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"Delegation to Independent Agencies: a comparative analysis between the food safety and pharmaceutical sector in Britain and Spain"

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ABSTRACT

This paper analyses patterns of delegation to regulatory agencies in the food safety and pharmaceutical sector in two European countries –Britain and Spain—in order to explain: (1) why do governments delegate their political power to regulatory agencies in both sectors; (2) at what extend regulatory reforms led to the adoption of similar organizational structures in terms of regulatory competencies and degree of delegation. Delegation is partly explained by principal agent theories and international policy transfers but functional explanations and mimetic processes are unable to give a full explanation of why delegation occurs in particular policy subsystems in some countries but not in others. A close analysis reveals that there is an important degree of delegation in the pharmaceutical sector in both countries, while in the food safety policy subsystem delegation only occurs in Britain but not in Spain. This paper argues that policy legacies and previous state structures are important to explain different patterns of delegation. In Spain, the distribution of competencies among central authorities and different levels of government in food safety does not allow delegation of powers to an independent regulatory agency. Similar institutional constraints does not exist in the pharmaceutical sector neither in the food safety policy subsystem in Britain, where the delegation process is also promoted by broader state reforms including the proliferation of agency type organizations within public administration reform programmes.

Introduction

During the last decade, some governments have delegated an important part of their regulatory functions related to pharmaceuticals and food safety to agency-like organizations. In Britain and Spain there is an important degree of delegation in the pharmaceutical sector. The *Medicines and Healthcare Regulatory Agency* (MHRA) in Britain and the *Agencia Española del Medicamento* (Agemed) in Spain have quite similar regulatory competences and function as independent agencies. However, in food safety the *Food Standard Agency* (FSA) has regulatory powers while the *Agencia Española de Seguridad Alimentaria* (AESA) is created as an agency-like organization but it has only an advisory role and a low degree of delegation.

The principal-agent approach is a good starting point for explaining the reasons of delegation. Credibility, blame avoidance, technical feasibility are among the functional advantages that explain why politicians decide to delegate their political authority to independent agencies like the Agemed, the FSA or the MHRA. But functional explanations cannot explain differences in the political independence of agencies among countries neither the variations in the timing of their creation, or/and why the Spanish government decides to delegate its regulatory competencies in the pharmaceutical sector, but not in the food safety. Other approaches (mainly from the neoinstitutional perspective) complement

functionalist theories taking into account explanatory variables such as state traditions and existing state structures; international policy transfers; or broader state reforms (like new public management reforms) giving a more comprehensive explanation.

In this paper we argue that state traditions and existing state structures are significant variables explaining patterns of delegation. Fragmentation of political power among ministries and between local, regional and central governments constitute the main barrier to create a more independent regulatory agency that assumes the responsibility to control food safety in Spain. Broader state reforms and international policy transfers are important variables that contribute to explain why governments decide to create agency-like organizations, but they give little explanation about the actual delegation of political power in different policy subsystems. The creation of specific programs for the reform of public administration that promote the creation of independent agencies at national level; or the development of supranational networks of experts and regulators open a *window of opportunity* (Kingdon 1984) to generate a regulatory change, but the possibility that ideas about agencification get into the agenda depends on the institutional features of each policy subsystem.

Delegation to independent regulatory agencies takes many institutional forms, making difficult to arrive to a final definition of the concept. Some authors defend a narrow definition of agency as an organization with its own powers and responsibilities under public law; organisationally separated from ministries, neither directly elected nor managed by elected officials (Thatcher 2001: 127). According to this definition, only few organizations could be labelled as independent agencies, leaving aside most of the agency-type organizations that become part of this international shift towards a new regulatory mode of governance. In this paper we follow a broader definition of what an agency is. Following Majone (2000:290) independent agencies are an omnibus label to describe a variety of organizations established by statute as independent administrative authorities, that perform functions of a governmental nature, and which often exist outside the normal departmental framework of government. They are independent in the sense that they are allowed to operate outside the line of hierarchical control by the departments of central government, but this does not mean to exercise power with complete independence, either vertically or horizontally (for example the USA food and drug administration is located within the Department of Health and Human Services) or to exclude the possibility of political intervention when the issue under consideration has broad social implications (Majone 1997:7). In general terms we are referring to organizations separated from Ministries, with its own powers and responsibilities defined and subject to public law; not managed by elected officials but controlled by them; financed at some extend but not necessary by the state budget; and composed (mostly) by public servants that carry out public tasks such as licensing service provision, certification, or adjudication (Pollit et al 2001: 274, Majone 1997, Thatcher 2001).

The paper is organized as follows. The first part presents a discussion of the food safety and pharmaceuticals regulation. The second and third part focus on the most relevant theoretical approaches for the analysis of the creation of independent agencies, including functional explanations and policy transfer processes. The fourth part compares the formal structures of the four agencies in order to explain their degree of political independence. We use quantitative indicators already tested by other authors, mainly those used by Gilardi (2002) and Thatcher (2001). The last part of the paper analyses the relevance of national variables such as state traditions and exiting state structures in explaining patterns of delegation.

1. Food safety and pharmaceuticals regulation

The regulation of food and pharmaceuticals products shares some important features. In both sectors, government intervention is aimed to guarantee access to first-need products, and to protect consumer's interest by reducing information asymmetries, and avoiding negative externalities. State intervention is oriented to avoid that the consumption of one individual has an unintended negative impact on the utility of another individual (negative externalities), and to provide accurate information to enable consumers to make an informed and safe selection of products (information failures). In order to achieve these goals most governments develop a more or less strict regulatory framework oriented to guarantee the quality, security and efficacy of food products and medicines by setting controls and monitoring processes before and/or after the entry into the market.

Regulation of pharmaceutical products is larger than food regulations in both authorisation and registration procedures and ex-post regulations (such us control of side-effects of medicines). Different levels of state intervention are explained by: the fragmentation of the market (Krapohl 2004) –the food market is much more fragmented than the pharmaceutical market— and the characteristics of the demand[1]. In the pharmaceutical sector, information failures and uncertainty about the consequences upon people health of taking medicines are large, especially after the technological revolution of the fifties when the production of medicines becomes industrialized. From that moment (and especially after the Thalidomine affair) the responsibility about the quality, security and efficacy of drugs relies not only on private actors –pharmacist and physicians— but also on the State that develops a more rigorous set of regulations oriented to control medicines before and after their commercialization. The State regulates a system of licensing of new drugs, authorises and controls the clinical trials and other pre-marketing tests and (from

[1] Prices do not give enough information to consumers to make the adequate selection of medicines according to their necessities or preferences. Besides consumer do not have enough knowledge about medicines. Consequently pharmaceuticals demand is divided into the physician who takes the decision about which is the best medicine for the patient; and the patient who finally takes the medicine prescribed by physicians. In most EU countries the state also intervenes in the demand of pharmaceutical products as the agent that pays for most part of the medicines consumed in its territory (more than 90% in Spain).

the mid eighties) develops programs for controlling side-effects (pharmacovigilance) of the medicines already in the market in order to make sure the quality, security and efficacy of drugs.

In contrast, State intervention in food safety issues is not so intensive. The regulation of food safety is traditionally left to private actors – mainly business and retailers—, and public authorities only assume a role for premarketing regulations (definition of food standards or labelling), food law enforcement (inspections) alert systems management and product liability. There is no control of side-effects like the one existing in the pharmaceutical sector. Farmers' responsibility on food safety is not as intense as that of the industry, mainly because it is understood that food safety problems coming from the first stages of the food chain can be eliminated through controls established at the industrial stage during transformation. New technologies applied to food, such as genetic manipulation, the globalization of markets and the crisis generated by events such us the "mad cow" scandal, are transforming public authorities approach to food safety. Most governments are developing new regulations based on an integral approach "from farm to table" extending controls through the whole food chain, including farmers, and applying preventive measures based on risk analysis, which are replacing existing "ad hoc" reactive measures. There is also an increasing interest to control side-effects oriented to reduce information asymmetries and uncertainty (for example in relation to the effects of genetically modified food upon people's health) but in any case they are as extensive as in the case of pharmaceuticals.

This new policy paradigm in food safety is introduced in Britain in 1999, once the new labour government passes a new Food Standards Act after the "mad cow" scandal. This new Act substitutes the Food Safety Act passed in 1990 after the crisis over Salmonella in eggs, which introduced significant policy reforms, including the implementation of European legislations requirements[2]. The new Food Standards Act, transforms food regulation in line with the new integrated approach –"from farm to table"— and limits the power of the Ministry of Agriculture, Fish and Food (MAFF) by the creation of the Food Safety Agency. In Spain, similar policy reforms are introduced in 2000, after the "mad cow scandal" arrived. The Law 11/2001, *por la que se crea la Agencia Española de Seguridad Alimentaria*, is the first attempt of the Spanish government to make food safety regulation more coherent. It creates the Spanish Food Agency (AESA) and establishes some of the general principles of the food safety policy, although it does not eliminate the legal dispersion that characterizes the food safety policy subsystem for decades[3].

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[2] After the crisis over Salmonella in eggs, although Thatcher strongly commitment to de-regulation as part of its globalizing vision, she was forced to pass new legislation. The Food Safety Act (1990) brought together and updated all food legislation into one comprehensive regulation and implemented some European legislations requirements (Official Control of Foodstuffs Directive 89/397/CEE). The Act set out to modernize regulations and procedures and introduced the "due diligence" defence provision, reinforcing self-regulation by industry through HACCP systems.

[3] Food safety policy goals are traditionally established in Spain within broad regulations such as the Consumer's Protection Law (1984) and the General Health Law (1986), passed after the massive food poisoning caused by adulterated colza oil in 1981. The introduction of European legislation requirements

The evolution of pharmaceuticals regulation in Britain and Spain also present some interesting differences. In Britain, the basis of the regulation of medicines is set by the Medicines Act of 1968, in which for the first time, manufacturers are obliged to prove the safety and efficacy of pharmaceutical products. From this moment a *Medicines Division* within the Department of Health is established as the drug regulatory authority (see Graham and Abraham 2001:58). In Spain, the first attempt to establish pre-marketing controls of safety and efficacy of medicines is taken in 1978 (with the approval of 8 Decrees) although most of its implementation not came into force until the late eighties. The *Dirección General de Farmacia* is created in 1978 as the medicines regulatory authority but it lacks resources to carry out most of its tasks related to pre-marketing controls of medicines. In 1990, the Spanish law of medicines is passed (more than three decades later than the UK) establishing the principles of the rational use of medicines which basically means to ensure a therapeutically sound and cost-effective use of medicines by health professionals and consumers.

At the end of the nineties the regulation of pharmaceuticals and food safety in Britain and Spain is delegated to independent agencies, created as a new type of organization capable to reduce information failures and negative externalities more efficiently than the already existing institutions. The Medicines Control Agency substitutes the Medical Division on the regulation of ex-ante and ex-post marketing controls of medicines. The *Agencia Española del Medicamento* assumes these regulatory functions in Spain[4]. In food safety, the Food Standards Agency assumes advisory competencies but also regulatory and executive functions, taking over many of the MAFF competencies in food safety, including meat inspections and hygiene controls. In contrast, the *Agencia Española de Seguridad Alimentaria* has only advisory competencies, and regulatory and executive powers remain within the Ministry of Health and Consumers Affairs (MSyC), the Ministry of Agriculture and Fisheries (MAPA) and regional authorities.

2. Functional explanations

The principal-agent approach has dominated the theoretical debate, focusing on the functional logic of delegation. Politicians (principals) decide to delegate their political power because regulatory agencies (agents) can fulfil important functions to them such as dealing with information asymmetries, increasing credible commitment, taking blame for unpopular decisions, rising technical efficiency of regulation; or helping to prevent political opponents from controlling the policy making process when they take power (Moe 1995; Elgie

(Directive 89/397/CEE) takes place in 1995, five year later than in Britain, through the Royal Decree 1397/1995 and Royal Decree 2207/1995.

[4] The Agemed assumes the functions performed by the *Subdirección General Evaluación de Medicamentos; Subdirección General Control Farmacèutico*; and the *Centro Nacional de Farmacobiologia* of the Minsitry of Health and Competences about medicines of veterinary use of the *Dirección General de Ganaderia* of the Ministry of Agriculture.

2006:208; Pollack 2002, Thatcher and Stone 2002). Politicians decide to create independent agencies taking into account the benefits of delegation and the costs that represent loosing control over the policy process. Delegation is understood as a rational process in which principals engage in a cost-benefit analysis in order to avoid agency looses[5], and to reduce transaction cost. According to this rational process, politicians define the formal institutional design of delegation –nomination of agency members, objectives, functions and administrative procedures, budget-setting, legislative vetoes or/and re-organisation of the agency structure— and determine the actual powers and degree of statutory discretion of an agency.

Delegation to regulatory agencies in the pharmaceutical and food safety sectors is partly explained by this functional logic. In both cases independent agencies are aimed to: (1) increase technical efficiency. This means to provide expert knowledge for the regulation of highly complex food safety or pharmaceutical issues, or to improve the implementation of regulatory procedures like to speed up the process of authorization and registration of a new drug in order to avoid delays in the commercialization of new products that reduce the patent-life period; (2) to increase political commitment to follow long term policy goals, leaving industrial interest in a second term, and (3) to facilitate the harmonization of regulations across countries avoiding the use of food safety or pharmaceuticals rules as non-tariff barriers to trade[6]. In the case of food safety, independent agencies are also aimed to restore policy credibility and social trust of public authorities –most of the food agencies are established after the "mad cow" scandal—; and to take blame for unpopular or controversial policy decisions, especially risk regulation. Risk regulation is not a simple matter since usually "there is a tension between factual and perceived risks, between technical, rational or expert approaches, and perceptions of the public and implications for policy" (Hellebo 2004:127). An illustrative example is the "mad cow" scandal characterized by a considerable expert disagreement and lack of knowledge on risk to humans that takes years of discussion. In these situations, politicians prefer to delegate policy decisions to independent agencies in order to avoid the (political) costs of taking decisions on problems over which there is uncertainty, especially if decisions may have an impact over public health.

Following the functional logic, in both sectors agencies accomplish similar objectives, but the reasons for its establishment respond to quite different

[5] In this process, principals take into account the costs of applying controls (large political controls damage the functions that the agency is supposed to perform and question the reasons for delegation) and their benefits (to move agencies closer to their preferences and avoid that agents follow its own preferences which diverge from those of its principal). The principal-agent model identify as agency looses what is called shirking (agent follows its own preferences which diverge from those of its principal) and slippage (institutional incentives causing the agent to behave contrary to the wishes of its principal)

[6] The globalization of food and pharmaceutical markets emphasizes the need for harmonized international regulatory regimes. For example, Controls on food additives were amongst the first harmonisation measures agreed in the European Economic Community (EEC). It was recognised that differences in food additive legislation caused substantial barriers to trade in the early Community. It was at this stage that the Community introduced the concept of E-numbers for additives used in both foods and animal feeds.

processes. In the case of food safety, regulatory change is an abrupt change directly connected to the "mad cow" scandal that puts into question the existing regulatory regime and institutions, while in the case of pharmaceuticals regulatory transformation is generated as a response to the demands of the pharmaceutical industry, mainly multinational firms. There is not a dramatic reduction of the credibility of pharmaceutical public authorities, but a general agreement exists about the necessity to improve the functioning of authorisation and registration procedures in order to increase the competitiveness of the European pharmaceutical industry. The creation of an independent agency is aimed to speed up the process of licensing of a new drug, and to guarantee the application of objective criteria and transparency avoiding the use of registration and authorisation procedures as a protectionist measure or as an instrument to favour some firms (national versus multinational).

Some data about research and development activities of the pharmaceutical industry illustrates the necessity for regulatory change and its connection with competitiveness. Research and development activities in the pharmaceutical industry are (1) lengthy: by the time a medicinal product is placed in the market, an average of twelve years will have elapsed since the synthesis of the new active substance; (2) costly: the cost of a new medicine is estimated in 870 million euros in 2001, while in 1987 it is only 344 million euros; (3) risky: on average, one out of every 10.000 substances synthesised in laboratories will successfully pass all the pre-marketing controls and become a marketable medicine (Di Masi et al. 2003); and (4) easy to copy. This is the main argument used by research based pharmaceutical firms to enlarge their monopoly power over medicines through a product-patent system that permits them to recover R&D investments. Improvements in the licensing of new products allow a faster commercialization of a new drug, enlargers the monopoly power of patents, and reduces bureaucratic procedures, creating a more favourable environment for the competitiveness of European pharmaceutical firms.

Summing up, the "mad cow" scandal and the competitiveness of the pharmaceutical industry are the driving forces that have motivated politicians to adopt a regulatory change and delegate some of its authority to regulatory agencies in order to recover policy credibility (more connected to food safety) and increase technical efficiency (more connected to pharmaceuticals). These functional advantages are important factors explaining regulatory change, but are unable to give a full explanation (Thatcher 2002:136; Wilks and Bartle 2002). Policy credibility or technical efficiency are important but not sufficient to explain why the Spanish government decide to delegate its political power in pharmaceuticals but not in food safety; or why there is a food safety agency with regulatory powers in Britain but not in Spain. It is necessary to draw on other analytical frameworks, different from functionalism, in order to understand why delegation in a particular policy subsystem takes place in some countries, but no in others in spite of the same functional reasons for delegation; why the timing of agency creation is different; or why independent agencies have different institutional features among countries and sectors.

3. Policy transfers and delegation to agencies

Following the neoinstitutional approach some authors stress the relevance of international policy transfers as an explanatory variable for the creation of independent agencies (Jordana and Levi-Faur 2004). The basic assumption is that nation-states are influenced by power dynamics and borrow policy ideas and practices from each other in order to maintain their position and status in the global system of states. Following DiMaggio and Power (1983), Guillen et al. (2005) identify three different processes of policy transfers: (1) *coercive isomorphism:* exertion of pressures for homogeneity by the state and other powerful actors in the domestic and international context; (2) n*ormative emulation:* imitation among countries linked to each other through social ties; and (3) c*ompetitive mimicry:* process of social competition stemming from the pressure to remain economically effective and efficient relative to relevant others[7]. This perspective focuses on the interdependencies of regulatory reforms among countries and sectors, establishes a link between supranational and national factors, and brings about the relevance of supranational regulations and policy communities to explain policy and institutional convergence.

The diffusion of regulatory agencies in the pharmaceuticals and food safety sectors across Europe is partly explained by a process of normative emulation. In pharmaceuticals, the creation of the European Agency for the Evaluation of Medical Products (EMEA) in 1993, and the transformation of the marketing authorisation procedures fostered a regulatory change towards agencification. From the mid-nineties there are two European routes of marketing authorisation of pharmaceutical products. Under the *centralised procedure*, marketing authorizations can be granted directly by the European Commission who officially takes the decisions about the licensing of a new drug, but based on the product evaluation undertaken by the EMEA. This procedure is only compulsory for products derived from biotechnology, and optional by the rest of innovative pharmaceutical products. Under the *decentralised procedure* authorisation is granted by the national authorities of a member state chosen by the firm, and the procedure operates by mutual recognition, this is, once the marketing authorization is granted by a member state, the firm may submit the same application in another member state, requesting to mutually recognize the marketing authorisation already granted.

The decentralized procedure is aimed to reduce systematic objections presented by member states in order to avoid (or delay) the registration and authorisation of a new drugs in its territory, and to guarantee the use of technical criteria for the licensing of pharmaceutical products. Once a product is authorized by a member state, other EU countries can only reject the application

[7] This is an effective strategy under conditions of uncertainty and bounded rationality because it helps decision-makers keep search costs within reasonable limits, sort out alternatives and legitimize their actions and prevents erosion of one's market position and social and political status. State's dependency on capital and its consequent need to appease capital by committing itself to provide and attractive market environment and stable regime for investment (Radaelli 2004).

according to objective and technical criteria, under the supervision of the EMEA. The mutual recognition procedure opens a new scenario in which national agencies compete to each other in other to get the initial application for the marketing of a new drug. Firms will submit their applications to those agencies which perform their tasks more efficiently in order to guarantee that once the initial application has successfully obtained the marketing authorisation in one country, there will be no trouble to obtain the recognition in other EU countries in a short period of time. As a consequence most member states create pharmaceutical agencies as a new type of organization, more performance and costumer oriented and capable to perform its tasks faster, less expensive and, at the same time, more technically rigorous[8] than its European counterparts.

As the EMEA, the European Food Safety Authority (EFSA) has no regulatory powers but it contributes to establish a network of experts and food warning systems across Europe, fostering cooperation and a shared vision of food safety problems and policies among national agencies and experts. At present, all food agencies across Europe share the same integrated approach to food safety "from farm to table" and its policy instruments designed mainly at the European level[9]. However, the EFSA impact on national agencies has been different in Britain and Spain. The Spanish Food Safety Agency goals, organizational form and working procedures are highly influenced by the EFSA. Spanish authorities clearly stated that the Spanish Agency would be designed in line with the new European Food Authority. They both work as independent institutions responsible for risk assessment while risk management remains with governmental institutions (the European Commission at the European level and the Ministries of Health and Agriculture in Spain). In contrast, the FSA in Britain goes beyond and has, in addition to advisory competencies, regulatory powers in line with the USA Food and Drug Administration. This makes clear that policy transfer cannot explain different patterns of delegation across countries.

European integration is an important factors that explains partially the diffusion of regulatory agencies. On the one hand, it is a new institutional setting heading a convergence processes in the goals and form of regulation across member states in economic and social aspects. On the other hand, the European Union becomes a new policy venue in which government officials and bureaucrats of different member states are strongly connected to one another, constantly assess policy and organizational developments in other countries, and tend to imitate each other's behaviour patterns as a way to conform to shared norms that appear legitimate (Guillén et al. 2001). European integration fosters the creation of networks of regulators across member states that share a common professional identity and favours similar regulatory changes across countries[10].

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[8] For more information about the EMEA and the marketing authorisation procedures see www.emea.eu.int

[9] New policy instruments include risk analysis based on risk assessment, risk management and risk communication; the application of the precautionary principle; increasing corresponsability of food actors for food safety through HACCP systems; traceability or new warning mechanisms.

[10] But the pharmaceutical agency is an exception since it has obtained important regulatory capabilities (Feick 2002)

For example, the EMEA has four working committees formed by scientific experts representing all member states. In 2003, 386 meetings (569 days of working) were held and more than 4.047 experts met to analyse and discuss about the European pharmaceutical market setting strong connections among experts and politicians at the European level (EMEA 2004).

Functionalist approaches and policy transfers explain convergence towards agencification across countries. Both are conceptual tools that help to understand why agencies become a new type of organization that most European countries adapt in the pharmaceutical and food sector as a result of a process of normative emulation in order to get economic and political advantages (technical expertise, credibility, blame avoidance). But regional integration is unconvincing when one examines the general patterns of diffusion of regulatory agencies at the national level. Policy transfer has a direct influence in the diffusion of agencies, but the timing and institutional design – degree of delegation— is explained by national factors. In Britain, the Medicines Control Agency is created some years before their European counterpart by a specific program enclosed in a broader reform of the public sector (Pollit et al. 2001:272). By contrast, the Spanish agency is created some years after as an acceptable alternative to increase efficiency and quality of the bureaucratic system, without any specific program that defines goals and strategies. In contrast, in food safety, the British, Spanish and European agencies are established almost simultaneously as a response to the BSE (Bovine Spongiform Encephalopathy) scandal but only the FSA has regulatory powers. What explains differences in their institutional design are different state traditions and existing state structures that limit delegation of regulatory competencies.

The following section first describes the level of formal independence and institutional structure of the four regulatory agencies. Then, those variables that best account for these differences are explained. Different patters of delegation among countries and policy sectors show the pitfalls of the functional logic of delegation and the need for additional explanatory variables based on domestic factors. The argument is that institutions do not automatically converge toward a new regulatory model, but the creation of agency-like organizations is a result of a historical process determined by policy legacies, and previous state structures. Regional integration and broader regulatory reforms at the national level, open a *window of opportunity* to generate a regulatory change but the possibilities that this change occurs depends on the institutional framework of the pharmaceutical and food safety policy subsystem

4. Pharmaceuticals and Food safety Agencies: a comparison

A comparison of the functions (key activities) performed by each agency reveals that regulatory competences are important in all cases but the AESA. Regulatory activities carried out by the Agemed and the MHRA are quite similar: both operate a system of licensing, classification, monitoring and enforcement to ensure that medicines sold or supplied in its territory are of an acceptable

standard; authorise, control and monitor investigation of medicines in clinical trials; maintain a register of medicines; and operate a system of post-marketing surveillance. Both agencies are responsible to concede, reject, restrict or withdraw the marketing authorisation of medicines. The main difference is that the Agemed has also regulatory competences upon medicines of animal use (like the EMEA in Europe) while in the UK these competences are a responsibility of the Food Safety Agency.

In food safety, both the FSA and the AESA have advisory competencies and provide scientific advice on food safety and regulation. They promote coordination of research activities and food alert systems among public authorities, and represent the country in front of international organizations. However, the FSA has also regulatory competencies which mean to issue general codes of practices and coordinate, monitor and audit local public health authorities. The FSA is also responsible for performing meat controls (the Meat Hygiene Services moves from the MAFF to the FSA); it has a role in the licensing and approval of food products and processes in the UK; carries out checks at borders and evaluates the safety of pesticides and veterinary medicines. It also incorporates parts of the State Veterinary Service to coordinate surveillance of animals aspects of food safety. In contrast, the AESA does not have responsibilities related to inspection or/and food law enforcement, which remain in the hands of regional authorities. It is responsible for the management of the General Foods Register but does not have safety evaluation competencies, neither responsibilities related to veterinary services (keep within the Ministry of Agriculture) or borders controls (keep within the Ministry of Health).

According to the indicators developed by Gilardi (2002) to measure formal independence of the agencies, there are important differences in the average degree of delegation of political power across sectors and countries (see annex 1). Delegation is larger in Britain than in Spain, especially in those aspects related to financial and organizational autonomy. The MHRA is financed almost completely by external funds (it is defined as a trading fund), while the rest of agencies are mainly financed by the state general budget. This is especially the case of the Spanish agencies. Only 20% of the financial resources of the Agemed are external funding while in the case of the MHRA public resources are marginal. The MHRA also has complete autonomy to control financial and human resources, while the rest of agencies only have a limited control over their resources and internal structure. Important variations also exist in the relationship between agencies and elected politicians. In the case of the pharmaceutical sector, both agencies have to present an annual report to inform the government about their activities, but no formal obligations exists vis-à-vis the Parliament. Besides the decisions taken by the MHRA and the Agemed can only be overturned by a court, at least in formal terms. In contrast, the Spanish and British food agencies are fully accountable to the government, have to present an annual report to inform the Parliament about their activities and their decisions can be overturn by the government (although in the case of the British agency only exceptionally).

Delegation of political authority is also determined by the characteristics of the agency head and management board members status. Agencies define a set of institutional mechanisms aimed to avoid the politicization of agency regulators and increase the probability that the agency performs its tasks independently from elected politicians. In the case of pharmaceuticals, there are almost no formal requirements (defined in the statutes) oriented to guarantee the independence of the agency director: the agency head cannot hold other offices in government, but one or two ministers appoint and dismiss the agency head discretionally, there are no limits for appointment renewals, and independence is not formally required (although normally is). In the case of food safety, the term of office is fixed by law and the appointment of agency head is more restricted, but in general terms independence controls are quite low in all cases. The degree of politicisation can also be measured by the percentage of agency members holding or standing for public office before or after the agency term (Thatcher et al. 2001). This gives more information about the actual level of independence of the agency head. It is interesting that in the case of the Agemed, two of the four agency directors from 1999 to 2006 have been appointed *Director General de Farmacia* after their agency term, one of the highest governmental positions in the Ministry of Health, with a strong political bias.

Finally, there are important similarities between British agencies in relation to management board members. In both cases, the board is composed only by experts, appointed by one Minister, renewable without limits that perform their tasks for no fixed term. In contrast, board members of the Agemed are both experts and members of government (mainly the Ministry of Health and the Ministry of Agriculture) that have a direct control upon the agency annual report, and annual budget). The case of AESA is especially interesting. The board is composed by experts, members of government and social groups that exchange ideas, resources and information about food safety policy goals and strategies. The features of the board represent the characteristics of the Spanish food safety policy subsystem characterized by the fragmentation of power inside and outside government.

Differences between the MHRA and the FSA are quite consistent with the existing literature about British agencies. According to Pollit et al. (2001: 280) significant variations occur in the degree of delegation of political power among British agencies: “the larger agencies are self-sufficient in terms of traditional management functions of finance and human resource management, but others still rely extensively on their parent ministries”. Most British agencies have formally received a great deal of delegated authority over personnel and financial issues, but even this authority is still constrained by central government controls and guidance that operates differently for different agencies. Most agencies continue to be responsible to individual ministries, carry out their tasks within frameworks agreements with their parent departments; work with specific budgets and targets defined in an annual report reviewed by the government; and answer operational issues directly although the extend to which these replies are actively screened by the government varies a good deal (Pollit et al. 2001:280). By the same token, differences between the Agemed and the AESA illustrate one

of the main characteristics of the process of agencification in Spain. Until present[11], there is not a global programme that fosters the creation of agencies as a new form of regulation across sectors, but the flexibility of the regulation of public bodies makes possible the creation of agency-like organizations that in most cases are an imitation of the organizations adopted elsewhere. As a consequence, Spanish agencies are quiet heterogeneous in both, their organizational form and their regulatory competences.

Summing up, the degree of delegation to agency-like organizations is larger in Britain than in Spain, and is also larger in pharmaceuticals than food safety. In comparative terms, delegation to the MHRA is high. According to its legal framework, it has more financial and organizational autonomy, and a larger capacity to take decisions outside the control of elected politicians than the Agemed, despite both agencies have similar regulatory competences. The main difference between the MHRA and the FSA relies also on its organizational autonomy and the capacity of the Department of Health to overrun its decisions in exceptional situations. Finally, the main difference between British and Spanish food agencies is that delegation of political power to the AESA never occurs. The next and final part of the paper is aimed to explain why the Spanish food agency does not have regulatory powers.

5. State structures and broader state reforms

The FSA and the AESA are created within a year of difference, after the BSE scandal. Both are public bodies, attached to the Ministry of Health, but while the FSA has regulatory powers and a moderate degree of political independence, the AESA has only advisory powers and its degree of independence is quiet low. Both organizations are created as a result of a crisis situation that brings about the pitfalls of the previous regulatory system and force a change towards a new policy paradigm ("from farm to table"). The question is why the British and the Spanish food agencies are given different regulatory powers. Policy legacies and the lack of broader state reforms –including the proliferation of agency-like organizations within public administration reform processes—, explain the lack of regulatory powers of the AESA.

In Britain, the "mad cow" scandal made clear that state institutions where in urgent need for reform. Despite many experts informed about the possibility that the BSE could be transferred to humans, the "mad cow" disease was defined by the MAFF as a problem of agriculture rather than one of public health, putting industrial and agricultural interests in a quite advantageous position. In 1996, when the British government officially announced its transmission to humans, the MAFF reduced its already questioned credibility to manage food safety issues. In contrast to other countries, in Britain the Department of Health (DoH)

[11] The *Ley de Agencias* (Agencies law) is going to be passed next autumn 2006 (at present is in the last stage of the parliamentary discussion). This law is aimed to reduce heterogeneity and to create a favourable environment for the creation of these organizations more performance and client oriented and more autonomous from elected politicians.

had a marginal role in food safety issues. For decades, the MAFF centralizes most aspects related to food safety, including responsibilities for hygienic and sanitary aspects (Smith, 1991)[12] which means that the MAFF has to deal with two separate but sometimes opposite policy goals: promoting the food and farm industries development and protecting public health through the food chain.

The BSE scandal illustrates that the MAFF serves excessively commercial interest, eroding public confidence in the current system of food safety controls and governmental institutions. Consumers, public authorities, groups of experts, members of scientific committees as well as companies in the food producing, processing and retailing fields share the same position about the failings in the system, and agree on the idea that all sanitary aspects of food safety should be separated from the MAFF (James 1997). The BSE scandal opens a *window of opportunity* to prompt in depth policy reforms and not merely incremental policy adjustments. The pitfall of the previous system and the conflict of interest that represents the monopoly of the MAFF over food safety issues, facilitates the establishment of the Food Safety Agency[13], as a new regulatory institution that takes most of the MAFF responsibilities on food safety in order to increase technical efficiency of regulation, avoid manipulation of policy decisions in favour of particular interests and increase the credibility of political institutions. The MAFF is transformed into a new Department for Environment, Food and Rural Affairs (DEFRA) minimizing its responsibilities on food safety (it only keeps responsibilities on sensitive food issues such as genetically modified food, farm practices or animal health). No competencies disputes emerge among the MAFF and the DoH to get the control of the agency, since there is an agreement among public authorities and social actors that it is the DoH that has to take the lead on food safety.

Using Kingdon's approach, there is, in Britain, a coupling between three streams: a crisis that legitimates a reform supported by main political actors, a change in the national mood about credibility of public institutions; and an agreed idea about how the agency structure helps to increase public sector credibility and efficiency. In the UK, agencies are seen as the new answer to a variety of problems that emerged from the economic crisis of the seventies. Independent agencies are an important element of a broader state reform defined in the *Next Steps Report,* which encourages the creation of agencies as more autonomous, and more specialized public bodies capable to increase efficiency, restore trust in governmental institutions and improve the quality of public services. According to Pollit et at. (2001: 277)[14] the creation of independent

[12] The MAFF is the lead department on food standards, chemical safety of food (veterinary drug residues, pesticides and heavy metal contamination), food labelling, food technology and animal health and feeding. It is also responsible to provide meat inspection service to licensed meat premises and enforce hygiene and welfare laws in slaughterhouses through the Meat Hygiene Service (MHS).

[13] The FSA is established as a Crown body within the DoH and concentrates food safety competencies, including the coordination, monitor and audit of local authorities activities on food safety –food law enforcement and inspections—.

[14] Following New Public Management reforms, Mrs Thatcher announces that "to the greatest extent practicable the executive functions of government, as distinct from policy advice, should be carried out by units clearly designated within Departments, referred to as "agencies"' (*House of Commons Debates*, 18

agencies is a way of freeing civil servants engaged in operational tasks to manage in a more flexible and professional way. This is illustrated by the fact that in 1995, more than 75% of all British civil servants fall under a next steps agency regime (Kickert, 1996). It is also a way to put in place business like management and more specifically to develop performance measurement and reporting mechanisms. "In any event, each year each agency publishes a report in which it sets out to what extend it has achieved the targets it has been set an what targets are being put in place for the year to come" (Pollit et al. 2001: 278). The Spanish agencies lack the sophisticated performance measurements that characterize the British agencies. Systematic sets of performance indicators are not available, and annual reports contain only brief references of quantified performance data. Performance contracting ideas are not implemented despite the emphasis of the Spanish government on the necessity to transform the public administration according to the principles of new public management.

In contrast to the British case, the creation of agency-like organizations in Spain, as most parts of the reform of the public administration, is the result of an unplanned process that brings about the rigidities and limitations of the Spanish public administration. Most of the agencies created in the last decade in Spain are an imitation of the agency model developed in other European countries and the European Union. This is partly explained by the fact that there is not a specific program that defines the general rules for the creation of this new type of public bodies –as a consequence 47% of the 139 public bodies created in the last decade have an especial status (*regulation à-la-carte)*—. The lack of a general programme, plus the flexibility of Spanish regulations facilitate the creation of a broad array of public bodies (quite heterogeneous in its internal structure and functions) oriented to solve problems related to efficiency, lack of autonomy, specialization and quality of public service provision. This unplanned process also illustrates that in contrast to Britain, the Spanish government do not have such a clear idea about the institutional reforms that should be taken in order to guarantee a better response to social, economic and political demands. There is not a report such as the *Next Steps Report* which stresses the relevance of agency-like organizations across sectors, from telecommunications to pharmaceuticals.

The lack of a strong idea (about the benefits of agencies) plus the fragmentation of power explains why there is not delegation in food safety. The Spanish food safety policy subsystem is characterized by the fragmentation of political power at the national level between the Ministry of Health and the Ministry of Agriculture, and between different levels of government –national, regional and local authorities—. In contrast to Britain, the Ministry of Health monopolizes responsibilities for food safety issues –including national legislation on sanitary and hygiene aspects of food controls—, while the Ministry of Agriculture and Fisheries deals with non-sanitary aspects of specific areas related

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February 1988, column 1149).This is also the main message of Major's white paper 'Citizen's Charter' in 1991. The Labour government has continued the reform process initiated by the Conservatives and in 1999 published a Modernizing Government White Paper

to food safety[15]. The distribution of competences between Spanish ministries – the defence of public health is not within the same department responsible for defending agriculture and industrial interest— limits the potential conflicts of interests, but also blurs the responsibility between the actors involved in the policy process, and generates problems of coordination. These coordination problems occur not only at the national level (between the two ministries), but also between different levels of government. Regional governments have important competences in food safety –mainly food law enforcement, regional legislation and implementation of the official control requirements— and, at least in formal terms, they have to coordinate their activities with the central government. But in most cases regional governments develop their activities in isolation from each other, and the institutions created to coordinate activities between the central and regional governments has never worked as such[16].

Coordination problems are made explicit to public opinion when the "mad cow" scandal arrives to Spain. The central and regional governments involved in food safety are unable to coordinate their activities and give a coherent answer to the crisis, making clear that public authorities should carefully reconsider food safety regulation and institutional design. The Ministry of Health evades its responsibility arguing that the BSE is an animal health problem since there are no human cases in Spain; the Ministry of Agriculture also try to avoid responsibilities arguing that food competencies have been transferred to regional authorities; the *Comunidades Autónomas* (CCAA) are unable to coordinate with central authorities, and each CCAA adopt a different strategy over its territory without taking into account the strategy taken by other CCAA arguing that central government has been unable to coordinate a unified answer to the crisis. As in the British case, the "mad cow" scandal opens a *window of opportunity* to introduce a new policy paradigm in food safety and institutional reforms characterized by delegation to an independent regulatory agency. But in Spain, regulatory change is only partial. The AESA is established as an advisory institution without regulatory powers for several reasons. None of the involved institutions wants to loose its authority over food safety issues. Neither the Ministry of Agriculture nor the Ministry of Health wants to delegate its regulatory competencies to an independent institution managed by experts. Besides, regional governments are not willing to loose food safety competences already recognized in the Spanish constitution. The decentralized nature of the Spanish political system makes not possible to initiate a process of devolution among levels of governments as it occurs in Britain[17].

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[15] The MAPA is responsible for food quality control activities, animal and vegetal health, including the control of animal feed and chemical safety of food (fertilizers, pesticides and heavy metals).

[16] There has been much criticism about the decision taken in the Constitution 1978 to delegate food safety competences to regional authorities and not to keep them at the central level as it occurred with pharmaceuticals.

[17] For example, competences related to food safety issues were devolved from local authorities to the central government in 1990 when the inspection services related to meat control where transferred from local authorities to the Meat Hygiene Services within the MAFF. When the FSA is established local authorities keep responsible for food law enforcement, but their activities are coordinated, monitored and audited by the FSA, including the establishment of standards of performance. In Spain, it is not possible to establish a similar system to coordinate activities among regional authorities through a single food

In opposition to the British case there is not agreement among public authorities and social actors about which is the best alternative to avoid food safety scandals. Alternative ideas as to how overcome institutional constraints come from the European level. The Spanish authorities imitate the decision taken by the EU to establish a non-regulatory agency and define an agency quite similar to the EFSA. The AESA is a halfway model created to avoid the problems inherit from the past – basically the lack of technical efficiency and scientific advice in the policy-making process— and the limits of the existing state structures –mainly problems of coordination among ministries and levels of government—. Policy legacies and institutional constraints eliminate the possibility of broader reforms involving delegation of regulatory competencies to a state agency as in the case of the British Food Safety Agency.

These limitations do not exist in the pharmaceutical sector. In Spain, the Ministry of Health concentrates the competences about pharmaceuticals since the late seventies, and regional and local governments do not have any regulatory competence in these issues eliminating one of the structural limitations that exist in the food safety policy subsystem. Besides, there is an agreement among business organizations, consumers and experts groups about the benefits of the creation of an independent agency capable to increase technical efficiency in authorisation and registration procedures. This agreement not came until some years after the entry of Spain into the European Union, once Spanish firms have had some time to accommodate to the EU legislation, especially the legislation related to the patent system and the elimination of trade barriers[18]. In the case of Britain, the Department of Health also monopolizes the regulation of pharmaceutical issues since the creation of the MCA in 1989 (later MHRA), and there is also an agreement among social groups about the benefits of the creation of an agency. This agreement comes earlier in Britain, as a response of the necessities of the British pharmaceutical firms which are more internationally and R&D oriented than the Spanish firms, and perceives licensing regulations across European countries as a trade barrier that limits their competitiveness in front USA pharmaceutical firms. The differences in the moment of the creation of the MHRA and the Agemed are related to the characteristics of the pharmaceutical industry in each country. The concentration of power in the executive, and the agreement among public and private actors about the benefits of agency-like organizations contribute to the creation of the Agemed and the MHRA as regulatory agencies aimed to improve technical efficiency on the regulation of issues related to the quality, security and efficacy of medicines.

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authority because of institutional constrictions. Besides, in municipalities of more than 50.000 inhabitants, local authorities are responsible for inspection of food establishments (retail sector).

[18] Spanish authorities implement EU regulations about the use of objective criteria for the licensing of new drugs once Spanish firms have had some time to adapt to the new market conditions, especially the EU patent system that prohibit the Spanish firms to copy the innovation made by foreign firms. For decades the Spanish government use licensing as a protectionist measure in order to favour national firms in front of multinationals and set a quite flexible patent system. At some extend this protectionist strategy has promoted that some pharmaceutical firms (for example Almirall-Prodesfarma) devote some of their resources to R&D activities and adopt an international strategy (Chaqués 2002).

Both agencies have similar regulatory competences, and the main differences rely on its organizational structure and degree of independence from elected politicians. These differences are explained by the inexistence of a broader state reform that transforms the institutional bases of Spanish public bodies as a whole.

Conclusions

(1) Functional explanations provide an interesting starting point for the analysis of delegation of regulatory competences to agency-like organizations in social sectors. From a functional logic, agencies in food safety and pharmaceuticals are aimed to achieve similar objectives – increase credible commitments, avoid unpopular decisions, or increase technical efficiency— but their establishment result from different processes. Food safety agencies result from a crisis situation (BSE scandal) which puts into question the model of regulation and the credibility of existing institutions responsible for food safety. In contrast, agencies in the pharmaceutical sector result from pressures from pharmaceutical companies so that public authorities work in a more efficient, fast, transparent and objective way. In the case of pharmaceuticals, regulatory change is related to industrial competitiveness while in the case of food safety is more related to the protection of public health.

(2) The analysis of food safety and pharmaceuticals in Britain and Spain suggest that the shift towards agency-like organizations is directly influenced by the increasing interdependencies of regulatory reforms among countries and policy sectors, and the interplay of national and supranational levels of government. The creation of the EMEA and the EFSA contributes to foster a shared vision of pharmaceutical and food problems and policies, increases cooperation among member states through networks of experts that work beyond borders, and promote the proliferation of agency-like organizations as the type of organization capable to better respond to policy issues across member states. This process of normative emulation is stronger in Spain than in Britain. The influence of the European Union is stronger in Spain, especially in the case of the AESA that imitates the goals, organizational form and working procedures of the EFSA working only as an advisory institution. By the contrary, the British FSA goes beyond since it has regulatory and executive competencies and a particular organizational form different from the European agency.

(3) Broader state reforms explain some of these differences in the patterns of delegation. In the case of Britain, regulatory agencies in both pharmaceuticals and food safety are created following a national program for the reform of the British public sector. Despite there are some differences among British agencies, both the MHRA and the FSA share

important features as new types of public bodies quite autonomous from the executive and more performance and client oriented than existing burocratic structures. In the case of Spain, there is not a national program that defines the benefits of agency-like organizations. There is not a clear idea of what an agency is and this results in the proliferation of agency-like organizations, quite heterogeneous among sectors that in most cases imitate the models defined elsewhere. Our *analysis suggest that (a) delegation to regulatory agencies is higher –in terms of functions performed, and organizational independence— in those countries involved in broader state reforms, and (b) the influence of the European Union is stronger in those countries without a defined model of agency.* Further research in other countries and policy sectors are required to test this hypothesis.

(4) Domestic variables, especially those related to policy legacies and existing state structures and traditions are important explanatory variables of delegation to agencies. *Our analysis suggest that the (c) the higher the concentration of competences on a single institution the easier the delegation of policy competencies to agency-like organizations.* In the case of pharmaceuticals and food safety in Britain, the concentration of power inside government plus the agreement among public and social actors about the benefits of agencies contribute to the delegation of regulatory powers. In the case of food safety in Spain, the fragmentation of power at the central level between the MAPA and the MSyC, and between different levels of government –national, regional and local— plus the lack of tradition on agencies and an unplanned processes of public administration reform, limit the possibilities of delegation to a regulatory agency.

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ANNEXE
Quantitative indicators used to measure the formal independence of regulatory agencies*

A. Agency head status	**Coding**	**AESA**	**FSA**	**Agemed**	**MHRA**
1. Term of office					
1.1. Fixed term by law	1	1	1		
1.2. No fixed term	0			0	0
2. Who appoints the agency head?					
2.1. Agency board members	1				
2.2. Mix of the executive and legislature	0.75		0.75		
2.3. Legislature	0.5				
2.4. Executive collectively	0.25	0.25			
2.5. One or two ministers	0			0	0
3. Dismissal					
3.1. Dismissal is impossible	1				
3.2. Only for reasons not related to policy	0.5				
3.3. Discretional	0	0	0	0	0
4.May the agency head hold other offices in government?					
4.1. No, incompatibility	1	1	1	1	1
4.2. Only in exceptional situations	0.5				
4.3. Yes, compatibility	0				
5. Is the appointment renewable?					
5.1. No, impossible	1				
5.2. Limited	0.5		0.5		
5.3. Yes, without limits	0	0		0	0
6. Is independence a formal requirement for the appointment?					
6.1. Yes	1				
6.2. No	0	0	0	0	0
B. Management board members' status					
7. Composition					
7.1. Only experts	1		1		1
7.2. Experts and politicians	0.75			0.75	
7.3. Experts, social groups and politicians	0.5	0.5			
7.3. Social groups and politicians	0.25				
7.4. Politicians	0				
8. Term of office					
8.1. Fixed term by law (all members)	1				
8.2. Fixed term only by some members (experts and social groups, no politicians)	0.5	0.5		0.5	
8.3. No fixed term (all members)	0		0		0
9. Who appoints the management board members?					
9.1. The agency head	1				
9.2. A mix of the executive and the legislature	0.75				
9.3. The legislature	0.5				
9.4. Executive collectively	0.25	0.25			
9.5. One or two ministers	0		0	0	0
10. Dismissal					
10.1. Dismissal is impossible	1				
10.2. Only for reasons not related to policy	0.5			0.5	0.5
10.3. Discretional	0	0	0		
11. Is the appointment renewable?					

11.1. No, impossible	1				
11.2. Limited	0.5				
11.3. Yes, without limits	0	0	0	0	0
C. Relationship with government and parliament					
12. Is the independence of the agency formally stated?					
12.1. Yes	1				
12.2. No	0	0	0	0	0
13. Which are the formal obligations of the agency vis-à-vis the government?					
13.1. None	1				
13.2. Presentation of an annual report for information only	0.67				
13.3. Presentation of an annual report that must be approved	0.33				
13.4. The agency is fully accountable	0	0	0	0	0
14.Which are the formal obligations of the agency vis-à-vis the parliament?					
14.1. None	1			1	1
14.2. Presentation of an annual report for information only	0.67	0.67	0.67		
14.3. Presentation of an annual report that must be approved	0.33				
14.4. The agency is fully accountable	0				
15. Who other than a court, can overturn the agency's decision?					
15.1. None	1			1	1
15.2. The European Union	0.67				
15.3. The government in exceptional situations	0.33		0.33		
15.4. The government unconditionally	0	0			
D. Financial and organizational autonomy					
16. Which is the source of the agency's budget?					
16.1. External funding only	1				1
16.2. External bigger than State General Budget	0.67				
16.3. State General Budget bigger than external	0.33	0.33	0.33	0.33	
16.4. State General Budget only	0				
17. Who controls the agency's budget?					
17.1. The agency only	1				1
17.2. The agency and one or two ministries	0.5	0.5	0.5	0.5	
17.3. The government only	0				
18. Who is in charge of the agency's personnel policy?					
18.1. The agency only	1			1	1
18.2. The agency and one or two ministries	0.5	0.5	0.5		
18.3. The government only	0				
19. Who is in charge of the agency's internal structure?					
19.1. The agency only	1		1	1	1
19.2. The agency and one or two ministries	0.5	0.5			
19.3. The government only	0				
E. Regulatory competencies					
20. Who is competent for regulation in the sector?					
20.1. The agency only	1		1	1	1
20.2. The agency an another independent authority	0.67				
20.3. The agency and another political institution	0.33				
20.5. The agency has only consultative competencies	0	0			
TOTAL		**0.30**	**0.43**	**0.43**	**0.48**

* Note: The higher the code (1) the more independent the agency. These indicators are based on Gilardi (2002) indicators to measure the formal independence of regulatory agencies. Some adjustment have been made to adapt them to the characteristics of the agencies under study. A new indicator measuring the composition of the management board (including politicians, experts and social groups representatives) has been introduced to reflect properly their variation across countries and policy sectors. In the variable referred to the possibilities of third bodies overturning the agency's decision, a category introducing the European Union has been introduced since the agencies work within a context of multilevel governance.