Committees implies that it is not in charge of highly uncertain issues. In fact, a few of European agencies, such as the Translation Centre for the Bodies of the European Union (CdT) and the Eurofound, do not have Scientific Committees. Among the agencies that have Scientific Committees, the background of members in these Scientific Committees should be looked at because they are the ones who process and produce agencies' information. In order to deal with highly technical and uncertain issues, members are required to have the highest level of education and enough experience in their specialized field as, for instance, a doctor or a scientist. Agencies make the scientific profile (curriculum vitae) of their members publicly accessible on their websites.

If politically salient issues involve high economic, scientific, political or normative stakes, conflict may arise among groups within a society and/or among nations at the international level due to their pursuance of interests in the policy areas. For instance, environmental issues are typically associated with high political salience because strict regulations of environment can have a negative impact on productivity growth of some nations' vital industries. By contrast, if policy issues are not salient, there is no conflict of interests among actors because the issues do not directly concern their interests. In most cases, if an issue is salient to some EU Member States, they express their concerns to an agency dealing with the policy topic in order to discuss and resolve conflict of their interests. They do this by participating in consultations or by sending written statements. Then, the agency publishes on its website what has been discussed in consultations or addresses Member States' concerns in its opinions. These documents can be collected on the agency's website.

Regarding information based on expertise and scientific knowledge as resources, it is also crucial to examine structurability of information. Structurability refers to the availability of knowledge relevant to information processors, and enables "1) to identify/ categorize incoming information smoothly, 2) to evaluate its relevance, 3) to relate them to other data, while 4) providing a context which lends a pragmatic meaning to the newly extracted information in terms of ensuring (courses of) actions" (Blom et al., 2008, p.12). Since

information is the main resources to exert influence in the policy-making procedure, it is important for European agencies to process and produce information in a timely manner with accuracy in order to maximize their possibilities of influence. Groenleer (2009, p.222), in his analysis of the EEA, implicitly suggests the importance of structurability in order to influence policy-making:

> "The EEA has become more capable of using its information strategically. It tried to influence policy choices by the findings and conclusions drawn from its analysis of data and information. […] So whereas in the early years the agency was busy discovering what information was needed and how it would have to be collected, over time it gained an understanding of what information was available and how it could be gathered. Interviewees agree that this enabled the EEA to have an impact on environmental policy-making through its information"

High structurability in an agency means that the agency has standardized procedures for processing and producing information in a fixed time frame in order to provide timely and up to date information, which will in return contribute to agency's high influence. By contrast, low structurability in an agency is associated with problems of 'overloading' in the procedure for processing and producing information, which affects agency's influence negatively. In this research, standardized procedures and problems of 'overloading' are measured firstly by checking whether or not there are guidance documents for processing and producing information on the agency's website; and secondly by analyzing the number of opinions adopted by an agency within time limits under the standardized procedure, in comparison to the number of opinions requested to an agency. This information is published in agencies' annual reports.

*b. Environment*

'Skills' are what Dahl and Stinebrickner (2003) propose as the second factor determining influence. Skills mean the way individuals seek to maximize opportunities to use their relevant resources to exert influence. However, agencies' opportunities and occasions to provide their information to the EU institutions are fixed in their founding regulations. Most of the cases, agencies provide opinions when they are asked by the EU institutions. Agencies may also issue opinions or recommendations on their own initiatives, but it is limited compared to the opinions issued upon request. Therefore, the way agencies utilize their resources will be examined in terms of the institutional environment, which is the

institutional setting in other words, where agencies perform their formal obligations and informal activities and decision making by policy-makers takes place.

In order to analyze the institutional environment, the level of coupling and formal restrictions imposed on decision-makers need to be examined since they are the most crucial factors that affect the behavior of decision-makers towards policy input of agencies. If European agencies operate in a strictly coupled environment, agencies have direct and relatively fixed consequences for the behavior of policy-makers in a way that is favorable to agencies. In other words, if a European agency is strictly coupled in the policy-making process, it means that interdependence between the agency and other involved actors, namely policy-makers, is high, and that decision making bodies do not actively seek to utilize outside information sources other than the agency. This, in return, will create more room for the agency to make its voice heard by decision-makers, and the chance of influencing policy-making will be higher. Thus, strict coupling is positively related to agencies' influence. By contrast, if an agency is loosely coupled in the policy-making process, decision-making bodies actively seek to collect information and opinions from various sources since they are not dependent on the agency. In this case, the agency will have less room to make its voice heard by the decision-makers and as a result, it will have less possibility to exert influence.

The level of coupling can be found by looking at the formal procedure of agency involvement particularly when the Commission drafts policy proposals. Strict coupling presents the formal procedure that policy-makers have to include European agencies for their policy input – through the forms of opinions, reports, statements or recommendations – while drafting policy proposals. Mandatory involvement of an agency can be found in the founding regulation of the agency.

Unlike the level of coupling which is seen only while policy proposals are drafted, formal restrictions imposed on decision-makers are observed both in the policy formulation and in the decision making stage. Formal restrictions are imposed in the forms of time constraints and the written procedure for taking decisions. If decision-makers work under high time constraints, it will be difficult for them to scrutinize agencies' opinions and to collect policy input from other sources. It would result in reliance on agencies' opinions. In addition, the type of decision making procedures is broadly the meeting procedure or the written procedure. In the written procedure, if no one raises any objection to a proposal within a time limit, it is considered as an approval. But, if at least one or more decision-makers raise objections in

writing within a time limit, the procedure is changed to the meeting procedure. Then, all decision-makers have to meet in a meeting where they explicitly discuss their views and vote on the proposal. Due to this procedural change and physical inconvenience that is caused by the change, the costs of the decision-makers for actively opposing a proposal in the written procedure are higher than for voting negatively under the meeting procedure (Krapohl, 2004). It means that in the written procedure, decision-makers would feel less free to oppose proposals, and it will increase the possibility for agencies to exert influence.

In fact, under the meeting procedure, even if policy proposals are perfectly in line with agencies' opinions, there is less possibility that final outcomes are in accordance with the contents of agencies' opinions. It is because the proposals (and agencies' opinions) need to be compromised with opinions of the decision-makers who have contrasting views. More importantly, since agencies cannot participate in voting in the decision making stage, there is nothing they can do at this stage. Therefore, high formal restrictions associated with time constraints and the written procedure, rather than the meeting procedure, imposed on decision-makers are positively related to agencies' high influence. The founding regulations of agencies have the information of formal restrictions.

c. Motivations

Motivations are analyzed through agencies' informal activities of networking with stakeholders. Networks can be defined in various ways, but at the most basic level, policy networks can be defined as:

> "a set of relatively stable relationships which are of non-hierarchical and interdependent nature linking a variety of actors, who share common interests with regard to a policy and who exchange resources to pursue these shared interests, acknowledging that cooperation is the best way to achieve common goals" (Börzel, 1997, p.1).

This definition, however, limits the scope of networking activities only to the actors who have shared interests. It is problematic because the force of networks "is not simply people's like-mindedness or their common socio-economic background or some other categorical trait, but is rather functional complementarity, cultural affinity, and sometimes the purposeful action of some governmental agency in need of popular legitimation" (Christiansen et al., 2003, p.11). In fact, when European agencies network with their stakeholders, not all

stakeholders share common interests with agencies. Therefore, I define networks in this thesis as personal relations among multi-lateral and multi-level actors and structures of such relations that remain in informal contact and activities for mutual assistance or support.

Among other indicators of influence, analysis on motivations has been mostly overlooked by scholars. As a consequence, systemic assessments of the added value of agencies' networks for stakeholder involvement and participation are still lacking (Busuioc, 2010a). Nevertheless, Borras (2006), after studying stakeholder involvement as input legitimacy of agencies, argues that agencies show a relative openness to stakeholders and a relatively good performance in terms of interactions. From a legal perspective, networking takes place first and foremost because the law has decreed that it must be so, as it has linked the relevant actors through a series of interrelating legal rights and obligations (de Visser, 2009). However, networking with stakeholders is not a clearly defined obligation as a main task of European agencies. Then, what are agencies' motivations to network with their main partners and stakeholders – the Commission, the Member States, industry, and interest organizations?

There are various motivations of agencies for networking with stakeholders. But in order for European agencies to exert high influence on policy-making, motivations should be directly and indirectly linked to satisfying the interest of policy-makers. The interest of the Commission in the draft stage of legislation is threefold: maximizing the inflow of useful information, having an early indication of likely voting intentions in the Council and Parliament, and legitimizing the proposed action from the outset (Christiansen and Larsson, 2007). Therefore, through the networks, (1) some agencies disseminate information to the Commission as well as to other stakeholders; (2) some try to find out conflicting views as well as what is generally expected from stakeholders; and (3) some seek to increase legitimacy by interacting with stakeholders. Additionally, I suggest that (4) some agencies network with stakeholders to extract specific information from them. For example, through the network with Commission officials, agencies can receive information on a potential legislative agenda. It will enable them to be better prepared with their opinions and thus, have more possibilities to exert high influence.

What is important to point out is that motivations (1) and (4) are directly connected with enhancing agencies' capacity to produce more informed opinions and to assist stakeholders with understanding and using agencies' opinions. Since agencies are created in order to utilize their expertise in the policy-making process, agencies' activities based on these two

motivations would increase their influence. Yet, it does not mean that the other two motivations are unnecessary. If activities based on motivations (2) and (3) can contribute to the production of scientific outputs of agencies – for example, agencies gather contrasting views expressed by stakeholders and offer appropriate scientific explanations on the issues – agencies would exert high influence.

By analyzing the frequency of contact between agencies and stakeholders and the type of activities organized for them (e.g. consultations and meetings), it will be clear with whom agencies network the most and in which forms networks are established. Based on them, it is possible to find out what agencies' motivations are. Data for this section can be gathered by analyzing annual reports and evaluation reports of agencies. Particularly on information about the number of contact between agencies and each stakeholder, data collected through interviewing staff and members of agencies as well as stakeholders can be useful.

### 4.3 Methodological framework

This research project requires a qualitative approach, and I use a case study approach to present the empirical application of the factors that determine agencies' influence. An empirically informed analysis of *de facto* influence of agencies can help us understand how, by whom and on what basis public policies are shaped and decided in practice. A case study is defined as an in-depth study of a single case where the purpose of that study is – at least in part – to shed light on features of a larger class of similar phenomena (a population) (Gerring, 2007). Since case studies "enjoy a natural advantage in research of an exploratory nature" (Gerring, 2004, p. 349; Gerring, 2007, p. 39), it is considered to be an appropriate approach to analyze relevant variables affecting influence of agencies.

Given the constraints of time and resources to conduct this research, I focus on small N research, and apply purposive sampling to choose two agencies out of total 23 Policy agencies in the EU. The two agencies selected for case studies are the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA). Since the cases are not selected randomly, some may raise selection bias criticism although scholars such as Bennet and Elman (2006, p.461) argue that "conventional arguments on selection bias are often misapplied to qualitative case studies". In this research, therefore, I apply the following

criteria to avoid the selection bias problem and at the same time, to analyze two agencies that can most effectively present the empirical application.

First of all, the scope of this thesis is limited to Policy agencies under the category of Regulatory agencies. Then, it eliminates other agencies that fall under different categorizations such as Common Security and Defense Policy agencies and Police and judicial cooperation in criminal matters agencies. Secondly, among many Policy agencies, the scope is narrowed once again by connecting the theoretical framework to the empirical part. It is explained earlier that the role of expertise is the most important aspect of technocratic governance, and the two elements – uncertainty and political salience – affect the level of influence of European agencies. Since high uncertainty requires scientific knowledge to understand and discuss issues, two types of policy process logics under high uncertainty – technocratic logic and epistemic communities – are chosen to consider. Lastly, among several agencies that can be place in these two logics, the final selection is primarily guided by the functions that agencies are set up to perform. Although their specialized policy areas are different (which result in the difference in political salience), the European Medicines Agency (EMA) and European Food Safety Authority (EFSA) have very similar tasks. They provide expert advice to policy-makers and more importantly, deal with individual applications that seek to receive the marketing authorization in the EU. The similarity in their functions will maximize the comparability of these two agencies.

Figure 3: Case selection

| | | **Uncertainty** | |
|---|---|---|---|
| | | Low | High |
| **Political Salience** | Low | n/a | ***European Medicines Agency (EMA)*** |
| | High | n/a | ***European Food Safety Authority (EFSA)*** |

Source: Author's compilation based on Radaelli (1999)

Although the cases are selected on the basis of the solid criteria, small N research may be open to the most common critique that it severely limits the potential to generalize from the findings of the samples to the wider population (Tansey, 2007). To some extent, it is true that the two agencies cannot represent all other agencies that perform different functions with a

different institutional design. However, the basic aim of research should be taken into consideration. Bennett and Elman (2006) argues that the notion of "causes-of-effects" should be distinct from "effects-of-causes". The latter is the conventional quantitative view because users of quantitative methods commonly direct their investigations to inferring systematically how much a cause contributes on average to an outcome within a given population (Bennett and Elman, 2006). In qualitative research, by contrast, the aim is not to gain the net effect of a cause over a large population, but to learn how causes interact in specific cases to produce an outcome.

During the data collection process of this research, documentary research is crucial. I conduct extensive literature review and document analysis of primary and secondary sources. The three main websites – Commission (http://ec.europa.eu/), EMA (http://www.ema.europa.eu/) and EFSA (http://www.efsa.europa.eu/) – are used to collect most of the primary sources. They include Commission's White Papers, press releases, the founding regulation of the agencies, annual reports, opinion statements, advisory reports and evaluation reports of European agencies that were conducted on behalf of the Commission. These primary documents provide not only Commission's opinion on technocratic governance and the use of agencies' opinions in general but also fundamental information on the main activities and the legal setting of the agencies. In particular, the Commission published a comprehensive evaluation report of 26 European agencies in 2009, and the agencies are also required to conduct its own evaluation on a regular basis. These reports give basic information on interactions between the agencies and stakeholders, as well as useful insight of the job performance of the agencies and the stakeholders' level of satisfaction on the work of agencies.

As for the secondary sources, there are many academic journal articles and books published on the topic of European agencies that explain the roles and the political and social aspects of expertise and scientific knowledge. They are helpful when conceptualizing and developing the criteria for indicators to measure influence.

However, these methods pose substantial limits to analyzing motivations as reasons why agencies network. As definitions of network stress the informal nature of networks, the activities of the agencies analyzed in this part are informal, and there is no written information on them. Indeed, a lack of research on informal arrangements is due to a great challenge as there might not be any announcements of meetings, nor documentation of any

outcomes, nor information on the participants in any process (Christiansen and Neuhold, forthcoming 2011). Therefore, semi-structured interviews become the essential source of data for the analysis of informal activities. Conducting research with qualitative interviews is especially good at describing political processes, that is, how and why things happen in that way (Rubin and Rubin, 2005). Moreover, it is useful when I delve into important personal networking behaviour. Through interviews, I can also counter-check and collect new information that has not been documented. I conducted total 13 interviews, 10 with members and staff in EMA and EFSA and 2 with staff from national competent authorities of pharmaceuticals. Due to the practical reason of distance, all interviews were held via phone and email.

### 4.4 Introduction of the case selection: EMA and EFSA

This section introduces the role of EMA and EFSA that are selected for the case studies. The safety and availability of medicines and food safety are the areas in which agency-based regulatory developments have proceeded furthest (Randall, 2006). EMA and FESA have two crucial features in common. Firstly, pharmaceuticals and food safety not only involve enormous economic interests but also concern the public health of millions of EU citizens (Groenleer, 2009). If pharmaceutical and food products are not regulated properly, consumers in large populations of the EU may be exposed to potentially harmful risks that can be life-threatening. Secondly, they are engaged in pre-market control with the role of evaluating individual applications for marketing authorizations.

There are also differences between the two agencies. EMA was created in 1993 during the second wave of agencification while EFSA was created in 2002 during the third wave. The budget of EMA has grown from €14.4 million in 1995 to almost €210 million in 2011. 80% of its total budget is from industry for services provided by EMA, and the rest is from the EU subsidies. The budget of EFSA has grown as well from €12 million in 2003 to €77 million in 2011, and the total budget is from the EU subsidies. Scientific work is carried out by members (experts) in 6 Scientific Committees[6] in EMA, and there are 10 Scientific Panels[7] and one Scientific Committee in EFSA.

[6] They are Committee for Medicinal Products for Human Use (CHMP); Committee for Medicinal Products for Veterinary Use (CVMP); Committee for Orphan Medicinal Products (COMP); Committee on Herbal Medicinal

Table 6: Overview of EMA and EFSA

| | EMA | EFSA |
|---|---|---|
| Established Year | 1993 | 2002 |
| Location | London, UK | Parma, Italy |
| Budget for 2011 (M€) | 208.9 | 77.3 |
| No. of Staff | 833 (in 2010) | 450 (in 2011) |
| No. of Committees | 6 Scientific Committees (1 more to be established in 2012[8]) | 1 Scientific Committee and 10 Scientific Panels |

Source: Author's compilation

#### 4.4.1 European Medicines Agency

The European Medicines Agency (formally the European Agency for the Evaluation of Medicinal Products) was established to create a European authorization system for pharmaceuticals. Before its establishment, the doctrine of mutual recognition was applied in the pharmaceutical area to mitigate the tensions between diverse national regulatory policies and the need for harmonization. However, national regulatory agencies did not mutually recognize each other's assessments of applications in terms of safety and/or efficacy evaluation (Abraham and Lewis 2000). Thus, mutual recognition failed to produce a single market for medicinal products (Regulation (EEC) No. 2309/93). Moreover, pharmaceutical harmonization was the contested areas in the 2004 EU enlargement process because the new members had to upgrade their existing authorization systems to meet EU standards, and their products had to obtain marketing authorizations according to EU rules or be withdrawn from the markets (Koutalakis 2007).

Against this background, the 'compulsory' centralized authorization procedure was developed in 2004. Under this procedure, pharmaceutical products with certain features (e.g. medicines derived from biotechnology and high-technology processes) must receive

Products (HMPC); Paediatric Committee (PDCO); and Committee for Advanced Therapies (CAT).

[7] They are Additives and products or substances used in animal feed (FEEDAP); Dietetic products, nutrition and allergies (NDA); Food additives and nutrient sources added to food (ANS); Food contact materials, enzymes, flavourings and processing aids (CEF);Genetically modified organisms (GMO); Plant protection products and their residues (PPR); Animal health and welfare (AHAW); Biological hazards (BIOHAZ); Contaminants in the food chain (CONTAM); and Plant health (PLH).

[8] In order to ensure the availability of the necessary expertise and resources for pharmacovigilance assessments at Union level, REGULATION (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 requires EMA to create the Pharmacovigilance Risk Assessment Committee within the Agency.

marketing authorizations at the European level. EMA is the central place to accept all applications from pharmaceutical companies seeking authorizations. Therefore, the chief task of the Agency is "to provide Community institutions and Member States with the best possible scientific opinions so as to enable them to exercise the powers regarding the authorization and supervision of medicinal products" (Regulation (EC) No 726/2004). EMA evaluates applications for both human and veterinary medicines, and the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) are responsible for preparing assessment reports on evaluations. If necessary, four other committees assist them when preparing reports. In 2008, 62% of the budget and 41% of staff were dedicated to perform the main task (Ramboll et al., 2009b).

The second task is to provide scientific advice to the Member States and the EU institutions on any question relating to the evaluation of the quality, safety and efficacy (Regulation (EC) No 726/2004). As part of this task, EMA is involved in referral or arbitration procedures that are used to resolve disagreements on medicines approved under the decentralized procedure by one of the Member States. In a referral, the suitable Scientific Committee in EMA issues a recommendation after conducting scientific assessment of the concerned medicine in order to assist the Commission who makes a decision on the matter.

EMA also stimulates innovation and research of medicines by providing scientific advice and support to small and medium-sized enterprises; operating procedures with shorter regulatory timeframes; and encouraging applications for products intended for non-EU markets in the context of cooperation with the WHO (EMA, 2010d).

### 4.4.2 European Food Safety Authority

Due to the 1996 BSE (bovine spongiform encephalopathy, which is more popularly known as mad cow disease) crisis, credibility of the European institutions in food safety was lost. In order to restore credibility, the Commission proposed the establishment of EFSA. In the White Paper on Food Safety, the Commission argued that "it is considered to be the most appropriate response to the need to guarantee a high level of food safety" (CEC, 2000, p.3). Accordingly, it is argued that the current institutional framework of EU food safety regulation is to a large extent a product of the political crisis of European food policy caused by the BSE outbreak (Vos and Wendler, 2006).

After considerable discussion about the issues of food bans and the location of EFSA for several years, EFSA was finally established in Brussels in 2002 (and later moved to Parma, Italy). EFSA defines its role as a risk assessor that is in charge of assessing and communicating on all risks associated with the food chain by reviewing scientific data and studies. It draws a line between risk assessment and risk management, and states that it is not involved in risk management processes. As the risk assessor, it issues scientific opinions and advice to provide a foundation for European policies and legislation and to support policy-makers in the EU and the Member States in taking risk management decisions. The separation from risk management stems from a broadly shared feeling by experts during the BSE crisis and dioxin scandal that politics should be more strictly separated from science (Groenleer, 2009).

Its main task is to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety (Regulation (EC) No 178/2002). As part of this task, EFSA is involved in scientific evaluation of regulated food products. As in the case of pharmaceutical products, the centralized authorization procedure is applied to certain products, and the suitable Scientific Panel in EFSA is chosen to evaluate applications. For example, genetically modified food, feed or derived products must receive the marketing authorization, and the GMO Panel evaluates these applications. Evaluating products, substances and claims that need to be authorized under EU law has steadily grown to be a large part of EFSA's workload (EFSA, 2010a). When EFSA's Scientific Panels produce opinions, they are usually assisted by scientific units, and these units may also produce scientific outputs on behalf of EFSA, for instance in response to urgent requests for scientific advice.

The second task of EFSA is to harmonize risk assessment approaches and data collection across Europe and promote the collaboration with national food standard authorities on scientific questions and data collection (Ramboll et al., 2009b). Moreover, it performs a role in collecting, analyzing and summarizing scientific data to ensure that it can provide scientific opinions in all cases.

Having explained three indicators and operationalization of them as well as the methods of this thesis, the next step is to empirically analyze the indicators in the context of two selected agencies. For the purpose of the conciseness of this thesis, among various medicines and food, I mainly address the human medicinal products and genetically modified organisms (GMOs)

in the empirical analyses. The following chapter will examine the first indicator of agencies' influence: resources.

# 5. ANALYSIS OF RESOURCES

Information is processed and produced by European agencies as the main resources for influence. In this chapter, information is analyzed in terms of its characteristics and structurability.

## 5.1. European Medicines Agency

*Characteristics of information*

In order to examine the characteristics of information, the level of uncertainty and political salience is looked at. As for the level of uncertainty, the background of members in Scientific Committees is considered. The Committee for Medicinal Products for Human Use (CHMP) is the one evaluating applications of medicinal products, and consists of 1 scientific expert and 1 alternate from each Member State, Norway and Iceland, and 5 co-opted members. Each Member State, after consultation of the Management Board, appoints one member and one alternate to the CHMP for a three-year period which is renewable (Regulation (EC) No. 726/2004, Art. 61). On the EMA website, the curriculum vitae of all 34 CHMP members are published including the background information on education, professional experience and areas of expertise.

All members hold a position as doctor, senior scientist or scientific advisor at national competent authorities where scientific assessment of medicinal products for national authorizations is conducted. Each of them has its own area of expertise and research interests, thus their expertise all together covers various topics, from diabetes and vaccines to cardiovascular pharmacotherapy and clinical trial methodology. Although they are nominated by the Member States, they are selected for scientific and not for political reasons (Kraphol, 2004). The founding legislation also states that members "shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the competent national authorities." (Art. 61(1)). In order to ensure the high quality of objective scientific opinions, furthermore, EMA brings together the scientific resources through a network of over 4,500 independent experts who have their specialized field of expertise in science. They can be asked by EMA to provide specific knowledge on certain

issues. The scientific profile of the members and other experts in the EMA's network reveals that the Agency deals with highly uncertain issues.

In addition, European industry has been generally supportive of EMA (Vogel, 1998). The pharmaceutical industry wants to remain commercially viable since the average new drug launch needs to achieve sales of $500-$900 million annually in order to recoup its high R&D (research and development) costs (Hay 2008). Moreover, patients desire to have access to more medicines on the market to cure diseases. Applying reliable and comparatively strict standards to grant the EU-wide authorization is both industry and patients' long-term interest. Moreover, since integrating pharmaceutical markets through the mutual recognition principle has failed, the Member States understand that if every Member State seeks to rely as far as possible on its own domestic authorization system, none can benefit from market integration (Gehring and Krapohl, 2007). Therefore, there is no sign of Member States' conflict in pharmaceutical regulation, and political salience is low.

*Structurability of information*

There are two types of guidance documents in EMA: one is the documents published for applicants to ensure that they prepare applications in a manner that will be recognized as valid; and the other documents are targeted to members of Scientific Committees in order to apply consistent and objective criteria to all applications. These two types of guidance documents are more specifically divided into three stages, covering from the pre-submission stage for regulatory and procedural guidance to the evaluation stage and finally to the post-authorization stage for follow-up measures and specific obligations. For each stage and for each targeted audience, the documents provide detailed information about procedural steps and technical standards. Moreover, guidance documents are intended to provide a basis for practical harmonization of the manner in which the Member States and EMA interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy (EMA website, http://www.ema.europa.eu/ema/index, accessed on 23 May, 2011).

All applicants have to follow the guidelines suggested by EMA even before they submit an application. If there is any part in the application that does not meet the criteria (even a trivial issue of the convertibility of the dossier in PDF format), it is sent back to the applicant. In case of human medicines, there are five aspects of scientific guidelines for applicants: quality, biological, non-clinical, clinical efficacy and safety, and multidisciplinary. Each of them is divided into more specific issue areas that contain several guidance documents. For example,

clinical efficacy and safety aspect is divided into 16 sub-topics, such as blood products and anti-infectives for systemic use, and each of the sub-topics is listed with more than 20 guideline documents.

Since 2007, EMA has received on average about 100 initial applications per year. Considering the small numbers of Scientific Committee members, 100 applications is a large number. It becomes more surprising when the size of one application is considered. The Agency has to process "the overwhelming amount of information included in an average application of some 250,000 pages" (Gehring and Krapohl, 2007, p.216). Then, it is easily expected that the high level of structurability is the necessary element for EMA to perform its main task efficiently. The whole process of evaluation is systematized, and is applicable to all applications.

The evaluation process begins with the applicant's 'Letter of Intent to submit an application'. Then, a Rapporteur and usually a Co-Rapporteur are assigned among members, co-opted members and alternates from an appropriate Scientific Committee – for human medicinal products, it is the CHMP. Once an application is submitted and validated, the CHMP needs to evaluate the application and adopt an opinion based on Rapporteurs' assessment report within 210 days. The appointed Rapporteurs are supported by a team of assessors/ experts (assessment team) to carry out the assessment of the application at their national competent authorities.

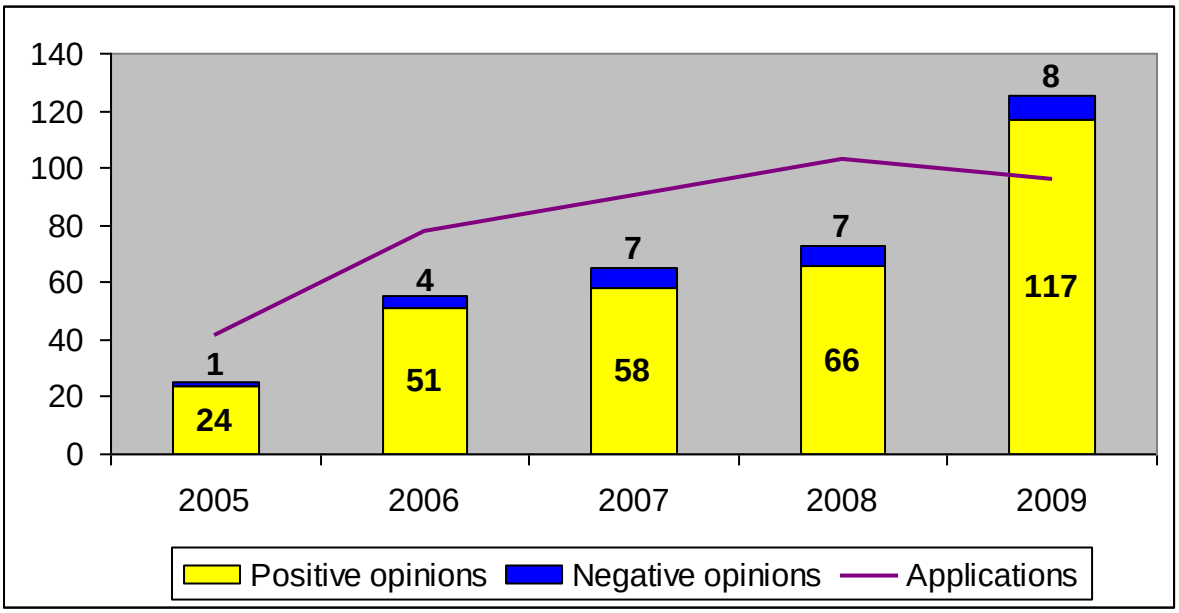
The whole evaluation period of 210 days can be divided largely into three parts. Firstly, by Day 120, the Rapporteur and the Co-Rapporteur with their assessment teams prepare the preliminary assessment reports separately, which are circulated in the CHMP for peer reviews, comments and questions. The list of questions and the issues raised by the CHMP is sent to the applicant, and the clock stops for the applicant to respond to the CHMP questions. Between Day 121 and 180, secondly, both Rapporteurs prepare a joint assessment report, and CHMP members give comments on it. A list of "outstanding issues" is sent to the applicant, and the clock stops again. After receiving responses and, if applicable, an oral explanation from the applicant, the last part of the assessment procedure begins. Between Day 181 and 210, the Rapporteurs evaluate the information submitted by the applicant, and make the final assessment report. On or before Day 210, the CHMP adopts its opinion by consensus or majority.

Table 7: Procedure steps for evaluation

| | |
|---|---|
| Day<br>0~120 | • Rapporteur and Co-Rapporteur prepare preliminary assessment reports.<br>• List of questions and issues is sent to the applicant. |
| Day<br>120~121 | • The applicant responds .<br>(the 'clock' is started again after the response.) |
| Day<br>121~180 | • Rapporteur and Co-Rapporteur prepare a joint assessment report.<br>• List of outstanding isseus is sent to the applicant. |
| Day<br>180~181 | • The applicant responds.<br>(the 'clock' is started again after the response.) |
| Day<br>180~210 | • The final report is made and the CHMP adopts its opinion. |

Source: Author's compilation

Figure 4: Number of applications and opinions adopted by EMA




Source: Author's compilation based on EMA's annual reports (2008; 2009a; 2010d)

According to Figure 4, until 2008 EMA was not able to evaluate all applications submitted to them. However, the past five-year record shows that the number of scientific opinions provided by EMA has increased every year, and the time limit of 210 days for evaluation has been met. It implies that the standardized procedure for scientific opinions is more routinized to members and staff of EMA. In 2009, the CHMP adopted the highest number of opinions ever adopted in one year. It was a total of 125 opinions – which was five times higher

compared to 25 opinions adopted in 2005 – 117 received a positive opinion and 8 received a negative opinion mainly because they did not meet the scientific standards of EMA. The CHMP took an average of 157 days for evaluation in 2009, thus 100% of applications were evaluated within the time limit (EMA, 2010d).

### 5.2 European Food Safety Authority

*Characteristics of information*

In EFSA, the main task of scientific assessment is conducted by 10 Scientific Panels, and the Scientific Committee is responsible for harmonizing opinions from different Panels. Unlike Scientific Committee members in EMA, members of the Scientific Panels in EFSA are not representatives from national competent authorities but independent risk assessment experts from a number of European countries. Each Scientific Panel has 21 members including one Chair and one or two Vice-Chair(s), and the Scientific Committee has 16 members – ten of them are Chairs of the Scientific Panels and six are independent experts.

Panel Members are appointed through an open selection procedure on the basis of their proven scientific excellence. The selection of members begins with publication in the Official Journal, on EFSA's website and in relevant leading scientific journals. Among those people expressed their interest, the Executive Director of EFSA draws a short list, and the Management Board appoints members for a three-year term which is renewable (Regulation (EC) No 178/2002, Art. 28(5)). All members hold a professional position as scientist, scientific advisor and professor.

Although highly qualified scientific experts carry out assessment of food safety based on objective knowledge, there have been many occasions that the Member States express concern over safety on human and animal health and negative environmental impact in the EU. In particular, issues related to the authorization of GMOs have caused a furious controversy among the Member States and between the Member States and the Commission. Under the current regulatory scheme, once GM food and feed products are authorized by the Commission, all EU Member States are obliged to open their markets to them. However, a number of Member States have invoked the so-called 'safeguard clause' to ban authorized GMOs from their markets, and six Member States are currently applying safeguard clauses on GMO events: Austria, France, Greece, Hungary, Germany and Luxembourg (Commission

Website, http://ec.europa.eu/food/food/biotechnology, accessed on 9 May, 2011). It shows that some Member States disagree with policy outcomes from the Commission on food policy.

Conflicting views from the Member States are included in opinions from the GMO Panel. Almost all scientific opinions on applications of GMO authorizations include a part called 'Issues raised by Member States'[9]. Moreover, citizens' concern over GMOs is also revealed in a survey result in 2006 that "overall Europeans think that GM food should not be encouraged; GM food is widely seen as not being useful, as morally unacceptable and as a risk for society" (Eurobarometer, 2006, p.4). They imply that issues of food safety, and specifically safety of GMOs, are politically salient to the Member States.

*Structurability of information*

Before the establishment of EFSA, the system dealing with complex scientific issues of food safety was at the limit of its capacity and delivered around 100 scientific opinions per year, and in its first years EFSA delivered around 200 opinions (Ramboll et al., 2009b). However, EFSA has made efforts to develop more systemized procedures to assist those who request scientific evaluation from EFSA as well as EFSA staff and members who produce information. In order to clarify EFSA's approach to risk assessment and assist applicant with preparing application dossiers, EFSA has published guidance documents that can be used by industry. In 2008 alone, EFSA produced 29 guidance reports. Each Scientific Panels also adopts guidance documents that fit in its specialized area. For instance, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has developed administrative guidelines including a "completeness checklist" for applicants and technical guidelines. The technical part itself includes 20 guidance documents. In addition, the GMO Panel currently presents eight guidance documents on its website, and the size of these documents varies from 4 pages to over 120 pages.

Furthermore, the workflow for scientific opinions is systemized with three steps: receipt of request, assessment, and adoption and communication. In the first step, EFSA's Mandate Review Committee screens all requests and sends the requests to the suitable Scientific Panel(s). The assessment step begins with identifying scientists from the relevant Panel by EFSA Secretariat and organizing a working group of the selected experts. The working group

[9] The contents of scientific comments raised by the Member States are not directly stated in opinions of the GMO Panel. They are addressed in 'Annex' of the EFSA overall opinion, which can be obtained by sending a request through the EFSA website.

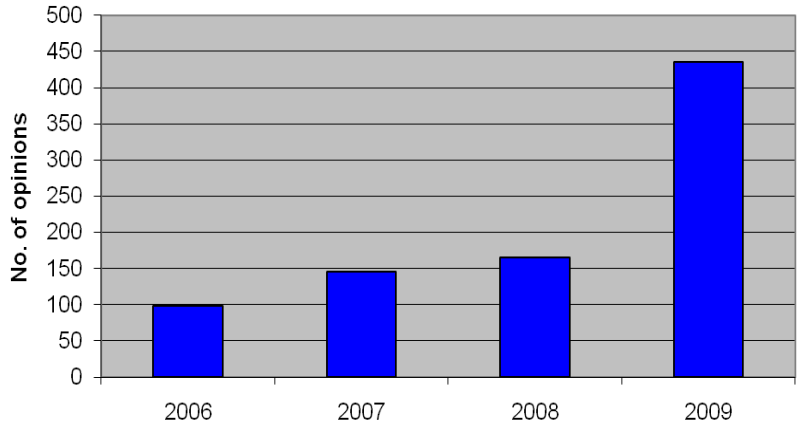
reviews available information and data to draw up a draft opinion. The Panel may decide to involve stakeholders and hold an open consultation to gather scientific input. In the last step, the draft opinion is adopted usually by consensus by the Scientific Panel, and in case it is adopted by majority, the minority view is mentioned in the opinion.

In 2008, the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC Panel) was replaced by two panels – the Panel on food additives and nutrient sources added to food (ANS Panel) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF Panel) – in order to divide work more efficiently. This new organization of the work helped EFSA to meet the deadline of evaluation of nutrient sources used in food supplements (EFSA, 2010a).

With regard to the GM food and feed authorization, all applications are regulated under Regulation (EC) 1829/2003 that provides the standardized procedure for evaluation within the time limit of six months. The assessment of GMO applications was further streamlined in 2009, and the GMO Panel has more than halved the time from validation of an application until the delivery of the first letter to applicants with questions or requests for further data (EFSA, 2010a). After an application is validated, the GMO Panel conducts risk assessment following the three steps described in the workflow above.

EFSA's commitment to delivering high quality outputs flourished in 2009 with total 636 scientific outputs compared with 489 the year before (EFSA, 2010a). With regard to GM food and feed authorizations, the standardized procedure enabled the GMO Panel to adopt three times more opinions on GMO applications in 2009 (14 opinions covering 18 applications compared to four opinions covering five applications in 2008) (EFSA, 2010a). When considering all opinions adopted by the Scientific Panels through evaluating applications, the number has increased continuously in the past four years as shown in Figure 5 – from 99 opinions in 2006 to 435 in 2009. Although the total number of applications submitted to the Panels in EFSA is not officially stated in their annual reports, it is clear that there have been efficiency gains resulting from the increase in resources dealing with applications (two new Panels) and a significant increase in their productivity based on structured procedures (EFSA, 2010a). In the same way, a qualitative survey conducted in 2009 on EFSA's handling of work concluded that "EFSA has demonstrated its capacity to deal with a huge workload" (EFSA, 2010b, p.13).

Figure 5: Number of opinions adopted with regard to evaluating applications in EFSA




Source: Author's compilation based on EFSA's annual reports (2008; 2009; 2010a)

### 5.3 Findings

Table 8: Comparison of resources in EMA and EFSA

| | | Relation to influence | EMA | EFSA |
|---|---|---|---|---|
| Political salience | High | Negative | | X |
| | Low | Positive | X | |
| Uncertainty | High | Positive | X | X |
| | Low | Negative | | |
| Structurability of information | High | Positive | X | X |
| | Low | Negative | | |

Source: Author's compilation

While the information of EMA is characterized with high uncertainty and low political salience, both uncertainty and salience are high in the EFSA's information. The highly structured procedure has enabled EMA to process a large amount of information and also to produce timely information. One evaluation report of EMA addresses that EMA shows a permanent willingness to develop an on-going improvement process (Ernst & Young et Associés, 2010). It appears that the information processing ability is one of the most

important assets of EMA. During the past few years, structurability of processing and producing information in EFSA has increasingly improved. It mainly results from a systemized approach to the workflow for scientific opinions and the re-organization of the Scientific Panels. The analysis in this chapter shows that the resources of EMA are positively related to influence while influence of EFSA can be undermined due to high political salience.

# 6. ANALYSIS OF ENVIRONMENT

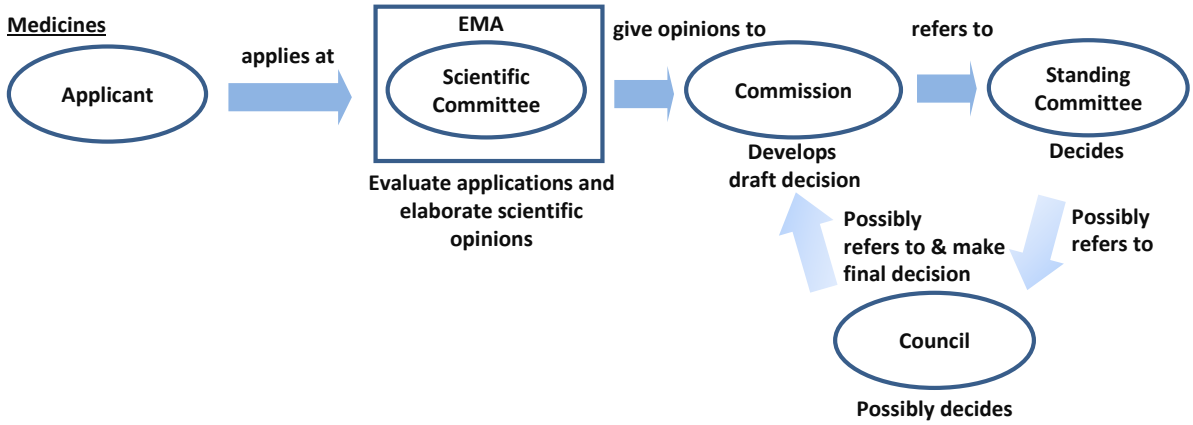
'Environment' is the second indicator of agencies' influence, and is understood in this thesis as the institutional setting in which agencies utilizes their resources and decision-makers adopt decisions on policy issues. In this chapter, environment is analyzed in terms of the level of coupling and formal restrictions imposed on decision-makers in the policy-making process.

## 6.1 European Medicines Agency

*Coupling*

As explained earlier, the main task of EMA is to provide the EU institutions and the Member States with the best possible scientific opinions in order to assist them with authorizing medicinal products. Under the centralized authorization system in the EU, all medicinal products for human and veterinary use derived from biotechnology or high-technology process; products intended for the treatment of HIV/Aids, diabetes, cancer or other immune dysfunctions; and orphan medicinal products which are used for rare diseases must receive marketing authorizations. In addition, applications of generic medicinal products, which are normally authorized under decentralized procedure through national competent authorities, can be accepted for consideration under the centralized procedure if the applicant shows that the generic medicinal product constitutes a significant therapeutic, scientific or technical innovation; or the granting of a Community authorization for the medicinal product is in the interest of patients at Community level (EMA, 2011). Once the marketing authorization is granted to a medicinal product through this system, the product can be marketed in all EU Member States, Iceland, Lichtenstein and Norway under one product name.

Figure 6: Centralized authorization procedure for medicinal products




Source: Author's compilation

As Figure 6 describes, the centralized procedure begins, conforming article 4 of the founding regulations of EMA, when an application for the marketing authorizations under the centralized procedure is submitted to EMA, Although EMA is the one who evaluates the whole application, it does not take a decision on granting the authorization to the medicinal product. The Commission draws up a draft decision, and the Standing Committee on Medicinal Products for Human Use where all Member States are represented makes a decision on the Commission's draft. Only when the Standing Committee fails to reach a decision, the matter is referred to the Council of Ministers. If a decision is not reached again at the Council, it is the Commission who makes the final decision.

At first glance, EMA as an advisory body does not seem to play an important role in this procedure. However, it is worth pointing out the founding regulation of EMA which states that:

> "only after a single scientific evaluation procedure addressing the quality, safety and efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards, should marketing authorization be granted by the Community" (Regulation (EC) No 726/2004).

It means that involvement of EMA cannot be sidestepped in the centralized authorization procedure. All applications are submitted to EMA, not the Commission, and necessary measures are taken by the Scientific Committees of EMA to scientifically evaluate applications. In case the Commission has scientific or technical doubts about the opinion of EMA, the Commission cannot itself amend, or ignore, the opinion, but must refer the matter

back to EMA where it is examined again by the Scientific Committee (Gehring and Krapohl, 2007). Since the first stage of the authorization procedure is dominated by EMA, Gehring and Krapohl (2007, p.215) argue that "[EMA's] scientific opinions inevitably set the agenda for subsequent decision stage". It proves that EMA is strictly coupled in the procedure.

*Formal restrictions*

Although none of the Commission and the Standing Committee is formally obliged to follow EMA's opinions, there are procedural measures that make them indirectly bound by the contents of EMA's opinions. Firstly, the Commission's proposals are indirectly bound by EMA's opinions. Within 15 days after EMA adopts its opinion, it should transmit the opinion to the Committee who formulates a draft decision. The founding regulation of EMA states that in case a draft decision of the Commission is not in accordance with the opinion of EMA, the Commission needs to provide a detailed explanation of the reasons for the differences. While it indicates that the Commission is allowed to deviate from EMA's opinions, in reality justifying the deviation may be too difficult. This is because each opinion from EMA means that it has been adopted by the Scientific Committees of the Agency where members are the representatives of national competent authorities in the EU. In this context, the Commission's deviation from EMA's opinion is the same as the deviation from the opinion of all or at least a majority of authorities from the Member States.

Moreover, Article 10(1) of the founding regulation of EMA states that the Commission should prepare a draft decision to be taken in respect of the application within 15 days after receipt of EMA's opinion. The time limit of 15 days would be too short for the Commission to seek outside opinions, and Gehring and Krapohl (2007) also argue that the Commission does not even make use of a separate scientific apparatus to scrutinize EMA opinions.

Secondly, the Standing Committee's decisions are also indirectly bound by EMA's opinions. After a draft decision is formulated by the Commission, it is delivered to the Standing Committee for a decision. Article 10(3) of the founding regulation of EMA requires that within 22 days, the Standing Committee has to forward their written observations on the Commission's draft. If there is no Member State raising any written objections or questions about the draft within this time period, it is counted as an approval of the Commission's draft. Then, during the next 15 days, the Commission issues a decision to grant the marketing authorization for 5 years which is renewable.

There are two conditions that cause a change of the written procedure to the meeting procedure in the Standing Committee: the first case is when the Commission sends an EMA's opinion back to EMA for re-evaluation; and the second case is when at least one Member State in the Standing Committee requests in writing that the Commission's draft should be discussed by a plenary meeting. In order to ask for a meeting, the concerned Member States have to state their reasons in detail as required by Art. 10(3) of EMA's founding regulation. In a plenary meeting, the Commission's draft can be rejected only when these reasons are convincing enough to change the position of a majority of the Member States that have not objected the proposal initially. Since this task is burdensome, it is not the usual path that the Member States take in the Standing Committee. Decision-makers involved in the procedure of authorizing pharmaceuticals function under high restrictions.

### 6.2 European Food and Safety Authority

*Coupling*

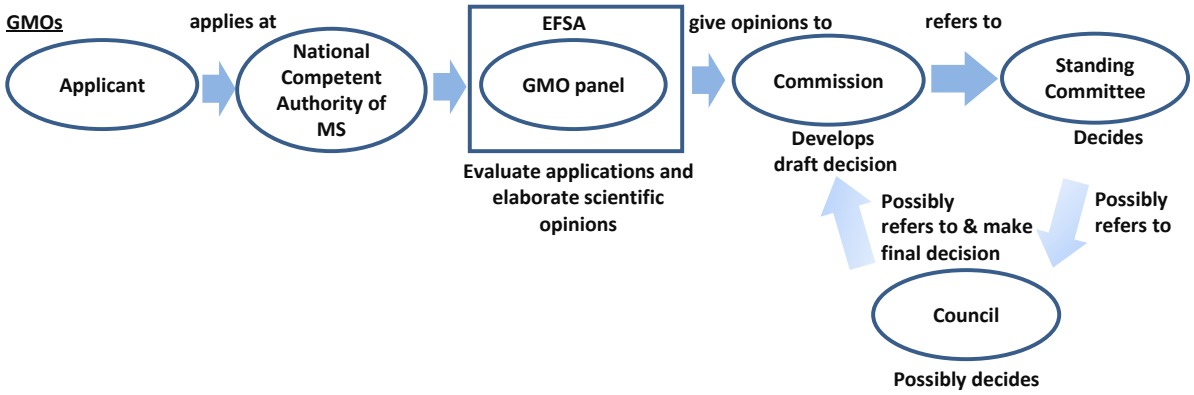
EFSA is involved in scientific evaluation of regulated food products or substances, and in 2009, evaluating applications represented 68% of scientific outputs of EFSA and consumed an ever-growing amount of EFSA's resources (budget and staff) (EFSA, 2010). Six out of ten Scientific Panels[10] are engaged with scientific evaluation of applications, and the subject areas cover additives and products or substances used in animal feed; food additives, nutrient sources and other substances deliberately added to food; enzymes, flavourings and processing aids; GMOs and GM food and feed; nutrition and food allergies; and pesticides.

Figure 7 below demonstrates the centralized procedure under which the GMO Panel evaluates applications on GM food and feed. Other Scientific Panels also take the similar procedure in their specialized issue area. The centralized procedure is very similar to the one authorizing medicinal products; yet there is one clear difference. All applications are not submitted to EFSA but to one of national competent authorities. After receipt of an application, the national competent authority informs EFSA without delay and makes all

[10] Six Scientific Panels are the Panel on Food Additives and Nutrient Sources Added to Food (ANS); the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); the Panel on Genetically Modified Organisms (GMO); the Panel on Dietetic Products, Nutrition and Allergies (NDA); and the Panel on Plant Protection Products and their Residues (PPR).

other supplementary information supplied by the applicant available to EFSA (Regulation (EC) No 1829/2003, Art. 5(2)).

Figure 7: Centralized authorization procedure for GM food and feed




Source: Author's compilation

Article 6 of the Regulation (EC) No 1829/2003 on GM food and feed states that the time limit allowed for the GMO Panel to conduct risk assessment on the application and adopt an opinion at a plenary session is six months. The GMO panel does not carry out its own studies, but makes a full risk assessment based on the data received from the applicant. In case the data is insufficient, the GMO Panel asks the applicant to provide the necessary data before the Panel proceeds with further assessment. Requiring more data or information before delivering the Panel's final risk assessment has happened in 96 % of cases (EFSA, 2010a). When an opinion is adopted by the GMO Panel, it is sent to the Commission where a draft decision is formulated. The following steps are the same as the procedure for medicinal products. Once the final decision is made to authorize the product, the 10-year marketing authorization is granted, which is renewable.

Although the beginning of the authorization procedure is initiated at one of the national competent authorities, it does not affect EFSA's level of coupling in the whole procedure. One EFSA official explained that the national competent authority "functions as a post-box and does not have to assess the dossier" (Respondent #13). EFSA checks if the dossier is complete and evaluates the dossier if it is a valid application. Since the Commission has to receive opinions from EFSA on evaluation of applications, involvement of EFSA cannot be sidestepped in the authorization procedure.

Besides the main task of evaluation of applications, EFSA responds to requests for scientific advice from the Commission, the European Parliament or EU Member States, and it may also

issue opinions on its own initiative. The Scientific Panels that are not responsible for the centralized authorization mainly focus on this task. Indeed, up to 2007 the majority of EFSA's work was about providing scientific advice to the EU institutions and the Member States. Requests for scientific advice, mainly from the Commission among others, grew from around 200 in 2007 to 285 in 2008, and in 2009 the number increased to 317 (EFSA, 2008; 2010). Through the tasks of evaluating applications and providing scientific advice to policy-makers, EFSA shows that it is strictly coupled in the food related policy process.

*Formal restrictions*

In the centralized authorization system for GM food and feed products, the level of formal restrictions imposed on decision-makers is low. Firstly, although there are time limits for each step in the decision-making stage, time constraint is low. Article 7 of the Regulation (EC) No 1829/2003 sets the time limit of three months for the Commission to formulate a draft decision. Moreover, the Standing Committee on the Food Chain and Animal Health (SCFCAH) also has three months to adopt the Commission's draft in respect to the application. If the draft of the Commission is agreed in the SCFCAH, the Commission can grant the marketing authorization. In case the Council is referred due to the failure to reach an agreement by the SCFCAH, the Council also receives the time limit of three months to make a decision on the draft.

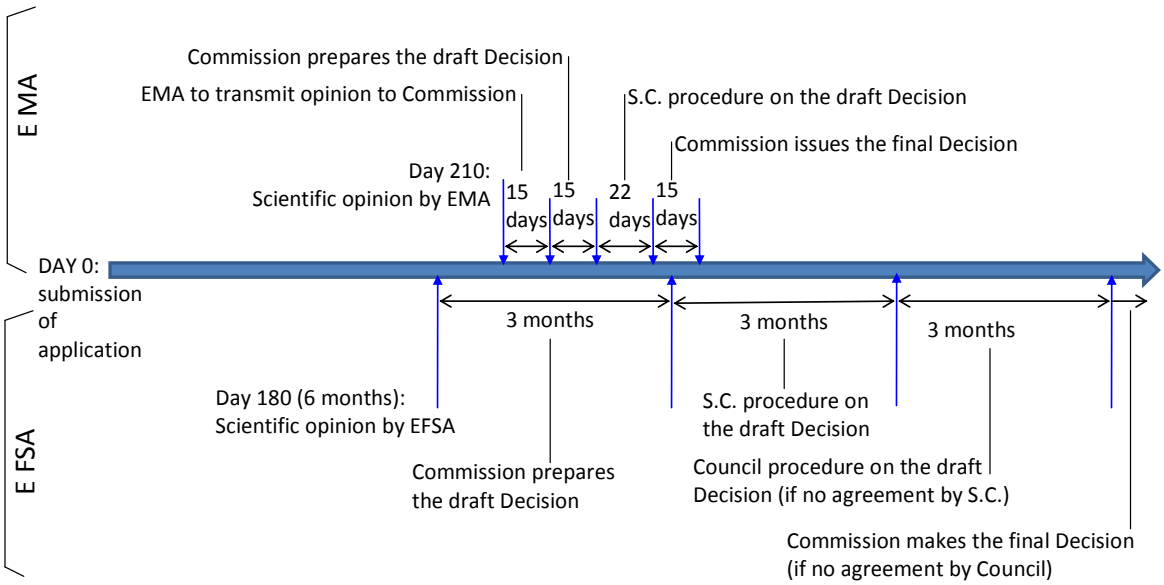
Secondly, the written procedure is not applied in the SCFCAH. Adopting a draft from the Commission is done based on the meeting procedure. In the SCFCAH, agreement on the Commission's draft requires a qualified majority vote. The meeting procedure with a qualified majority vote is also applied in case the Commission's draft is referred to the Council. Overall, low time constraints and the meeting procedure in the decision-making stage demonstrate that the formal restrictions imposed on decision-makers are low.

### 6.3 Findings

Both EMA and EFSA are strictly coupled in the policy-making procedure in the EU. They evaluate individual applications and issue their opinions. The Commission must receive these opinions in order to formulate draft decisions. Although the Commission and the Standing Committees are not legally obliged to formulate policy proposals and adopt decisions in

accordance with opinions of EMA and EFSA, in case of pharmaceuticals authorizations, there are high restrictions imposed on decision-makers. As Figure 8 shows, the total number of days allowed for decision-makers to reach a decision after EMA issues an opinion is 67 days. However, it is at least 6 months for food related authorizations (and it is more than 9 months if a draft of the Commission is referred to the Council). It implies that for EMA's opinions, the Commission does not have much time to scrutinize them by requesting and comparing separate opinions from other sources.

Figure 8: Time dimension of the centralized procedures for medicines and foodstuffs




Source: Author's compilation

Table 9: Comparison of environment for EMA and EFSA

| | | Relation to Influence | EMA | EFSA |
|---|---|---|---|---|
| Coupling | Strict | Positive | X | X |
| | Loose | Negative | | |
| Formal restrictions | High | Positive | X | |
| | Low | Negative | | X |

Source: Author's compilation

Moreover, decision-making in the Standing Committee is based on the written procedure for pharmaceuticals. Due to the burdensome features of the written procedure, decision-makers have less discretion to deviate from opinions of EMA. By contrast, decision-makers dealing with food authorizations adopt a decision based on the meeting procedure which allows more opportunities to reflect contradicting views. Therefore, all elements of the environment are in positive relations with influence of EMA; yet low restrictions imposed on decision-makers would undermine EFSA's influence.

# 7. ANALYSIS OF MOTIVATIONS

'Motivations' of agencies to network with certain stakeholders affect their level of influence on policy-making in the EU. As explained earlier, agencies have broadly four motivations for networking: (1) to disseminate information that they produce; (2) to find out conflicting views as well as what is generally expected from stakeholders; and (3) to increase legitimacy by interacting with stakeholders; and (4) to extract specialized information from them. In order to analyze motivations, the frequency of contact with stakeholders and the type of activities organized for stakeholders are examined in the context of EMA and EFSA.

## 7.1 European Medicines Agency

Main partners and stakeholders of EMA are the Commission, national competent authorities that deal with national authorizations of medicines, industry that develop medicines and seek marketing authorizations through the centralized procedure, and interest organizations of patients, consumers and healthcare professionals. On the EMA website, it is stated that "[EMA] has daily contact with the European Commission on issues related to the safety and efficacy of medicines". Since the Management Board of EMA has two representatives from the Commission as Board members, there are formal interactions between them through Management Board meetings. Additionally, informal informing practices have emerged in Management Board meetings that EMA director gives a verbal "highlights" presentation, in which he briefly reviews the agency's activities over the previous three months and discusses the planning for the following three months (Busuioc, 2010a, p.64).

Besides, according to EMA staff, a high number of exchanges between EMA and the Commission occurs after EMA issues an opinion (Respondent #7). At this point, the main partner among many 'Directorate-Generals' in the Commission is the "Pharmaceuticals" unit within the Directorate-General for Health and Consumers[11]. Since the decision-making process is initiated within the unit, EMA's motivation is to make them aware of EMA's opinions and to provide them with necessary information for their policy formulation.

Motivations for EMA's interactions with industry and national competent authorities are related to providing and gathering scientific information. EMA interacts with industry most

[11] On 1 March 2010, the regulation of medicinal products was transferred from Directorate-General for Enterprise and Industry to Directorate-General for Health and Consumers.

frequently during the pre-authorization stage. Pharmaceutical companies may request scientific opinions from EMA on the development of medicines. Moreover, when a company prepares to submit an application, it has pre-submission meetings with EMA (which take place approximately 7 months prior to the anticipated date of submission of the application) to obtain procedural, regulatory and legal advice from EMA (EMA, 2007). It is also possible to meet directly with Rapporteur and Co-Rapporteur to review the application from both a technical and scientific viewpoint. During the evaluation of the application, the applicant is contacted regularly on Day 120 and Day 180 for further information (see Table 7 Procedural steps for evaluation, p.52). Besides these two occasions, Rapporteurs may contact the applicant whenever it is necessary to request more information.

Between EMA and national competent authorities, there is very well organized and continuous contact during the evaluation period (Respondent #5). Firstly, members of the Scientific Committees in EMA are the representatives from about 40 national competent authorities. They attend regular meetings of the Scientific Committees. For example, the CHMP holds a meeting for one week per month. EMA and these members maintain regular contact through Committee meetings, and when interactions via email are counted, they have daily contact (Respondents #3, #4). Since members function as the contact points that connect EMA and national competent authorities, other experts or staff in national competent authorities neither have good knowledge of EMA nor directly contact EMA (Respondents #5, #8, #9).

Secondly, since Rapporteurs (together with assessment teams) evaluate applications at their national competent authorities, it is natural for EMA to cooperate with them. The Member States receive 50% of EMA's fee revenue for scientific work carried out by their exerts from national authorities, and in 2008 they were paid approximately €60 million (Ramboll et al., 2009b). Moreover, EMA is a member of the 'Heads of Medicines Agencies' (HMA) which is a network of the heads of the national competent authorities. There are four meetings organized by the HMA per year where EMA builds networks with national authorities to facilitate information exchange activities and cooperation between them.

The networks of EMA with interest groups focus on providing adequate information on medicines and its scientific opinions. As part of the public consultation process, EMA published a draft document on 'Transparency Policy' in 2009. It stated that the rationale for the development of such an policy is "to better address the increasing need for information

from civil society", and the objective is "to provide clarity on the Agency's opinion/decision-making process, not only from a procedural perspective, but even more importantly with respect to the (scientific) rationale for the [EMA] opinion/decision-making" (EMA, 2009b, p.1-3). Recently, EMA conducted an extensive survey among organizations of patients, consumers and healthcare professionals in order to find out their expectations on information on the benefit-risk evaluation of medicines, and published the result in 2009. In the report, EMA (2009c, p.1) highlights that:

> "[EMA] will continue to work with patients, consumers and healthcare professionals *to improve the quality of information* on medicines based on the recommendations made in this survey. In particular, the Agency will consider *involving more stakeholders in preparing relevant information*, making outcome of scientific assessments more accessible and using additional communication tools" (italics added).

Involvement of patients' organizations in scientific activities of producing information is most evident in the Patients' and Consumers' Working Party in EMA. Interviewees highlighted that since patients have a clear understanding of a positive benefit-risk balance and the type and magnitude of risk they are willing to take, they can be helpful when members make opinions on the approval of certain medicines, such as anti-obesity, cancer or others with less severe conditions but affecting the lifestyle (Respondents #2, #3, #6). While interviewees agreed that interest groups could add value to EMA's scientific activities, a lack of involvement of interest groups from non-English speaking countries, especially the Southern and Eastern European countries, was mentioned as a problem (Respondent #3).

In addition, what is crucial to address with regard to EMA's motivations for networks is that members understand the importance of producing high-quality, up to date and accurate information on each medicine. In order to discuss scientific information-related or procedure-related matters, extensive interactions among members are "key" and "in a positive sense, unavoidable" (Respondent #6). In preparation of an opinion, Rapporteur and Co-Rapporteur regularly (sometimes on a weekly basis) contact each other, and members meet face-to-face for several days a month for Committee meetings and have on average 3 to 4 teleconferences and one web-based meeting per month (Respondents #1, #6). Moreover, a system of "working dinner" has been put in place to improve information exchanges between the Chairs of the Scientific Committees (Ramboll et al., 2009b). Some activities mentioned above –

especially in relation to industry, interest groups and members within EMA – are not parts of EMA's responsibilities described in the founding regulation. Yet, its commitment to produce and exchange high-quality information (motivations (1) and (4)) motivates EMA to network with stakeholders.

### 7.2 European Food Safety Authority

EFSA has three main stakeholders: the Commission, the EU Member States and interest groups. The Member States should be understood as the governments, not national competent authorities. Unlike EMA, national competent authorities are not considered as main stakeholders since members of the Scientific Panels and the Scientific Committee in EFSA are independent experts and not the representatives from national competent authorities. As a consequence, EFSA only occasionally interacts with national competent authorities when they attend Panel meetings as guests (Respondent #10). In the case of the GMO Panel, there are on average 4 official meetings organized for national competent authorities per year (Respondent #12). Moreover, EFSA's interaction with industry is limited as EFSA does not provide pre-submission meetings or scientific consultation (Respondent #13). The only occasion that industry can interact with EFSA is during the evaluation period. Rapporteurs in the responsible Scientific Panel may contact applicants in case they need more information from applicants. Yet, the timing of contacting them is sporadic on a case by case basis (Respondent #13).

EFSA's contact with the Commission is frequent since the Commission sends one member and one alternate to the Management Board of EFSA. Annually, 5 meetings are held in the Management Board. Although EFSA is not obliged to invite the Commission and the Commission is not obliged to attend, Commission officials join most Panel meetings and Working Group meetings as observers (Respondents #10, #11, #12). On average, the Scientific Panels in EFSA hold 8 plenary meetings per year, and usually one Commission official (but as many as 5 officials) from the Directorate-General for Health and Consumers is present in Panel meetings. Through these occasions, EFSA delivers scientific information and its position on certain issues to the Commission.

What is significant in EFSA's networking activities is that EFSA has set "the huge engagement task" to reach out to the stakeholders who often express concerns about EFSA's

scientific outputs (EFSA, 2010b, p.8). The targeted audiences are the Member States and interest groups, and EFSA organizes consultations and meetings for them. Among other Scientific Panels in EFSA, the GMO Panel is the most active in networking with the Member States. It organizes meetings for them, and these meetings can be bilateral, involving experts from one Member State, or networking meetings, with experts from several Member States (EFSA website, http://www.efsa.europa.eu/en/gmo/gmomsmeetings.htm, accessed on 1 June 2011). In the past three years, total 13 meetings were held between EFSA and the Member States, and information on EFSA's scientific outputs and scientific issues that concerned the Member States were the main discussion topics. Besides, from the Member States side, they may express their opinions to EFSA concerning applications under the centralized authorization procedure within three months after the date of acknowledgement of valid applications. It appears that EFSA's motivations to interact with the Member States are based on the need to give the Member States opportunities to express their concerns on scientific outputs of EFSA.

EFSA's interaction with interest groups is more extensive. In 2009, 341consultations and meetings were held by EFSA (EFSA, 2010c). Dialogue with stakeholders continued to be the hallmark, and in 2010 EFSA organized more than 90 public consultations (EFSA, 2011). Interest groups involved in these consultations and meetings represent various policy areas, from environment and agriculture to food contamination and chemicals substances. It appears that EFSA considers public consultations as a key tool to reduce gaps between diverse interests and views on food related topics (motivation (2)). While it is acknowledged that EFSA has been working hard to develop close interactions with stakeholders (Respondent #12), the recent survey on EFSA's communication with stakeholders pointed out that "EFSA is overdoing it and spending too much time on meetings with all kinds of stakeholders" (EFSA, 2010b, p.50). Similarly, meetings organized by EFSA for stakeholders are seen as not sufficiently engaging in strategic debate since EFSA's presentations are too technical for the audiences to understand and there is no follow-up actions taken by EFSA on the comments delivered from stakeholders (EFSA, 2010b).

At this point, it is worth noting that extensive interactions with interest groups are not the result of mismanagement of activities by EFSA. Rather, they result from the belief that "when EFSA is dealing with controversial issues or popular foods, there is a need for more consultation that can go beyond the [scientific] opinion itself" (EFSA, 2005, p.40). In other words, the political controversy surrounding food related issues requires not only scientific

solutions about effective regulation but also a constitutive element connected to the legitimacy of the EU. It implies EFSA's motivation for increasing legitimacy (motivation (3)). Furthermore, Borras (2007) argues that issues on GMOs, in particular, have the trans-boundary nature, cutting across several policy areas and cutting across several interests and therefore, a large number of private interests need to be considered from the perspective of democracy.

According to 'Work Plan 2011' published on the EFSA website, active dialogue with all stakeholders, including applicants, will continue to be a vital feature of EFSA's work (http://www.efsa.europa.eu/en/corporate/doc/wp11.pdf, accessed on 1 June 2011). Moreover, enhancing dialogue with stakeholders is listed as one of the key strategic priorities in the communication strategy plan, which covers three years from 2010 to 2013 (EFSA, 2010d). Notwithstanding the increasing effort of EFSA to interact more with its stakeholders, interviewees from the GMO Panels expressed concerns over strengthening the relationships between EFSA and particularly interest groups. It stems from the fact that some interest groups have by definition negative opinions about some scientific outputs of EFSA, especially with regard to favorable opinions on GMO authorizations which are not in line with objectives of some non-governmental organizations (NGOs) (Respondent #10). It sometimes results in interest groups' "attack" on EFSA representatives and experts, rather than open discussions on scientific subjects (Respondent #11). In addition, there is a view that more involvement of interest groups is "not fruitful" for keeping scientific independence of the experts away from influence of interest groups (Respondents #10, #11).

### 7.3 Findings

EMA demonstrates that producing and disseminating scientific information are main motivations of its interactions with stakeholders. Especially, EMA maintains well organized and continuous contact with national competent authorities on a daily basis. Moreover, members of the Scientific Committees remain in daily contact with each other to exchange scientific information of medicines. In EFSA, interactions with interest groups are most extensive due to the trans-boundary nature of controversial issues on food. Although there are interactions with industry and the Commission for information exchanges, what is prevailing in EFSA are meetings and consultations based on motivations of reducing gaps among various interests and presenting legitimacy by including non-scientists. Thus, motivations of

EMA are in positive relations with its influence on policy-making while motivations of EFSA are in negative relations with influence as EFSA' interactions with stakeholders do not enhance scientific outputs of EFSA.

Table 10: Comparison of motivations of EMA and EFSA

| **Frequency / type of contact** | **EMA** | **EFSA** |
|---|---|---|
| Commission | Daily / Management Board meetings, informal information exchange | Monthly/ Management Board meetings, Panel meetings |
| Member States | n/a | Monthly/ Member State meetings |
| National competent authorities | Daily/ Committee meetings | 4 per year/ Panel meetings |
| Industry | Monthly/ consultations, pre-submission meetings, informal information exchange | Occasional/ informal information exchange |
| Interest groups | Monthly/ working party meetings | Daily/ consultations, meetings |

Source: Author's compilation

# 8. CONCLUSION

This research began with the main question that seeks to analyze the conditions that formally and informally affect influence of European agencies on policy-making. Since influence of agencies is understood as persuasion, agencies need to facilitate the production and usage of accurate information, argumentation or explanation. Based on this background, I suggested three indicators that affect the level of influence of European agencies. In the previous three chapters, resources, environment, and motivations were analyzed as the indicators of influence in the context EMA and EFSA. Below, I present influence of agencies based on the results of the case studies, and also discuss the results in relation to the concerns of technocratic governance. Lastly, I suggest likely implications on agencification and topics for future research in order to advance an understanding of European policy-making in practice.

## 8.1 formal and informal influence of agencies

In the case study of EMA, all indicators show positive relations to influence. Pharmaceutical issues, especially authorizing newly developed medicinal products, involve high uncertainty; yet, political salience is low since those issues do not directly affect the interest of most people. Thus, EMA functions in the policy process where the technocratic logic is applied. The procedure to process a large amount of information in a fixed time period and to produce scientifically accurate information in a timely manner is highly structured in EMA, which results in increasing numbers of scientific outputs. Moreover, involvement of EMA is strictly coupled in the centralized authorization procedure of pharmaceutical applications, and there are high restrictions imposed on decision-makers that make decision-makers informally bound by EMA's opinions in the decision-making stage. In addition, informal activities of EMA are concentrated on gaining and exchanging scientific information with its main partners and stakeholders.

The analysis of EFSA presents both similarities and differences compared to EMA. Based on the re-organization of the Scientific Panels and the systemization of the workflow of scientific outputs, EFSA has established the highly structured procedures for processing and producing information. It has brought an important impact on its scientific output that the number has increased from 99 opinions in 2006 to 435 opinions in 2009. On issues related to food safety, EFSA is also strictly coupled in the policy-making process. However, the nature

of food related issues certainly cause difference in the level of political salience and motivations for informal activities. While regulation on food safety involves high uncertainty which necessitates involvement of expertise, it also requires consideration on value and culture. The features of high political salience and involvement of trans-boundary interests partly affect EFSA's "huge engagement" with interest groups. Moreover, low time constraints and the meeting procedure in the Standing Committee and the Council allow decision-makers to easily deviate from EFSA's opinions.

Based on these findings, EMA is likely to exert high *de facto* influence while EFSA's *de facto* influence on policy-making is likely to be low. Is EMA indeed influential? In order to find this out, the content of Commission proposals and final decisions should be compared with opinions of EMA to see whether decision-makers have deviated from EMA's opinions. Since the centralized authorization procedure was applied in the EU, "the Commission has never yet departed from the content of the EMA opinions" on evaluation of applications (Respondent #7; Busuioc, 2010, p.174; see also Gehring and Krapohl, 2007). In the same way, the evaluation report of EMA which was published in 2010 stated that opinions from the Scientific Committees, such as CHMP, CVMP (Committee for Medicinal Products for Veterinary Use) and COMP (Committee for Orphan Medicinal Products), are "directly followed by a European Commission decision" (Ernst & Young et Associés, 2010, p.193).

As explained in Chapter 1, what I also suggest as a sign of high *de facto* influence is stakeholders' support on agency's work. The evaluation report of EMA which was presented to the Commission in 2009 concluded that EMA's work is supported by all stakeholders because of EMA's contribution to "an efficiency gain" compared to the previous system of national marketing authorizations (Ramboll et al., 2009, p.118). Similarly, another report states that:

> "since its creation in 1993, EMA has made considerable progress in setting up and maintaining an effective European authorization system [...]. In a quite limited timeframe, EMA has gained great consideration from all stakeholders, at European, at Member States level as well as at international level" (Ernst & Young et Associés, 2010, p.191).

Scientific outputs of EMA and stakeholders' support prove that EMA has high *de facto* influence on policy-making. Then, in the case of EFSA, is its *de facto* influence indeed low? Based on the criteria that either Commission's draft proposals or the outcome of decisions (or

both of them) are usually deviated from agencies' opinions, the answer is yes. In fact, draft decisions of the Commission have been in accordance with EFSA's opinions. However, the SCFCAH (the Standing Committee that adopts or rejects Commission's proposals) has *never* been able to adopt draft decisions of the Commission by a qualified majority vote. As a following step, the Council is referred to make decisions on Commission's draft decisions. The result is the same in the Council again: the Council has *never* been able to adopt draft decisions of the Commission. Again as a following step, the Commission becomes the one who makes the final decision.

Draft measures from the Commission are rejected only in cases of a timely negative vote of the Standing Committee or the Council through a sufficient qualified majority. However, they have never been able to adopt or reject Commission's proposals through a qualified majority vote. In all cases of food authorizations, the Commission has always approved its drafts and granted authorizations accordingly even though Member States' representatives both in the Standing Committee and the Council have failed to reach an agreement. Since Commission's proposals have been in line with opinions of EFSA, Commission's approval means that food authorizations have been in line with opinions of EFSA. However, it has resulted purely from the procedural steps – it does not mean that decision-makers have agreed with EFSA's opinions.

Moreover, the stakeholders' support of EFSA's work has mixed pictures. Generally, stakeholders support EFSA's work, and EFSA's response to authorizations is considered as satisfactory; yet, some stakeholders point out that the process of scientific outputs could be improved (Ramboll et al., 2009). Likewise, EFSA is seen by some stakeholders as "succumbing to politics in sensitive dossiers like GMOs" and as "not being bold enough, afraid to speak up clearly its positions" (EFSA, 2010b, p.7).

The analyses of the indicators and findings suggest that the hypothesis of this research is supported: indeed, European agencies can exert high *de facto* influence on policy-making, which may go beyond their *de jure* influence, when all three indicators – resources, environment and motivations – in agencies are focused on enhancing the production and usage of information. When only formal functions are looked at, EMA and EFSA look alike. Formally, these agencies are designed to be advisory bodies to policy-makers in the EU institutions and the Member States. Since policy-makers are not legally obliged to follow opinions from agencies, agencies have limited *de jure* influence. However, this thesis

redresses the important blind spot in the current policy-making pattern in the EU, and highlights that informal influence of European agencies on policy-making takes place in practice.

In the effort of analytically distinguishing formal influence and informal influence in the decision-making process, it should be clear what "formal" and "informal" mean. Formal influence is *de jure* influence that is exercised based only on formal processes, which are "man-made rules of behavior restricting and facilitating human interaction" (Héritier, forthcoming 2011). Formal processes are also "written down and recognized as binding on behavior under defined circumstances" (Brie and Stölting, forthcoming 2011). By contrast, informal influence is *de facto* influence that is exercised based both on formal and informal processes. Informal processes are not written down, and refer to social interactions that occur in formal contexts as well as outside the official channels of rule creation (Brie and Stölting, forthcoming 2011; Héritier, forthcoming 2011). It describes that formal influence arises through fixed rules, and informal influence is formed through flexible interactions within and outside the formal institutional setting.

According to above definitions, the second indicator – environment – is the one that determines agencies' formal influence. It is because the elements of coupling and formal restrictions are written down in the founding regulations of EMA and EFSA as rules of behavior. What is noticeable in this sense is that even on the formal side, the institutional design of EFSA limits its potential to influence in the policy-making process. As discussed earlier, formal restrictions imposed on decision-makers in the food authorization procedure are low, thus decision-makers have more room to seek outside opinions and reflect on diverse views.

Resources and motivations are the ones that determine informal influence of agencies. Although the characteristics of information are given to each agency naturally when it is established, uncertainty and political salience are not written rules. Rather, they are understood as informal factors that exist in the policy process because they indirectly determine who become the main actors and what become the main resources. Similarly, structurability and motivations are not man-made rules. They are formulated over time during actors interact with each other in certain procedures. When resources and motivations are compared in EMA and EFSA, only high structurability within resources is in common. The characteristics of information and motivations are different.

Then, among three different factors of EFSA that differ from EMA – formal restrictions, characteristics of information and motivations – what could be the crucial one for EFSA's low *de facto* influence? The formal restrictions partly determine influence; yet, in my view, when decision-makers face with issues related to food, and especially when it comes to GMOs, even high time pressure and the written procedure would not change the fact that the Standing Committee and the Council are not able to reach a decision. Issues related to foodstuffs are much more open for political interpretations, and Member States' interests can more easily influence the final decision (Krapohl, 2004). As a consequence, Member States' opinions on the matters of GMOs are "not only fairly evenly divided among the Member States, but are also politically charged, with most actors set in rather entrenched positions on this matter" (Christiansen and Polak, 2009, p. 7). Thus, even with the written procedure, the Member States are likely to raise objections in writing as they already do during the three-month period allowed for them to express their concerns in the centralized authorization procedure.

With regard to high political salience of EFSA, it is important to remember that few policy areas have the low political salience for the public or the broad social consensus across member states that allow them to be delegated to non-accountable EU institutions (Scharpf, 2001, p.14). Thus, it would be absurd to conclude all agencies under high political salience have low *de facto* influence. In fact, as mentioned in the beginning of this thesis, the European Environment Agency manages highly salient topics, but has learned to exert high informal influence through informal resources and informal institutionalization processes (see Martens, 2010).

Motivations should be considered as the crucial informal mechanism for high *de facto* influence. The analysis of EMA demonstrated that collecting scientific inputs from stakeholders and disseminating EMA's outputs are its motivations to network with stakeholders. By enhancing the production and usage of its scientific information, it is considered that, in practice, the outputs of EMA are more binding, and have more political impact even though EMA has a scientific advisory function (Ernst & Young et Associés, 2010). In the case of EFSA, its motivations are to give stakeholders opportunities to express their views and to show legitimacy that EFSA accommodates all kinds of stakeholders. Although it is not avoidable that partly the nature of EFSA's topics grabs attention from various interest groups and the need of their participation increases, the analysis of EFSA's motivations presents that the improvement of legitimacy is not the best way to increase

influence. What implications does it give to agencies functioning under technocratic governance?

### 8.2 Towards legitimate technocratic governance

In technocratic governance, the most notorious concern is decreased influence of democratically elected politicians and exclusion of ordinary citizens in the policy-making process. Therefore, the new challenge of the EU is to find a way to combine the need for more democratic elements while maintaining efficiency and effectiveness of policy outcomes. Radaelli (1999) argues that the balance between technocratization and politicization is frequently shifting across time and situations. Then, current technocratic governance should be modified with the situation the EU is in now and what is generally asked by the people in the EU. In this sense, while expertise as the main source remains necessary for the regulatory type of EU policies, at the same time, the new demand of stakeholders' participation as input legitimacy should also be incorporated as a necessary element of technocratic governance. The underlying assumption is that "for good governance and governance structures to be successful, it/they must be both effective and legitimate" (Heard-Laureote, 2010, p.17). De Visser (2009) also argues that the legitimacy consequent upon effectiveness is enhanced further if the inputs and procedures used can be shown to be legitimate. Indeed, this is evident in EMA. EMA includes patients' groups in the process of producing scientific outputs, and it has contributed to the increase of effectiveness as well as legitimacy (both input and output sides), which eventually enhance influence.

It seems that EFSA's motivations related to input legitimacy are overused. Although there is the natural need to involve stakeholders, EFSA should consider the right balance between effectiveness of outcomes and the degree of participation. The simple causality between participation and effectiveness of policies, or the increase of influence, may not happen that easily in reality. Participation should be accommodated to the extent that it contributes to the production and the use of information and that it does not undermine effectiveness. For example, instead of trying to involve all kinds of stakeholders, EFSA needs to find contending parties whose stakes are the biggest and create opportunities for them to reflect their positions in policy-making. Moreover, instead of organizing "political types" of meetings that discuss what they think is right, EFSA may provide stakeholders with more

access to staff and scientists by organizing "scientific" meetings that discuss what is scientifically right (Respondent #12). Additionally, if there are certain issues that receive many concerned comments from participants during a meeting, EFSA may publish follow-up documents that describe scientific evidence on which EFSA makes opinions (Respondent #13). These opportunities serve a critical role in legitimate technocratic governance. Participation of stakeholders is ensured, and it not only increases scientific inputs but also can increase influence.

The technocratic mode of governance per se is not an alternative of democracy, and decision-making based on expertise is not itself a sign of the legitimacy deficit. Since regulatory policies require problem-solving capacities, what could be the source of agencies' influence are expertise and the ability to persuade and supply information in the policy-making process. The point that is desired (yet challenging) is to find the right balance between ensuring participation of stakeholders and maintaining effectiveness and efficiency in policy-making. Effectiveness and legitimacy in technocratic governance do not have to be mutually exclusive; rather, they can co-exist and can even be complementary as seen in EMA.

### 8.3 Implications on existing and new agencies in the EU

The establishment of agencies is considered to be one of the most important institutional developments in the EU. Likewise, Majone (1996) argues that non-majoritarian institutions, such as European agencies, are bound to play an increasingly important role in Europe. Moreover, since agency option is merely complimentary to other means of EU governance such as comitology, it is very likely that European agencies will be established in the future on a case-by-case basis (Thatcher and Coen, 2008). If agencification and reliance on European agencies are not avoidable in policy-making, it is important to understand how agencies formally and informally influence policy-making, and how policies are shaped and decided in practice.

I have analyzed two agencies functioning under technocratic logic and epistemic communities, and showed that indeed EMA under technocratic logic exerts high *de facto* influence. As an expansion of this research, agencies located in other policy process such as bureaucratic politics and politicization (see Figure 2) could be compared together with EMA and EFSA. It would enable to see whether the current hypothesis is still supported. Moreover,

by analyzing more cases with different features, other indicators of influence may possibly emerge.

In this sense, what could be interesting is the role of national competent authorities in policy-making at the European level. National competent authorities are also the bodies with the ability to provide expertise and scientific knowledge to policy-makers, and they may directly reach the Commission with their policy inputs. Direct interactions of national competent authorities with the Commission can be considered as an external factor that may affect the level of European agencies' influence. Exploring potential factors that may determine influence of agencies seems to be promising next step to advance out understanding on European policy-making in practice. It would reveal by whom, based on what, and through what procedure policies are made in the EU.

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## Appendix: List of interview respondents

► For data collection on European Medicines Agency

| No. | Respondent | Position | Organization |
|---|---|---|---|
| 1 | Alar Irs | CHMP member/ Chair of the Committee for Advanced Therapies (CAT) | EMA |
| 2 | Beatriz Silva Lima | CHMP member/ CAT member | EMA |
| 3 | Harald Enzmann | CHMP member | EMA |
| 4 | Zsuzsanna Buzas | CHMP member/ CAT alternate member | EMA |
| 5 | Tamas L. Paal | Management Board member | EMA |
| 6 | Anonymous | Member (Scientific Committee) | EMA |
| 7 | Anonymous | Staff | EMA |
| 8 | Anonymous | Policy Support Officer | NCA* (United Kingdom) |
| 9 | Anonymous | Staff | NCA (Czech Republic) |

► For data collection on European Food Safety Authority

| No. | Respondent | Position | Organization |
|---|---|---|---|
| 10 | Christoph Tebbe | GMO panel member | EFSA |
| 11 | Detlef Bartsch | GMO panel member | EFSA |
| 12 | Anonymous | Member (Scientific Panel) | EFSA |
| 13 | Anonymous | Staff | EFSA |

* NCA (National Competent Authority)