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Institutional Polymorphism: The Designing of the European Food Safety Authority with regard to the European Medicines Agency

David Demortain

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David Demortain[1]

Abstract

This paper looks at the formation and designing of the European Food Safety Authority (EFSA). It seeks to assess the reality of institutional isomorphism in the European Union. It does so by analysing why references were made during the formation of the EFSA to the European Medicines Agency (EMEA), and the active differentiation of its design by actors involved in the process. The paper argues that institutional design is the encounter between a political decision to create an agency and the norms and practices that constitute sector-specific regulatory regimes. Institutional design across sectors derives from the same institutional principles, but detailed rules and structures eventually differ because they reflect the prevailing conception of the job of the future agency, such as assessing risks or approving products, which substantiate and legitimize the decision to establish it.

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[1] Correspondence: David Demortain, ERSC Centre for Analysis of Risk and Regulation, London School of Economics and Political Science, Houghton Street, London WC2A 2AE. (d.demortain@lse.ac.uk)

Introduction

The proliferation of independent agencies in the European Union seems to make the case for institutional isomorphism (DiMaggio and Powell 1983). The independent agency as an organizational form is replicated across polities and policy sectors (Pollitt et al. 2001). The availability of the legitimated rules and structures that are encapsulated in the agency form plays a role in the decision to delegate powers to independent agencies (Thatcher 2002).

This article aims to characterize more precisely the reality of institutional isomorphism, by comparing two agencies: the European Medicines Agency (EMEA) and the European Food Safety Authority (EFSA).[2] This comparison is of particular value for assessing isomorphic phenomena because comparisons have been and continue being made between these two agencies, by scholars[3] as well as by institutional actors. The institutional design used for EMEA provided a point of reference for the formation of EFSA.[4] They both have limited powers and are closely linked to their national counterparts through networks of experts or work sharing arrangements. When the European Commission first laid out an institutional design for EFSA in its White Paper on Food Safety, it sought to replicate the successful cooperation between member states that EMEA managed to orchestrate. In that respect, EFSA was modelled after EMEA.

However, the two agencies differ in a number of ways, notably, the procedure for risk assessment and decision-making. EMEA prepares decisions, whereas EFSA only publishes opinion, which the European Commission uses to make decisions. EMEA's management board comprises representatives of member states, while that of EFSA has mostly stakeholders with a few member-state representatives. Finally, the experts on the agencies' scientific committees are appointed by member states for EMEA, whereas they are reputed to be fully independent and selected through an open procedure by EFSA.

Despite many references to the EMEA model during the formation of EFSA, the participants to the negotiations on the founding Regulation did chose to specific design rules and structures which were not borrowed wholesale from EMEA. This seems to confirm that there is no unique 'model' of Community independent agencies (Chiti 2004). The two agencies belong to two different 'waves' of creation (Kreher 1997). In short, EFSA is not a replica of EMEA in its forms or in its success in asserting its authority and becoming institutionalized (Metcalfe 2000, Vos 2000, Dehousse 2002, Groenleer 2005).

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[2] This agency was previously the European Agency for the Evaluation of Medicinal Products which changed its name in 2005 to the European Medicines Agency. However, the original acronym stayed in use, and will also be used in this paper.

[3] Vos 2000, Taylor and Millar 2002, Krapohl 2004, Groenleer 2005. See Demortain 2007 for a review of this literature.

[4] The legislation that created EMEA was adopted in 1993. It consisted of a Directive that created the so-called decentralized procedure of marketing authorization and a Regulation that established the centralized procedure and description of the role of EMEA in the running of this procedure. EMEA started operating in early 1995 on the basis of Regulation 2309/93/EC. EFSA was set up in 2002 after the adoption of Regulation 178/2002/EC and became operational in the course of 2003.

This paper aims to understand why comparisons, benchmarking and cross-references between the two European agencies did not result in more isomorphism. This question has not been solved so far. Rational choice institutionalism has inspired the idea that rules vary from issue-area to issue-area (Pollack 1997), without really explaining why. On the other hand, institutional isomorphism has been recognized to be a valid argument, but is hardly compatible with the rationalist perspective that inspires much of the analysis of institutional design.

Rather than use norms or interests as a priori and external independent variables, this paper develops an approach attentive to the sequence of events and to the norms and practices that provided the template for the design of agencies. It defends the following idea: the design of agencies is based on the same institutional principles, but detailed rules and structures differ because they reflect the norms and practices that constitute sector-specific regulatory regimes. The designing of an agency is the encounter between a political decision and the prevailing or emergent conception of the job of assessing risks and approving products, which substantiate and legitimize this very decision. This results in an original pattern of 'differentiation yet comparability' of forms, termed institutional polymorphism.

This paper focuses on the period of formation of EFSA, from the first proposals (including the unsuccessful ones) to the launching of the agency. It uses three kinds of data: 24 semi-structured interviews (with Commission officials, officials of national food and medicines administration involved in the negotiations in Brussels, scientific experts, representatives of interest groups and think tanks, members of the European Parliament), insider information collected by public affairs advisers of the agro-food and pharmaceutical businesses that tried to influence the formation of the agencies, documents such as public and confidential reports, and legislation.

The paper first discusses the concept of institutional isomorphism to assess whether it can fully respond to the research question. It then depicts similarities between EFSA and EMEA as two agencies belonging to the field of regulatory agencies, and the differences in their design. The third part discusses the way in which political imperatives to create agencies encounter sectoral norms and practices through the designing of organizational forms.

Institutional design and isomorphism

A potential case of coercive or mimetic isomorphism

DiMaggio and Powell (1983) characterize institutional isomorphism as the process of imitating organizational forms driven by the taken-for-grantedness and legitimacy of organizational forms, rather than by the conscious strategic decision to adopt efficient ones. As is well known, the authors have distinguished three analytical types of isomorphism: coercive isomorphism which is driven by political imperatives and legitimacy and occurs through imposition of norms or rules; mimetic isomorphism which is driven by imitation or emulation between organizations, and lastly, normative isomorphism which is driven by professional affiliations.

Coercive isomorphism could apply to the European independent agencies: the principals – the European Commission, member states and the European Parliament – chose this organizational form for its legitimacy and imposed it as a political imperative. In the particular case of EMEA and EFSA, the network form of organization, beyond its alleged efficiency, was the only way to render the creation of an agency acceptable and legitimate by preserving the powers of member states and the principle of the institutional balance between them (i.e. the Council of Ministers and the European Commission). The so-called Meroni doctrine of the European Court of Justice holds that the European Commission cannot delegate powers it received from member states, as it needs to preserve the balance between the powers of the latter and those that are granted to supranational institutions, and requires establishing mechanisms of control of the agency (Lenaerts 1993, Yataganas 2001). Although this doctrine may have been wrongly applied to the case of EFSA (Dehousse 2002), it seems to have played a key role in the process. The Commission overcame its reluctance to delegate powers to independent agencies (Steinberg 2001) and justified the restriction on powers of the European Food Safety Authority through this constitutional rhetoric (Majone 2001), and explicitely named the EMEA as a success in the organization of such transnational cooperation.

Mimetic isomorphism is also potentially at play here, with institutional actors of one policy sector (the area of food safety, embodied by the Commission Directorate-General XXIV, called Directorate-General for Health and Consumer Protection after 1999) taking as example institutions successfully created in another sector, that of pharmaceutical regulation – also concerned with health, but with stronger emphasis on objectives such as market integration and industrial innovation and under the responsibility of the Commission Directorate-General (DG) for Enterprise. At the time that the European Commission drew up plans for a European Food Safety Authority, EMEA emerged as a successful form of organized regulatory cooperation between member states. This appeared as a way out of the conflict between the European Commission, discredited for mismanaging the BSE issue, the European Parliament with its fear the that member states would capture the agency, and the resistance of member states to delegating more powers to a central EU regulatory institution.

European agencies as sui generis forms

Nevertheless, as hinted to in the introduction, the two agencies appear too different to argue persuasively that isomorphic pressures shaped their structure. The attempt to define European agencies has mobilized very generic traits, such as that of having a legal legal personality, headed by a management board composed of member-states' representatives, and the product of legislative decision-making (Kreher 1997). Similarities can only be understood in highly abstract functionalist terms, as in the definition coined by Everson and Majone (1999):

> The essential characteristic of an agency is not its institutional separateness, but its functional independence, that is, the decisional autonomy it enjoys with respect to some defined policy areas. As long as an administrative office is in complete charge of a programme, it is an agency even if it is a sub-part of a larger unit.

These definitions do not manage to conceal the great diversity of forms and functions of agencies (Commission 2002, Pollitt et al. 2001). The term 'agency' seems to be nothing more than a label that is applied to highly different organizations with some form of independence from governmental organizations (Metcalfe 2000).

Institutional isomorphism hardly has a place here. One explanation is that the two European agencies do not belong to the same organizational field. According to DiMaggio and Powell, isomorphism takes place between organizations that share similar operations and goals, constitute each other's environment or are under the rule of the same political institutions. It is measured through the level of homogeneity across this field.

That EFSA does not resemble EMEA may mean that they are not part of the same environment. Indeed, they belong to different policy sectors. Although they belong to the same polity, that of the European Union, the complexity and multi-layered nature of that polity, in which different principals compete for power, makes it unrealistic to think of an over-determination of agency creation by trans-sectoral political imperatives and prescriptions coming from the level of the college of Commissioners or the Presidency of the Commission. The EU is a highly sectorized polity, with few trans-sectoral power arenas (Smith 2004, Carter and Smith 2008). As agencies are proposed by particular DGs of the European Commission and the founding Regulations are discussed and adopted by sectoral committees of the European Parliament and of the Council of Ministers, this limits the potential for both coercive and mimetic isomorphism. European independent agencies are always sui generis, because their formations are decided and controlled by sectoral actors, with few overarching organizational models to draw from. Isomorphism is limited to very superficial institutional principles, which take form 'locally'. It is limited to imposing generic requirements of non-autonomous agency or of creating 'networks', that can materialize through very diverse formal or informal rules.

It may also mean that their operations and goals differ. Approving substances submitted by a highly technical and concentrated pharmaceutical industry which generates high turnovers, compared to assessing the risks posed by manufactured as well as natural substances are exercises which rely on different modes of practice, conventions and procedures of decision-making. This is the source of major differences between the two agencies, not least in their capacity to receive positive commitments from member states and become a source of authoritative assessments (Krapohl 2004).

The determination of organizational forms by regulatory content

The analytical apparatus of institutional isomorphism does not seem to be able to explain why the norms and practices of the regulatory process has an influence on the designing of an independent agency, arguably a highly political process in which 'principals' try to secure the capacity to control the future independent agent, a process that takes the form of inter-institutional power plays at the European level (Kelemen 2002).

The new institutionalist framework is limited by its assumption that forms and content are separated. As astutely recalled by Fourcade (2006), DiMaggio and Powell assume a decoupling between formal traits that disseminate and the practices that are invented in their name once imported by an organization: 'They represent diffusion largely as a process of "decoupling" where some external features are adopted ceremoniously but contents remain largely determined by local processes and institutions' (Fourcade 2006). This seems to be a structural problem of new institutionalism, which allocates much less attention to the work and activities of organizations, that is, what is going on inside agencies (Pollitt et al. 2001, Demortain 2006), than to their forms (Frumkin and Galaskiewicz 2004, Hirsch 1997). The rationale consists in assessing similarity and differences between different forms, all other things being equal – notably the operations and goals of these agencies.

This separation prevents an analysis of how the regulatory regime, as a complex of practices, norms, policies which organize regulatory interventions, can be a source of templates and arguments to legitimize certain institutional forms or argue against others. The legitimacy of chosen rules and structures may come from their perceived efficiency to carry out the regulatory operations and goals. The hypothesis explored by this paper is that the regulatory regime is the cognitive and normative context within which organizational forms gain their legitimacy, and the participants to the formation of the agency with most influence on its forms are those that are socialized to this regime.

Same function, different forms? EFSA compared to EMEA

Risk regulation as an organizational field

EFSA was created by a Regulation adopted by the Council of Ministers and the European Parliament in 2002. It was launched later that year and stepped up its activity progressively in 2003. The creation of EFSA opened a 'third wave' of independent agencies, after those of the 1970s and of the early 1990s (Kreher 1997). Despite their belonging to two different phases of organizational creation, EFSA and EMEA can be seen as part of the same organizational field: that of regulatory agencies. According to Vos (2003), both EMEA and EFSA are regulatory agencies (as opposed to information agencies) in the sense that they make regulatory decisions possible by providing the scientific input. The European Commission also includes the two agencies in the category of regulatory agencies. They are both 'actively involved in the executive function by enacting instruments that help to regulate a specific sector. The majority of them are intended to make such regulation more consistent and effective by combining and networking at Community level activities which are initially a matter for the Member States' (Commission 2002). They both provide assistance in the form of opinions and recommendations.[5]

[5] As opposed to agencies that provide assistance in the form of inspection reports and those empowered to adopt individual legally binding decisions (Commission 2002).

This classification is underscored by a vision of the European Union as a regulatory state, i.e. a state for which regulation is the main form of policy intervention. The creation of agencies is typical of regulatory states, as argued by Majone (1999). It is a response to challenges on the policy credibility of public authorities. This credibility problem is specifically acute for the European Commission. The traditional Community method (decentralized enforcement through directives) is not adapted to the treatment of increasingly complex technical issues, such as that of food and medicines safety, which relate to 'risk regulation' (Dehousse 2002). Expertise is missing and the degree of politicization of policy-making prevents the efficient treatment of these issues (Majone 2000). Furthermore, most of the powers of implementation reside with member states, while standards are set at the European level. The Commission's credibility suffers from this regulatory gap, which impedes effectiveness.

In all of these aspects, delegating regulatory functions to independent agencies is a solution. It gathers together the necessary expertise, shields regulation from political interests and leaves the possibility for the European Commission to turn itself into a strategic policy planning administration (Vos 2000, Kelemen 2002). Regulatory agencies are particularly beneficial when they take the form of a network of national agencies, coordinated at the European level by a European body, as it helps to bridge the gap between national and European levels. This is the foundation of a 'structural logic' (Dehousse 1997) that unites EMEA and EFSA, whereby cooperation between national agencies creates convergence, whether or not the European agency has authority on national ones, through the diffusion of information (Dehousse 1997, Majone 1997). The emergence of a new governance underlies the creation of these agencies (Flinders 2004, Eberlein and Krewer 2002). Isomorphism, in this case, relates to the emulation of this 'governance by network' (Dehousse 1997) approach and the organizing of cooperation between member states under similar forms. In the case of EMEA, it took the following main forms: a centralized procedure of product authorization,[6] the representation of member states in the European scientific committees through national scientific experts and on the board of administration of the agency, the redistribution of fees paid by pharmaceutical companies to the national agency which evaluated the dossier.

EFSA and 'governance by network'

It is likely that the European Commission cited EMEA's governance by network as a successful example for emulation and to assert the necessity for EFSA to cooperate with national counterparts.

The formation of EFSA is the result of a particular context, the aftermath of the 'mad cow' (hereafter BSE) and dioxin crises. The Commission resigned collectively in 1999, under pressure from the European Parliament and from accusations linked to the BSE crisis as well as other matters of corruption. Romano

[6] The Committee for Proprietary Medicinal Products (CPMP) would evaluate dossiers submitted directly by companies at the supranational level. The decision would be prepared by the CPMP, on the basis of the conclusions of a national expert. The agency would support and coordinate the work of the CPMP. The evaluation of products is centralized, but member states remain the key stakeholders of the system.

Prodi, then nominee candidate for the Commission presidency announced in June 1999, his intention to create a 'food and drug authority'. Prodi put forward the fact that the Commission President should not be held accountable for contaminations in the food chain. Creating an agency for scientific advice was an ideal solution for shifting the blame.

The Commission published a White Paper on Food Safety in 1999. At the time, the EMEA system of collaboration between member states had proved successful enough for the Commission to refer to it as an efficient form to emulate. The Commission thus admitted in the White Paper on Food Safety that the example set by EMEA had been used to reflect on the design of the future food agency. A year after the White Paper, the Commission released the proposal for a Regulation establishing EFSA and reforming food law. The following argument was made in the explanatory memorandum:[7]

> It is proposed that the Authority will enlist the expertise of the Member States for the drafting of an initial assessment report on the basis of the authorization dossier in preparation for final evaluation by one of the specific scientific panels.[8] This procedure draws on the successful experience of the EMEA which is able to meet strict time-limits for the evaluation of dossiers for the authorization of medicinal products in the Community. It is therefore intended that, where appropriate, the European Food Authority[9] may remunerate such competent organizations for their assistance with authorization dossiers in order to ensure time delays and common quality standards are met.

This positive reference to EMEA is motivated by the fact that the agency successfully managed to orchestrate cooperation between member states for the joint authorization of medicines. The Commission intends to emulate that success for the authorization of products, which EFSA is competent for (such as pesticides, novel foods, genetically modified foods, food and feed additives).

The politics behind this choice seems quite clear: transnational cooperation orchestrated at the European level solves the dilemmas of European integration. The centralization of more policy-making and regulation at the EU level is limited by the lack of resources of the European Commission. Approving products and assessing risks are activities, which increased steeply in the 1990s and for which there was insufficient Commission staff. The creation of an agency helped to solve this shortage. Independent agencies are funded from a different budget to that of the European Commission. Creating an agency is a way to attract resources for executive activities at the European level, without arousing as much opposition from member states as if competences were directly granted to the Commission. Agencies' cooperation with member states also offers the opportunity to increase regulatory convergence, even in the absence of a regulatory authority. Soft

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[7] Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food.

[8] National agencies would first carry out an evaluation of the data submitted by a company to have its product authorized. In a second step, the conclusions of this evaluation would be reviewed by national experts gathered as a committee of the European agency.

[9] The name originally chosen by the Commission, later changed to European Food Safety Authority through an amendment adopted by the European Parliament.

cooperation through scientific deliberation and exchange of information limit discrepancies between national approaches (Majone 1997, Dehousse 1997, Eberlein and Grande 2005). An agency thus solves the risk of dissent between scientific risk assessments made separately by member states, as was the case during the BSE crisis and 'beef war' between France and the United Kingdom.
In this regard, isomorphism did take place: EFSA has been designed, much like EMEA, as an independent yet not autonomous agency. Most of its tasks are to be carried out in cooperation with national bodies, be it the collection of surveillance data or the selection of priority topics.

The inappropriateness of EMEA design for food safety

However, the coordination and cooperation of member states takes different forms. In the case of EFSA, national agencies are not represented in the agency in the same way. Firstly, members of the scientific committees of EFSA have no official function as representatives of member states. Representing member states directly within scientific committees would be unacceptable in the aftermath of the BSE crisis, which highlighted the lack of independence of scientists who were advising the European Commission on veterinary issues at the national level.

Secondly, the EFSA management board does not comprise national representatives, but a variety of stakeholders who represent the different segments of the food chain. There again, the lessons drawn from the BSE crisis and the accusations made by the European Parliament to the European Commission and member states made unacceptable the idea that the agency could be captured or steered by member states through its board. Accordingly, the cooperation of national agencies with EFSA, is organized through a non-operational advisory forum, in which representatives of national food agencies discuss the EFSA working programme.

The impossibility of replicating these forms is due to the context of the political crisis in which the decision to create the EFSA emerged (Clergeau 2005, Zwanenberg and Millstone 2005). Following the revelation that the BSE could be transmitted to humans and a thorough inquiry into the functioning of the DG for Agriculture and the Standing Veterinary Committee, the Commission came under very strong pressure from member states and from the European Parliament. It was accused of being biased towards industrial interests and of giving priority to the objective of achieving the single market over public health. The creation of the agency was a crisis-ending strategy for the Commission, to state its willingness to put safety first and follow scientific advice of the highest possible quality and independence. In the aftermath of the crisis, the main imperative was to separate science from politics, or, in the terms of the risk analysis principle (NRC 1983), to draw a line between risk assessment and risk management.

Product approval, and specifically medicine licensing is by comparison a much more integrated process, in which all aspects involved – risk/benefit assessment, decision concerning the distribution and labelling of the product as well as the social and political judgements involved in evaluating the collective need for medication and industrial innovation – are absorbed in the evaluation of the industrial dossier and managed by professional experts, which retain the authority

to control the entire exercise (Hauray 2005). This is the source of a very high degree of independence for the agency in its operations and relations with firms and other stakeholders (Abraham and Lewis 2000, Metcalfe 2000, Gehring and Krapohl 2007).

This model of integration of risk assessment and risk management within the professional evaluation of medical experts was incompatible with the prevailing concept of food safety. The general belief of participants to food safety policy-making was that food is a complex matter, with various cultures, values, political views and economic interests bearing on decisions concerning the distribution and consumption of food products. The assessment of risk should be insulated as far as possible from these sources of bias. The scientists involved have no authority to arbitrate these aspects to prepare decisions, like medical experts. In such a 'politicized' domain (to use an expression frequently used by actors themselves), the authority of scientists must be well circumscribed to risk assessment.
In contrast with the pharmaceutical regulatory regime in which member states wanted to secure their participation to the processes conducted by the European agency, this did not appear as the most critical condition in food safety, i.e. risk management decisions are in the hands of the Commission and subjected to control by member states. This imperative of the independence of the agency and the separation between scientific advice and regulatory decision-making guided the choice of possible models for the future EFSA away from existing integrative models, such as the US Food and Drug Administration which has regulatory power (see Alemanno 2006) or EMEA.

Comparisons with and differentiation from EMEA in EFSA formation

The rules adopted for pharmaceutical regulation were justified by the need to facilitate cooperation between national agencies and national experts with an extensive regulatory authority. The rules were inappropriate for the creation of a food agency, which needed a boundary between the science of risk assessment and risk management. The fate of several proposals made by influential actors in the process of designing EFSA highlights it.

The officials of the DG XXIV kept the idea of a food safety agency alive during the transition between the Presidency of Jacques Santer and that of Romano Prodi in 1999. In particular, they considered the propositions advanced by a think tank, the European Policy Centre (EPC).[10] The EPC report used EMEA as a benchmark for the improvement it brought to product authorization procedures (EPC 1999). Medicine licensing was seen as exemplary for the clarity of the requirements and professionalism of the evaluation. Food companies considered it necessary to emulate this model for the authorization of their own products. A European food agency with the power to prepare or issue marketing authorization would be preferable to a risk assessment agency, in terms of accountability, performance,

[10] A senior consultant and member of the think tank headed a group of industry experts, who were representing major agri-food businesses such as Coca-Cola, Unilever, Masterfoods, etc. The intention of the companies in doing so was to bypass the European food trade association which originally adopted a negative stance on the creation of a food agency and seemed to be a rather inefficient vehicle for lobbying the European Commission on that matter.

legal certainty, and industrial competitiveness. However, the Commission rejected the proposal, on the grounds that it would not be in line with the principle of institutional balance and the Meroni doctrine to delegate power to prepare or issue marketing authorization decisions.

The Director of the DG XXIV also consulted three senior scientists who were members of its main scientific committee, the Scientific Steering Committee. The three scientists were asked to create a template for a European food agency[11]. The report delivered by these scientists in December 1999 (James 1999) contains an assessment of all possible organizational options: an internal Commission service, an inter-institutional organization (supervised by the European Parliament, the Commission and member states) and an independent agency. EMEA embodied the latter solution. The three scientists argued that this solution was inappropriate. They felt that firstly, risk assessment and risk management should be separate, and member states should not have the right to appoint experts as at EMEA. Secondly, risk assessment and risk management institutions must stay geographically close in order to ensure the best possible interaction and communication between regulators and the scientists that advise them. At present independent agencies are generally granted to member states as part of political deals. They are set up in cities across Europe, far from the main location of the European Commission in Brussels.

In this sense, and in spite of the permanent call for the creation of an agency as effective and successful as EMEA in the domain of food safety,[12] the evidence for institutional isomorphism is scarce. Similar functional and political challenges concerning the centralization of functions at the EU level meant that the 'governance by network' approach was used in both sectors. But the prevailing conception of the appropriate approach to the conduct of risk assessment and the regulation of food justified departing from the rules and forms adopted for the regulation of medicines.

Regulation and the legitimization of organizational forms

How can one explain that the design of an agency is determined by sectoral norms and practices of risk assessment and risk management, rather than by cross-sector isomorphism? The situation described above is one in which non-sectoral rules and actors are overtaken by sectoral ones. This section of the paper seeks to analyse the situation. It emphasizes the time dimension to show that the creation of agencies as an encounter between a process of regulatory reform and the decision, by principals, to adopt a reform and delegate powers. This encounter, however, is dominated by sectoral actors and their projects. In this context, the norms and practices of the

[11] In doing this, the DG XXIV was imitating Tony Blair and the British Labour Party which, in 1997, asked one of these three scientists, Philip James, to create a blue-print for what was to become the UK Food Standards Agency.

[12] Most of the actors who were consulted or tried to influence the design proposed by the European Commission referred to EMEA. Members of the European Parliament involved in the discussion of the White Paper on Food Safety exchanged ideas with their counterparts who follow pharmaceutical issues; officials of DG XXIV with DG Industry; DG XXIV scientific experts with members of the CPMP; the food industry European trade association with the European Federation of Pharmaceutical Industry and Associations.

regulatory regime are the templates through which designs are elaborated and legitimized by these actors.

The sequence of agency formation: the encounter between political action and regulatory reform

There is no doubt that the decision to create an agency is in the hands of principals. In the two cases of EFSA and EMEA, the agencies could not have seen the light of day without the definitive decision by the respective Commission Presidents, Romano Prodi and Jacques Delors, to externalize functions so far performed by the European Commission or enter into new forms of collaboration with member states. But the designing of the agency only occurs when the political decision to create an agency encounters a project of regulatory reform. The successive attempts to create a food and a medicines agency show that agencies are not established if only one of these two factors comes into play.

The first proposal to create an agency dates back to the mid-1980s. It was then related to the problem of meat hygiene. Deficient controls in the meat sector were emphasised by a White Paper as well as a parliamentary report in 1985. An agency was seen as a way to strengthen the capacity of the Commission to control national inspectorates and to improve compliance with food standards. The idea of establishing a European agency resurfaced in the late the 1980s in the context of the need to improve the scientific evaluation of novel foods. It was believed at the time that an agency could moderate the detrimental effects of unharmonized regulatory initiatives by member states. However, the Commission showed sensitivity to the industry arguments that an agency would be too bureaucratic and instead proposed to step up scientific cooperation between member states through informal scientific networks.

The accusations of mishandling of the BSE issue to the Commission explain that the creation of a European food agency was frequently called for after 1997. That year, Jacques Santer, then President of the Commission, proposed to turn the Commission food safety inspectorate into an independent agency, with support from Members of the European Parliament (Valverde et al. 1997). Eventually, however, the decision was to transform the inspectorate into a separate directorate of DG XXIV. This 'volte-face' (Kelemen 2002) was linked to an extensive evaluation of the organization of food control across European countries,[13] as well as to the difficulty of concentrating regulatory functions in an agency and to break

[13] This included the fifteen member states at the time, the US, New Zealand and Canada. The conclusion of this evaluation, made by the Commission Service of Administrative Inspection, was that food control formed part of the core regulatory authority of the European Commission and should not be delegated. In other words, the regime by which food matters were regulated, of which veterinary and sanitary inspections were as important a component as risk assessment is now, delegation of functions to an independent body appeared inappropriate. The Commissioner for Consumer Protection, Emma Bonnino, visited the US Food and Drug Administration in 1997 and concluded that this model could not be adapted for Europe given the regulatory powers granted to the FDA and its lack of independence.

the *modus vivendi* existing among the different directorates general involved in food matters.[14]

The commissioners for consumer protection and for agriculture however raized the idea again in 1998, before the European Parliament, as the importance of what was then called the 'scientific instrument' rose (Commission 1997). Food policy was re-interpreted as an issue of consumer health and uncertain risks that should be properly evaluated. In this context, it appeared legitimate to create an agency to distinguish between science and decision-making.

'EFSA's formation is special' (Buonnano 2006) indeed, because the decision for its creation has been an eminently public and political process.[15] The conception of a risk assessment agency is a result of the encounter between a political context in which the European Parliament acted as a 'power maximizer' in asking for guarantees of independence and transparency (Buonnano and Negent 2002), and the recognition of the importance of the instrument of risk assessment to address food safety issues since Romano Prodi's strategic decision met with the emerging risk analysis principle.

In a rather different fashion, the creation of the medicine agency was achieved thanks to the action of a political entrepreneur, who managed to build consensus and attract political support for a decade-old regulatory reform.

In spite of several attempts to reorganize the coordination of the marketing of medicines through mutual recognition or through the so-called 'multi-state' procedure, companies as well as member states made little use of the common European procedures (Hauray 2006). A lack of trust between member states and the reluctance of pharmaceutical companies to use mutual recognition or multi-state procedures plagued the process. These modes of Europeanisation did not prove efficient (Feick 2002). In the 1980s, an emerging regulatory crisis was signalled by the growing backlog of application dossiers at the national level. Sauer, then head of the Commission unit for pharmaceutical products, started to orchestrate and step up the cooperation between national experts through a biotechnology scientific committee. He began to argue consistently for the necessary coordination of product approval at the European level. He drew up long-term perspectives, defending the view that product approval would become more and more integrated[16] to match an increasingly concentrated and internationalized pharmaceutical industry, and that national authorities were participants and competitors within a common system (Hauray and Urfalino 2002). Sauer's reform project became part of the Commission Presidency's grand political scheme to

[14] Food hygiene and inspections were of the competence of DG VI (Agriculture). Regulation of novel foods was a competence of DG III. Consumer protection aspects grew in importance as the Service of Consumer Protection was transformed into DG XXIV in 1995.

[15] What reinforced the political nature of this process was the concomitant rise of the European Parliament, which gained powers with the entry into force of the new Treaty of the European Union of Amsterdam. During the BSE crisis, the Members of the European Parliament maximized the opportunity to gain power over the European Commission and made the most out of the wrongdoings of the main executive body.

[16] Including at the international level. The European Commission was instrumental in launching the process of international harmonization of standards and requirements for medicine licensing, known as the International Conference for Harmonisation.

achieve the European internal market by 1992 and stakeholders were given ownership over it, thanks to skilful political and tactical steering of the reform by Sauer (Hauray 2006).

In other words, the decisive act that launched the concrete designing of rules and structures to allow for risk assessment or product approval through an agency at the European level, was the result of a rather contingent encounter between long-term dynamics of regulatory reform and a political decision.

A sector-contained process

The particularity of the formation of agencies in the European Union is that this politicization does not result in the imposition of particular institutional forms because the formation of agencies remains in the hands of sectoral actors. The language in which the creation of EFSA was phrased is not neutral and originates from the dynamics of the sector. The principle of risk analysis was originally elaborated by a working group of the National Research Council of the United States in the early 1980s (NRC 1983). It was taken up by international organizations such as the Joint Expert Committee on Food Additives. But, crucially, the BSE crisis broke out after the risk analysis principle had been turned into an international rule. A guideline had been developed in the Codex Alimentarius,[17] which states that risk assessment and risk management should be 'functionally' separated, although not necessarily entrusted to two separate organizations. By then, the WTO agreements had been signed and the Codex Alimentarius recognized as the reference organization in food-related trade conflicts. This made risk analysis an international legal principle and increased the pressure on the European Commission to comply with it (Taylor and Millar 2002).

The use of the risk analysis principle thus follows from a normative climate and the active dissemination of the principle within the European Commission by members of the Commission's scientific committees or of the 'risk assessment' unit created by the DG XXIV in 1997. In the political context faced by the Commission and its leaders, this principle became a handy response to a rising health agenda and concerns for the use of the 'scientific instrument' (Commission 1997) in the face of growing uncertainties. It had the virtue of being principle-like: it could be promoted as a basic prescription of food law, and thus served as a way to solve the old struggles between different administrations, each responsible for a different part of a highly fragmented set of food regulations.

The pharmaceutical reform, which the creation of EMEA symbolized, was steered by sectoral actors. The main promoter of the reform of the pharmaceutical regulation, Sauer, was a pharmacist by training and made his entire career in the area of medicine regulation. His vision for the reform was itself based on that of an older regulatory expert from Luxembourg, Léon Robert, who mentored him in the European Commission. Robert was involved in the negotiation of the first piece of European legislation on pharmaceuticals and acted as chairman of the main

[17] The former is a scientific committee of the World Health Organization. The latter is the international body for food standards.

European scientific committee for pharmaceuticals (Committee for Proprietary Medicinal Products), created in 1975. He repeatedly argued for the creation of a central 'bureau' or agency for the authorization of medicinal product since the 1960s.

In both cases, the process leading to the adoption of the founding Regulations is carried out within sector-specific arenas. The proposals for Regulations establishing these agencies were drawn up by specific units of the European Commission. Their authors were officials, which were historically involved in the policy reforms of the domain or 'experts'. The proposals were negotiated by national experts in the Council of the European Union. On the food side, the proposal (and the risk analysis principle in particular) was discussed and refined during an intense six-month scrutiny by a dedicated 'Friends of the Presidency' group.[18] In contrast, non-sectoral actors, such as the Secretariat General of the European Commission, had very little influence on the design of agencies.

Regulatory norms and practices as organizational templates

The particular order of events which lead to the creation of agencies and the domination of sector-based actors over the process implies that the norms and practices of the sectoral regulatory regime constitute the basis for establishing future rules.[19]

The creation of an agency involves certain effects on power relationships that are hard to predict. Creating an agency means creating new participants, new roles and relationships in the regulatory process. The extent to which these participants – most notably the agency – will be able to strategically gain from the role they are given, to expand and gain more power, is uncertain (Tallberg 2002). Political actors are not necessarily as instrumental and far-sighted as they are depicted in the literature (Pierson 2000). Norms and practices around risk assessment and risk management form a kind of cognitive template (Hall and Taylor 1996), on the basis of which actors interpret proposed designs in terms of the consequences on them and elaborate new ones.

The negotiations on the design of EFSA were established in the language and vocabulary of the regime. While the risk analysis talk was unused until the mid-1990s, it became central to the interpretation of the BSE crisis around 1996 and 1997. The accepted narrative expressed by the European Commission, scientific experts, interest groups, members of the European Parliament as well as consumer groups, was that an insufficient separation of risk assessment and risk management (the capture of DG Agriculture by British veterinarians) led DG Agriculture to ignore the emerging BSE problem. The blurring of responsibilities now causes consumers to lose confidence in institutions and policies. Hence, consumer confidence should be restored by separating risk assessment and risk management.

[18] The member state which holds the rotating Presidency of the Council of the European Union has the right to stall the decision-making process and to establish a special expert group to discuss a Commission proposal.

[19] In Waterton and Wynne's terms, they constitute the 'political order' through which a vocabulary and identity for the agency are competitively developed (Waterton and Wynne 2004).

The principle of risk analysis, which supported such interpretation, permeated parliamentary reports, think tanks, interest group position papers, and Commissioners' speeches. Comparisons with food agencies of other countries and ways of separating risk assessment from risk management, were also extremely frequent. As noted above, the Commission administrative inspectorate evaluated all national models of organization of food control as well as the food agencies of the USA, New Zealand and Australia. The EPC experts looked at the agencies which were in the course of being created in Ireland, the UK and France. Similarly, the recently created medicines agencies in UK and France were mentioned as an example to follow by the Commission in its proposal for a Regulation creating EMEA.

In the Council, member states asked which institution of the Commission and the future agency would be in charge of risk communication or of the establishment of guidelines? They also rejected the Commission's idea to entrust the agency with the running of the food alert system on the grounds that the latter imply taking risk management measures. Specific questions thus remained on a long list of issues: who is accountable for the evaluation of the product, on what grounds should experts be nominated, has the applicant the right to choose a member-state for the evaluation of its products, has the agency the right to propose 'risk management options', the publication of its opinions, etc.? After the adoption of the founding Regulation in January 2002, Commission and EFSA officials, with the help of scientists, elaborated common routines in line with the risk analysis principle. They agreed on the presence of a Commission official during meetings of the various EFSA scientific panels to facilitate interpretation of the requests coming from the Commission and explaining possible legal complications.[20]

The formalization of the procedure of pharmaceutical marketing authorization was riddled with issues concerning the concrete division of labour between national experts and the European CPMP along the process, such as the list of products for which the centralized procedure was mandatory, the selection of national delegates to the CPMP and the staff and budget of the agency.

This shows that the designing of rules and structures was negotiated through the language of regulation and based on the prevailing conceptions of the central job of assessing risks and approving products. The risk analysis principle and the centralized procedure imagined by Sauer and his predecessor Robert provided a template and language to identify the critical points for the distribution of regulatory authority. If there is evidence of isomorphism and imitation of legitimate organizational forms, that takes place between organizations or actors which pertain to the same regulatory area or share references that constitute the sectoral regime. In new institutionalist terms, the 'organizational field' of relevance is not that of European regulatory agencies, but that formed by all the organizations across the different countries, which participate in the regulation of an industry.

[20] Interestingly, the general view in 1999, before the creation of EFSA was that the important decision was to separate risk assessment from risk management. As said by Gérard Pascal, one of the three senior scientists consulted by DG XXIV, 'there would always be some time later to organize the interaction between the two' – a choice that meant, in essence, that the designing of more precise rules was postponed until after the launch of the agency and delegated to sectoral technical actors.

Conclusion

EFSA is not designed in the same way as the EMEA because the issues, norms and practices that constitute the regulatory regime of each sector influences the designing of institutions. In medicine regulation, risk assessment and risk management are both owned by medical experts which retain the authority to deal with all aspects involved in the process – medical, regulatory and political. This is in strong contrasts with the then emerging food regulatory regime, based on the principle of the necessary separation of science from politics, and explains why certain rules and structures designed for medicine regulation were deemed inappropriate for food safety.

There is polymorphism rather than isomorphism at play here, in the sense of a differentiation occurring within a context of comparability. Agencies in each sector pose the same sort of issues for the distribution of powers. But this does not justify the imposition of an institutional model.

This helps to understand often heard arguments about the specificity of regulating food or medicines. These belong to political strategies which help participants in the formation of agencies to put all possible models at a distance. Alleged differences between each sector ('Food regulation is about evaluating risks and is more politicized than pharmaceutical regulation, that is about approving products', 'medicine licensing requires the provision of high quality medical evaluations of the risk/benefit ratio and keeps marketing time to a minimum') are not necessarily objective. They are strategies, for member states in particular, to prevent the imposition of rules and structures from outside the policy domain, owned by the European Commission.

The paper also shows that the conflict between two theoretical views, one based on norms and the other on interests pursued by rational actors, can be avoided. Firstly, that the effects of norms on agency design are related to particular contexts. Analytical frameworks must accommodate the factor of contingency and the particular order of events. Secondly, it appears that norms and practices of the regulatory regime are the language or templates through which rational actors can formulate their preferences. There is no such thing as the pure 'interest' of rational institutional actors, influencing the process as the *deux ex machina*. The particularity of the cases investigated here is, finally, that the rational preferences of institutional actors and norms converge. In a situation in which political and regulatory dynamics are contained within the boundaries of domains (Breyer 1993, Hood et al. 2001), the specificity of practices is by default favourable to actors who try to distance from institutional traditions, to design rules to their liking. In that sense, institutional designing is a form of regulatory action, and institutional creation a sequence of regulatory change.

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