The actual practice of agency autonomy: Tracing the developmental trajectories of the European Medicines Agency and the European Food Safety Authority
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ABSTRACT

In recent decades, a series of regulatory agencies has been created at the European Union (EU) level. The existing literature on EU agencies focuses either on autonomy as reason for their creation or on the autonomy that they are granted by design. As a result, we do not know much about how EU agencies’ de facto autonomy comes about. This paper therefore probes into the development over time of two particular agencies. On the basis of document analysis and interviews with agency officials and external actors, it explores why in practice the European Medicines Agency (EMA) seems to have developed a higher level of autonomy than the European Food Safety Agency (EFSA), whereas on paper EMA appears to be similarly autonomous as, or, if anything, less autonomous than EFSA. The paper demonstrates the importance of tracing the developmental trajectories of EU regulatory agencies for understanding the actual practice of their autonomy.

Keywords: autonomy, developmental trajectories, EFSA, EMA, European Union, regulatory agencies
THE ACTUAL PRACTICE OF AGENCY AUTONOMY: TRACING THE DEVELOPMENTAL TRAJECTORIES OF THE EUROPEAN MEDICINES AGENCY AND THE EUROPEAN FOOD SAFETY AUTHORITY

1. Introduction

On August 8, 2001, Bayer suddenly withdrew its anti-cholesterol medicine Baycol from the market. The reason for the withdrawal, according to a press release by the company, was increasing reports of side-effects involving muscular weakness. In June of the same year, changes had already been made to the drug prescribing information in the EU, of which health professionals were informed through so-called ‘Dear Doctor’ letters. The recall took the European Medicines Evaluation Agency (EMEA) and the member states by surprise.

Not much later, the high profile withdrawal of Baycol was followed by another much publicized recall. In September 2004, Vioxx, a painkiller, had to be withdrawn from the market by the company producing the drug, Merck, as it had appeared from a recently finished study that the drug caused an increased risk of heart attacks and strokes among patients with heart and vascular diseases. Merck fell into discredit when it became clear that it had been aware of the painkiller’s side-effects for a long time. EMEA already before the recall had concerns about the safety of medicines such as Vioxx, but it advised the member states to keep the product on the market, provided that the product package was adapted to better describe the side-effects.

Whereas both affairs negatively affected the image of the pharmaceuticals industry and the authority of regulatory agencies, in particular the U.S. Food and Drug Administration (FDA) (see Carpenter 2010), they left the EMEA’s reputation relatively unscathed. If the Baycol and Vioxx affairs had any consequences for the agency, they were positive. The recalls of medicines still approved and monitored underlined the necessity of an increased role for the agency, beyond pre-marketing evaluation, into post-marketing surveillance. Hence, the agency’s name change with the amendment of its constituent act, from European Medicines Evaluation Agency to European Medicines Agency (EMA).

How different were the effects of a scientific message on avian influenza (commonly known as bird flu) put out by the European Food Safety Authority (EFSA) (see also Gabbi 2007). Instead of reinforcing its role, the message, put out on EFSA’s own initiative, led the Commission and the member states to more closely watch the agency when communicating on food risks. On October 25, 2005, the Financial Times first reported “a precautionary warning” by EFSA, advising Europeans to avoid eating raw eggs and to cook chicken to decrease the risk of contracting bird flu. In the article Herman Koëter, then EFSA’s director of science, was quoted saying:

We have no proof at all that people can contract the virus through the digestive route. However, we cannot exclude that theoretically it would be possible for that to happen. […] Theoretically, it could be possible that, if you eat the raw blood of an infected chicken, the virus is then not totally killed in the stomach.

According to the agency the advice was in line with standard advice to combat more widespread diseases like salmonella. But the Commission and the member states, meeting that same day in the Standing Committee to decide on import bans following the detection of avian influenza in the UK, were taken by surprise. Not only were they annoyed by the uncoordinated action of the agency, they also considered the comparison with salmonella to be confusing and criticized EFSA for causing panic. The Commission and the member states, fearing that EFSA’s message would cause people to turn away from chicken and lead to economic losses for industry and reputational damage for member states, forced the agency to rectify its statements, which the agency did in a press release the next day.
When compared to other agencies established at the EU level, EMA and EFSA have been granted a relatively high level of formal autonomy from politicians, business and organized interests. Autonomy, even though not the main reason for its creation, is one of the cornerstones of EMA’s design, given the potential pressure from member states, pharmaceutical companies and patient groups to authorize particular medicinal products (e.g. Permanand and Mossialos 2005; Gehring and Krapohl 2007). In the case of EFSA, autonomy was the key rationale underlying its creation. In view of the politicization of expert decision making during the BSE (or mad cow disease) crisis and dioxin scandal, there was a broadly shared feeling that politics should be more strictly separated from science. To that end, EFSA was created, with independent risk assessment and communication capacity (e.g. Vos 2000a; Krapohl 2003; Lezaun and Groenleer 2006).

Despite their rather similar features with regard to creation and design, the two agencies are characterized by different dynamics with regard to their development. Once formally created, EMA increased its autonomy, whereas EFSA experienced difficulty in maintaining even the level of autonomy endowed with upon its establishment. If anything, we on the basis of the prevailing agency literature would have expected them to develop relatively similar levels of de facto autonomy. On closer inspection, we would perhaps have expected the more formally autonomous agency to develop a higher level of de facto autonomy, but not the other way around. This thus raises the question why EFSA, that arguably has a higher degree of autonomy on paper, seems to be less autonomous in practice, whereas EMA, that can be considered formally less autonomous, appears to have developed a higher level of autonomy.

The existing literature on EU agencies does not help us to answer this question as it focuses either on autonomy as reason for the creation of agencies or on the autonomy that they are granted by design. As a result, we do not know much about how an EU agency’s de facto autonomy comes about. Understanding the development of EU agencies requires starting from the historical background to their creation and their design characteristics, because these conditions are likely to shape their development in important ways. This paper argues that they are not the only conditions of importance and that it therefore is essential to inquire further into the organizational development of particular agencies. Hence, the paper provides an account of the creation, design and, in particular, the early development of EMA and EFSA. It examines to what extent their de jure autonomy corresponds with their de facto autonomy and explores the differences in development over time, going beyond design-oriented explanations.

Data have been collected through analysis of documents and semi-structured interviews. Documents analyzed include, among others, agencies’ constituent documents, their annual reports and external evaluations of their first five years of existence. In order to trace the processes by which EMA and EFSA developed, 23 key actors in these processes, including agency staff members and national experts, political actors, external stakeholders and clients, have been interviewed in a semi-structured way.

The paper proceeds as follows. In the next section a brief overview of the literature on the autonomy of EU agencies and the development of bureaucratic organizations more in general is given. After a methodological note on the comparability and generalizability of the EMA and EFSA cases (section 3), the paper examines to what extent EMA’s and EFSA’s formal autonomy corresponds with their actual autonomy (section 4). Section 5 then discusses the developmental trajectories that may account for the variation found between EMA and EFSA with regard to their de facto autonomy. The paper is concluded with a summary of the main findings, remarks on the limitations of this research and directions for further research (section 6).
2. Autonomy and development of EU agencies

Autonomy as reason for creation and as a design feature

In recent decades, a series of regulatory agencies has been created at the European Union (EU) level. One of the main official reasons for creation has been their *de jure* autonomy from political interference (see e.g. Majone 1997b; Dehousse 1997). EU agencies are supposed to provide independent expertise of a highly technical or scientific nature not readily available within the Commission. Indeed, “the independence of their technical and/or scientific assessments is […] their real *raison d’être*. The main advantage is that their decisions are based on purely technical evaluations of very high quality and are not influenced by political or contingent considerations.”4 As non-majoritarian institutions, not directly accountable to voters or to their elected representatives, EU agencies are said to be insulated from the political process. This insulation aims to ensure policy continuity, which is imperative to policy credibility (Dehousse et al. 1992; Majone 1997a, 2000; Vos 2000b).

By design, EU agencies have a limited degree of formal autonomy. As opposed to agencies in the EU member states and other countries, particularly the United States, they are generally not invested with broad regulatory powers: most EU agencies cannot take decisions on rules and standards and even if they can, they can only do so in individual cases. The European Commission and the member states remain in charge (Majone 1996; Yataganas 2001; Kelemen 2002; Geradin 2005). Yet, the Commission must usually take the opinions issued by these agencies into account or justify why it does not do so, and, whilst being issued in an individual case, these opinions in practice often have a more general effect, for instance being applicable to all products of a certain type. Moreover, the mandates given to agencies have developed over time, with recently created EU agencies (such as those in the areas of banking, securities, insurance and pensions) playing an increasingly important role in EU policy formulation and implementation.

Formal autonomy is laid down in an EU agency’s constituent document and can be operationalized into different dimensions, including legal, personnel, financial and policy autonomy (Kreher 1997; Bouckaert and Peters 2004; Gilardi 2002; Verhoest et al. 2004; see also Busuioc et al. 2011). In this paper, EU agencies are considered to be granted more formal autonomy when their statutes explicitly state that:

a) they are delegated broad regulatory tasks and powers,

b) their board, director, in-house staff and external experts are fully independent in exercising these tasks and powers, and

c) they have their own funding,

than when their regulations make only marginal reference thereto or remain silent at all thereon, or make explicit reference to EU agencies’ dependence on specific actors (Council, Commission, Parliament, industry, non-governmental organizations) when it comes to their tasks, powers, board, director, staff, experts and budget.

Development of EU agencies: actual autonomy and legitimacy

While some agencies may have been created more autonomous than others, this does not necessarily imply that these formally autonomous agencies develop more actual autonomy as well. The amount of autonomy an agency acquires in practice is not fixed (Carpenter 2001). That is, once an agency has been created, it may very well develop its own preferences and interests, separate from political actors, external stakeholders and clients (Majone 1996; Moe 1989). Hence, it is not enough to look at the autonomy that an agency has by design, as in that way informal adjustments or expansions of its
formal autonomy may be overlooked (Thatcher and Stone Sweet 2002).

In order to understand the development of EU agencies, we have to distinguish the formal autonomy of an agency from its actual or de facto autonomy (Verhoest et al. 2004; Yesilkagit 2004). This not only requires paying attention to amendments made to the agency’s legislative statute, but also investigating the behaviors developed on the basis of formal documents but not codified as such (Thatcher and Stone Sweet 2002). Actual autonomy can thus be assessed by tracing the process of autonomy development over time through document analysis and interviewing. In case of regulatory agencies such as EMA and EFSA, this means primarily focusing on the decisions or actions of their board, director, staff and experts with regard to providing technical and/or scientific advice.

The close relationships between agencies and other actors make it difficult to point to autonomy in practice, however. An agency may anticipate control by other actors or these actors may allow it to behave the way it likes because they lack an interest in the agency’s activities. Rather than distinguishing the presence of actual autonomy from the absence thereof (cf. Weingast and Moran 1983), this paper thus considers it more fruitful to study autonomy as a matter of degree, varying over time and depending on the particular actor in relation to which it is assessed.

On the basis of what is known about bureaucratic agencies in the national (mainly American) context, the de facto autonomy of EU agencies is likely to be conditional upon the acquisition of a level of legitimacy. Most bureaucratic agencies begin with at least a minimal level of legitimacy (Wilson 1989), but some over time develop higher levels of legitimacy than others. Their goals and policies are not questioned; their existence is taken for granted (Clark and Wilson 1961; Jepperson 1991). They are not only accepted for their objectives and the means to accomplish these objectives, but they are themselves considered appropriate within the cultural system and normative framework in which they operate (Suchman 1995; Khademian 1996).

Legitimacy has both an internal dimension, which can be gauged by the level of employee commitment and the extent to which they share the same values, and an external dimension, which can be measured by the relative balance of opposition to support from political actors, other agencies in the field, industry, non-governmental organizations and the media (see also Carpenter 2001). This paper concentrates on the external dimension, investigating the autonomy agencies acquire from the political actors in their external environments, including the Commission and the member states, but it also takes into account bureaucratic actors, such as national agencies (Ellison 1995; Meier and Bohte 2006). A high level of legitimacy is then indicated by:

a) extensions of the agency’s tasks and powers by political actors,

b) appropriation of a significant level of financial and human resources,

c) frequent requests for advice and regular provision of information, also when not obligatory,

d) cooperation sought by other agencies, and

e) a minimum of challenges to the agency’s actions and decisions.

Although legitimacy implies a widespread perception or assumption of appropriateness, a legitimate agency does not have to be accepted as appropriate by everyone all the time, which in turn affects the support from political and bureaucratic actors. Only few agencies inhabit environments in which their goals and policies always enjoy wide public support and are not at times opposed by well-organized regulated parties. Most agencies are at least from time to time contested by some people or groups, especially so when their environment is made up of a variety of actors with different preferences and interests, which is typically the case for regulatory agencies.
Managing legitimacy

The support agencies receive from political actors is key for their legitimacy. Agencies rely on them for budget appropriations, or, whenever they generate their own funding, for the approval to implement their budgets. Apart from financial appropriations, political actors invest the agency with the powers to perform its tasks. Some depend more on formal authority than others. An important factor here is the type of tasks delegated to agencies (Thompson 1967). Agencies that by the nature of their tasks do not generate much support from their stakeholders and clients, such as regulatory ones, very much rely on the formal powers that have been bestowed upon them to command compliance with their policies and decisions (Wilson 1978, 1980; Rourke 1984).

But the level of political support depends on more than just an agency’s tasks. For a newborn agency it is usually relatively easy to acquire support from its political parents, especially if they were the individuals and groups promoting the creation of the agency. But relations may change over time, with members of parliament being replaced, executives leaving office, or with shifts in public attention resulting in the agency’s creators to change their attitude (Wilson 1980, 1989; Moe 1984). Once founded, agencies therefore must sustain the support from political actors. From the literature on bureaucratic agencies, four ways by which they generally can do so are distinguished:

1) differentiation from other organizations in the field,
2) moderation towards their political parents,
3) balancing the demands and wishes of political actors, stakeholders and clients, and
4) networking with other (bureaucratic) organizations.

Agencies can first of all create a basis of support by demonstrating that they are uniquely capable of providing acceptable solutions to pressing problems (Carpenter 2001). Problem solving capacity is thus crucial here (Majone 1996). This strategy has been referred to as differentiation, that is, “the attempts of organizations to establish unchallengeable claims on valued resources by distinguishing their own products or programs from those of their competitors” (Sapolsky 1972: 43). Agencies want political actors to believe that no other organization can deliver the policies and run the programs as well as they do. They seek to avoid competition from other agencies by creating a unique organizational identity. Bureaucratic reputation is an important factor in this regard (Rourke 1984; Wilson 1989; Carpenter 2001; Whitford 2002; Krause and Douglas 2005). Through an agency’s reputation, i.e. the structure of beliefs as embedded within different audiences, politicians can observe and judge whether the agency is considered to be competent, qualified, careful etc. and whether it deserves their support (Carpenter 2010; Moe 1984).

Furthermore, in the early stages of an agency’s life, a minimal level of isolation may be a necessary condition to work out a distinct organizational identity (Selznick 1957). Some agencies thus try to establish a position of “virtually complete autonomy within the executive branch,” indeed even coming to regard themselves as “being a law unto themselves” (Rourke 1984: 72-73). However, an agency’s efforts at differentiation can alienate it from its environment and may thus come at serious cost for its long-term support. To ensure long-term support, agencies may follow what Sapolsky (1972) refers to as a strategy of moderation, that is, tempering forcible demonstrations of organizational autonomy by adopting a restrained approach towards other actors in their environments. Although certain objectives may be easily realized in terms of capacities and resources, agencies can decide not to obtain these objectives in their early years because their realization might lead to unnecessary hostility in their environments that would be harmful at a later stage.
1989: 283), is “to nurture mutually beneficial relationships with groups and politicians whose political support the agency needs.” This is most easily done with its initial supporters in the early years of an agency’s existence. “Over time, however, the agency will be driven to broaden its support base, and it may move away from some of its creators [...]” Agencies can then pay sequential attention to the demands of some political actors, thereby developing a level of autonomy from others (Dahl and Lindblom 1953; Wilson 1989; cf. Cyert and March 1963). Because their mandates are often broad and multi-interpretable, and therefore can be used to include the often contradictory demands and wishes of a variety of groups, agencies can also play off one actor against the other (Moe 1987: 482; Woolley 1993; Ringquist 1995). Yet, in spite of the increased possibilities for autonomy in case of ‘multiple principals’, agencies are often left with little choice but to collaborate with those actors that share their policy goals, attempting to build a coalition in favor of their own preferences and interests (Waterman and Meier 1998).

Finally, whereas close ties among bureaucratic agencies are generally assumed to result in autonomy loss for at least one of these agencies (e.g. Downs 1967; Thompson 1967; Aldrich 1976; Pfeffer and Salancik 1978), cooperative relationships do not necessarily result in autonomy loss. By being embedded in networks of organizations sharing common or complementary interests, the autonomy of agencies may actually be enhanced. In networks, organizations, though interdependent, are not subordinate to these organizations and remain separate from them (e.g. Mayntz 1993; Rhodes 1996; Börzel 1998). They coordinate their actions with other actors, thereby for instance increasing informational capacity, gaining efficiency, reducing risk or increasing their reputation, while they, at the same time, protect themselves from interference in their policies and decisions (e.g. Chisholm 1989; Provan and Milward 1995; 2001). Indeed, an agency and facing analogous problems, rather than as a new and often marginal addition to a huge central bureaucracy, is more motivated to defend its professional standards against external influence, and to co-operate with the other members of the network (Everson et al. 1999: 60-61).

3. Comparability and generalizability

Both the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) were established under the former Community pillar of the European Union and were invested with significant powers to regulate European markets. As such, these agencies may be expected to develop a high level of de facto autonomy from political actors at both the EU and national level.

In terms of comparability, however, these agencies, although both endowed with regulatory tasks and perhaps granted a higher level of formal autonomy than others, differ with regard to the precise reasons for their creation and on a number of important design features, as will be shown below. The same applies to the regulatory systems of which they are part and the preferences and interests of other actors in these systems, notably the Commission, the member states and their national agencies.

Moreover, it can be argued that regulating pharmaceuticals is something completely different than regulating foodstuffs because of the different nature of the products. Whereas pharmaceuticals are relatively homogenous products and can therefore be more easily authorized before sale, food products are relatively heterogeneous, which makes it difficult to subject them to pre-market authorization (Krapohl 2007). Food safety regulation is also often referred to as much more emotional and irrational than pharmaceuticals regulation, as is illustrated by the heated debate over Genetically Modified Organisms (GMOs), which arguably makes it more difficult for a food safety agency to behave in a similar way as a
While there is certainly some merit in the ‘specificity’ argument, it has often been used by actors in the food sector for strategic reasons, to prevent comparing with and borrowing from other sectors, notably the pharmaceuticals sector (Demortain 2008). Yet, regulating pharmaceuticals is not completely different from regulating food. Medicinal products have at least partly become so homogenous for the very fact that they have undergone strict regulation much longer than food products (Krapohl 2007). Also food products are likely to become shaped by the activities and decisions of regulatory actors over time.

The time aspect does, however, point to the importance of taking into account the history of medicines and food regulation in the EU when attempting to explore the differences in actual agency autonomy. Given the unique historical context in which it came into being, EFSA may be considered an exceptional case which in fact cannot and should not be compared to EMA. What is more, the creation and design of EMA as well as its development may have influenced the creation and design of EFSA, also making the EFSA case incomparable to the EMA case. This paper therefore traces the developmental trajectories of EMA and EFSA and the possible interaction between them, given the historical origins of both agencies and the resulting design choices.

As far as generalizability is concerned, both EMA and EFSA are examples of EU regulatory agencies. They have certain features in common with other agencies, such as the Office for the Harmonisation in the Internal Market, the European Aviation Safety Agency, the European Chemicals Agency and the three recently established EU agencies for banking, securities and insurances and pensions. But their characteristics cannot said to be sufficiently representative of a larger population and the possibilities for generalization are thus limited.

Generalization is not the main objective of this paper, however. Tracing the developmental trajectories of EMA and EFSA is pertinent precisely because EMA was created before EFSA and it is likely to have an effect on the creation, design and perhaps also the development of EFSA (cf. Carpenter 2010).

4. Creation and design: the autonomy of EMA and EFSA

4.1 EMA: de facto binding opinions

**Historical background**

The creation of EMA on July 22, 1993, was part of the first wave of agency creation at the EU level. The agency was supposed to function as a ‘secretariat’, validating the applications of pharmaceutical companies, coordinating the assessment of new medicines by national authorities and delivering the Commission opinions on which to base a decision. Although the agency was created to implement new Community legislation, this legislation supplemented legislative measures and institutional arrangements (such as comitology committees), already in place at the European level. In fact, EMA was the culmination of thirty years of EU pharmaceutical legislation (Hancher 1990, 1991; Vos 1999; Krapohl 2007). EMA’s historical background helps to explain why the agency was created as it was, with significant powers and tasks of its own, but firmly embedded in a multi-layered system for the evaluation of pharmaceuticals.

For a long time, national regulatory agencies were responsible for the approval of medicines before sale in their country, either through authorizing such medicines themselves or through recognizing the authorization by other national regulatory agencies. By the end of the 1980s, the European Commission, in particular its Directorate-General (DG) Enterprise, became concerned that the pharmaceutical sector, mainly as a result of distrust among national agencies
in each other’s evaluations and considerable delays in decentralized authorization procedures, would not make the 1992 deadline for the completion of the single market. Hence, the Commission, focusing on the removal of barriers to economic integration, convinced the pharmaceutical industry of the need for a centralized procedure. As opposed to the mutual recognition procedures, this procedure would not be dominated by national agencies but coordinated by a single EU agency, thus making the approval process more efficient (Deboyser 1995; Gardner 1996; Permanand 2002). The failure of the decentralized approach thus spurred the emergence of a supranational regulatory regime from which the industry and the Commission were the prime beneficiaries (Permanand and Mossialos 2005).

**Formal autonomy**

The agency’s primary task is risk assessment by performing scientific evaluations of medicinal products, initially concentrating on the most innovative products such as biotech products. Evaluations of medicines are carried out by scientific committees of experts, which are supported by the agency’s staff. If the relevant committee concludes that quality, safety and efficacy of the medicinal product are sufficiently proven, it adopts a favorable opinion, which is sent to the Commission to be transformed into a single marketing authorization valid for the entire EU. The Commission adopts a draft decision on the basis of which member states representative in the respective comitology committee can raise new scientific or technical questions. If no member state raises objections against the draft decision, the decision is adopted. The Commission and the member states thus ultimately decide, also taking into account issues other than just scientific and technical factors such as economic, ethical or political factors (for an overview of EMA’s formal autonomy see Table 1 below).

The scientific committees consist of experts nominated by member states’ medicines authorities and appointed by the agency’s management board. Member states may not give their experts instructions that conflict with the tasks they perform for the agency, respecting and guaranteeing their independence. As in most EU agencies created during the early 1990s, the board itself is primarily made up of representatives of member states’ medicines authorities, usually their heads, which are appointed by the Council. The Commission, the Parliament and, since the amendment of the agency’s constituent act in 2004, patient and doctor groups also have representatives on the board. The executive director of EMA is an EU official, appointed by the board on the basis of a short-list which is drawn up by the Commission. Although he is relatively independent in hiring people and allocating money, he has to follow the Commission’s staff and financial regulations.

Moreover, in order to ensure the agency’s autonomy vis-à-vis the EU institutions, EMA is one of the few agencies that is partially self-financed. Like other drug agencies around the world, it charges pharmaceutical companies fees for its services. Yet, the power to determine the level of fees is divided between the Commission and the Council, and about 50 percent of the income through fees is transferred to the member states for supplying experts to the committees. Furthermore, so the agency is not too dependent on industry, of which its statute expressly stipulates that it is supposed to be independent, the Commission contributes a subsidy, which in recent years makes up about 25 percent of EMA’s total revenues, and for which the agency is accountable to the Parliament and the Council.

**Actual autonomy**

The agency has been involved in the coordination of an increasing amount of different medicinal products. The centralized procedure is now also used for medicines against AIDS, diabetes, neurogenerative, auto-immune and viral diseases, amongst others. Formal scope extensions often followed established practice, as companies
already applied for authorization with the agency without an obligation thereto. In addition, as already mentioned in the introduction, the agency’s role in the post-marketing phase has grown over the years, not only informally, through exerting pressure on pharmaceutical companies, but also formally. Whereas surveillance of the pharmaceutical market initially was a member state responsibility, the agency’s coordinating role has been strengthened and it for instance now also has the possibility to conduct investigations into the safety of drugs already authorized for entry on the market.

Decision making in the agency’s expert committees is characterized by a high level of consensus. Most opinions rendered in the early years were positive and of these positive opinions the vast majority were adopted unanimously (Feick 2002; Garratini and Bertele 2004; Gehring and Krapohl 2007). Although most respondents consider this to be a sign of the will to work it out and that cooperation is constructive, some respondents regard the high level of agreement as forced, reflecting national interests or the position of national agencies and resulting from previous deliberations which tend to obscure experts’ personal evaluations (Garratini and Bertele 2004). To counter criticism that it is influenced by national agencies (or industry for that matter) EMA has followed a policy of openness and transparency. For example, meetings of committees commence with experts declaring their interests and the list of experts and their nominating authority is publicly available on the agency’s website.

The agency’s expert committees largely predetermine the Commission’s authorization decision (for an overview of EMA’s actual autonomy see Table 2 below). The drafts prepared by the committees are generally accepted by the Commission without changes. The member states typically follow the agency’s advice as well. They seldom ask additional questions and when they do the eventual advice rendered by the scientific committee rarely differs from its initial advice (Feick 2002). Member state representatives in the comitology committees have always been able to decide on the proposed decision; not a single decision has been referred to the Council. So whereas the agency does not have a legal right of decision, its opinions on the authorization of medicinal products have a de facto binding value because they are virtually rubberstamped by the Commission and the member states (Dehousse 2002; Gehring and Krapohl 2007).

Through their representation in the management board member states still wield considerable influence on agency decision making. Heads of national authorities are not likely to make decisions that endanger the position of their own organizations. As a result, initiatives strengthening the position of EMA vis-à-vis national agencies, especially those concerning the fee system, have been blocked. When pharmaceutical companies follow the centralized procedure, member states’ authorities lose income to EMA. National agencies thus ‘compete’ for funding with EMA, which makes both dependent on the pharmaceutical industry (Mossialos, Walley and Mrazek 2004). In combination with the fact that the percentage of funding from fees at EMA is substantially higher than at other drug agencies around the world, this has led some to question EMA’s ability to act independently (Garattini and Bertele 2004).

In addition, the behavior of board members is highly dependent on the interests that member states have in the agency’s activities. Countries with large pharmaceutical companies in particular want to keep a watchful eye on the agency’s activities, which has sometimes politicized discussions in the board (Metcalfe 2000). Yet, as a respondent says: ‘We have not seen a single case of EMA saying ‘This drug is dangerous’ and the member states saying ‘No, this is wrong’ or the EMEA saying ‘This drug should not enter the market’ and the member states saying ‘It should, we need this drug’.

Moreover, although the board adopts key documents such as the budget, the work programme and the annual budget, it is the director who actually runs the agency. As they meet only four times a year, receive documents for the meetings no more
than a few weeks in advance, and have not much time to prepare for the meetings, board members have a weaker information position than the director and his staff. In practice, this usually allows the director, often with the support of the Commission representative, to get his proposals adopted without much changes.

Even though EMA staff act in support capacity, they can exert considerable influence over the evaluation process, especially because a majority of the agency’s staff consists of scientists and specialists, for instance in regulatory affairs. They possess knowledge of the relevant EU legislation, which enables them to advise experts during committee meetings. They also take minutes during these meetings and prepare drafts for the committee’s consideration, thereby ensuring the consistency of opinions.

4.2 EFSA: regulating by authority?

**Historical background**

EFSA was the first of a new wave of EU-level agencies to be established. Its history is inextricably bound up with the repeated outbreaks of Bovine Spongiform Encephalitis (BSE) or ‘mad cow’ disease. Whereas economic interests and agricultural policy concerns were for a long time dominating issues of public health and consumer confidence, the BSE crisis in 1996 spurred the reform of the EU’s food policy and, together with other food scares such as the dioxin scandal, eventually prompted the adoption of a regulation for an independent EFSA on February 28, 2002.6 The new agency was to become the EU’s scientific point of reference in the area of food and therefore called ‘authority’ rather than ‘agency’.

Like pharmaceuticals regulation, food regulation goes back to the 1960s when the first moves were made towards the creation of a common foodstuffs market (Vogel 1995). Whereas barriers to trade were removed, public health concerns only played a minor role. It was precisely the success of the abolition of internal frontiers and checks that allowed BSE to spread during the 1980s and 1990s (Chambers 1999). The mismanagement of the BSE crisis and the subsequent dioxin scandal, as well as the growing concerns about genetically modified food products, provided the opportunity to reform the existing regulatory regime and create an independent food agency. The agency was the first agency created using the co-decision procedure which made it possible for the Parliament to exert strong influence over its design, restricting its competences to providing advice on food safety only (Chalmers 2003; Kelemen 2004; Buonanno 2006).

**Formal autonomy**

The agency assesses and detects (emerging) food risks, enabling the Commission and the member states to manage such risks. EFSA’s output mainly consists of opinions, rendered in response to questions formally addressed to it by the Commission, the member states and the Parliament. Based on its risk assessments the agency also communicates on food safety issues, a responsibility which it shares with the Commission and the member states. Similar to the case of EMA, the Commission and the member states remain responsible for political decision making, strictly separating risk assessment from risk management. On the basis of EFSA’s advice, the Commission develops policies and proposes legislation, while the member states in the relevant comitology committees decide on such policies and legislation. The Commission and the member states establish the level of acceptability of risks, also evaluating socio-economic concerns.7

Yet, there are few EU agencies that can claim as much formal autonomy as EFSA (for an overview of EFSA’s formal autonomy see Table 1 below). Its regulation specifies that the agency is supposed to establish confidence by virtue of its
independence, referring to the agency’s ability to express ‘independently’ its opinions. Moreover, it can provide advice on any matter within its mandate, acting on its own initiative, referred to as ‘self-tasking’. Its regulation further contains a separate provision focusing on the independence of the agency’s director and those individuals part of its management board, advisory forum and scientific committees and panels. Importantly, and as opposed to the EMA case, experts serving on EFSA’s committees and panels are independent scientists, appointed by the agency’s management board through an open selection procedure on the basis of proven scientific excellence. They are not paid for their services, merely reimbursed for expenses.

Unlike other agencies, EFSA’s board consists of 14 members, acting in a personal capacity, appointed by the Council after consulting the European Parliament on the basis of a short-list which is drawn up by the Commission following an open call for expressions of interest, as well as a representative of the Commission. The Commission draws up a short list for the position of executive

Table 1: Formal autonomy

<table>
<thead>
<tr>
<th></th>
<th>EMA</th>
<th>EFSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tasks</td>
<td>Risk assessment, some risk management (shared with Commission and member states)</td>
<td>Risk assessment (including emerging risks, self-tasking), some risk communication (shared with Commission and member states), but strictly no risk management</td>
</tr>
<tr>
<td>Powers</td>
<td>Advisory (Commission and member states ultimately decide)</td>
<td>Advisory (Commission and member states ultimately decide)</td>
</tr>
<tr>
<td>Board</td>
<td>Appointed by the Council, after nomination by national authorities</td>
<td>Appointed by the Council, after consulting the Parliament, on the basis of a short-list drawn up by the Commission</td>
</tr>
<tr>
<td>Director</td>
<td>Appointed by board, after consulting the Parliament and on the basis of a short-list drawn up by the Commission</td>
<td>Appointed by board, after consulting the Parliament and on the basis of a short-list drawn up by the Commission</td>
</tr>
<tr>
<td>Staff (in-house)</td>
<td>Recruited by director to perform administrative and procedural tasks</td>
<td>Recruited by director to perform administrative and procedural tasks</td>
</tr>
<tr>
<td>Experts (in committees and panels)</td>
<td>Nominated by national authorities and appointed by board</td>
<td>Selected through an open selection procedure and appointed by board on the basis of proven scientific excellence</td>
</tr>
<tr>
<td>Budget</td>
<td>Partially self-financed through fees from industry, the level of which is determined by the Council and the Commission</td>
<td>Entirely funded through EU subsidy</td>
</tr>
</tbody>
</table>
director, who is appointed by the board and can be removed by a majority vote. In order to compensate member states for the lack of representation in the board, EFSA has an advisory forum, composed of representatives of national food agencies. Advisory forum members only have a consultative role, advising the EFSA director. Finally, in order to act independently from industry and to be seen so acting, the agency is entirely funded through the Community budget. This means the agency depends on the Commission to propose a budget and on the Council and the Parliament to subsequently approve the budget.

**Actual autonomy**

Food safety issues have changed since BSE and dioxin. The most important issue regarding food safety is no longer the next food scandal or crisis. EFSA is now also concentrating on major public health concerns such as the safety of novel food products and unhealthy dietary habits of European citizens. Almost all pre-market approvals in the area of the food chain are centralized and performed by EFSA. The agency for instance has been given a formal role in the authorization of additives, flavorings, pesticides, and notably GMOs. It also assesses whether nutrition and health claims are scientifically substantiated. But EFSA’s expanded role has not gone uncontested. For example, not everyone believes the assessment of GMOs is an appropriate task for EFSA, considering it more an environmental and social issue than a food safety issue, which has thus become a bone of contention and led to major political interference.

While the member states and the Parliament may pose questions, it has most often been the Commission that asked EFSA for opinions (for an overview of EFSA’s actual autonomy see Table 2 below). Hence, EFSA’s actual autonomy is largely dependent on the Commission’s willingness to act on its advice. The question whether EFSA’s opinions are followed by the Commission is difficult to answer as it is often unclear what it means for the Commission to act on an advice as opinions have to be interpreted. Respondents say that not all opinions have been used, although most are taken into account. But those representing EFSA admit that especially in the early years, the agency often did not know what was done with its opinions.

Scholars claim that opinions do have some normative effects (Chalmers 2003; Kanska 2004; Alemanno 2008). For one thing, the Commission cannot simply disregard the advice. In the area of GM food and feed, it has to find equivalent scientific evidence and give reasons justifying its reliance thereon. But whereas clients and stakeholders generally judge the quality of EFSA’s opinions as high and there are many areas in which the agency delivers opinions without much opposition (e.g. pesticides, food contact material and even health claims), not all of EFSA’s opinions are undisputed and it would certainly be too strong to attribute a *de facto* binding value to them.

The bulk of the agency’s scientific output is produced by the independent experts in the scientific panels and committees. The fact that they are not nominated by the member states does not mean that they cannot be employed with national food agencies or government institutes or have previously worked for industry. Indeed, EFSA quite early on in its history adopted a broad view of independence, confronted with the dilemma that the most independent scientists are not always the best scientists, whereas the best scientists usually have links with industry. The agency has therefore attempted to strike a balance between relying on scientists linked to industry for some of its scientific advice, while retaining its independence from industry by also drawing from other sources of expertise.

Yet, especially with regard to heavily contested products such as GMOs, EFSA’s opinions are increasingly debated. They would go beyond objective advice, incorporating normative and risk management issues as science (Levidow and Carr 2007). In the early days, when advice on risk
management was by no means accepted, this led to concern about EFSA’s autonomy as it “could give way to ‘unhealthy’ trading-off discussions between the Commission and EFSA.” Member states as well as non-governmental organizations (NGOs) have accused the Commission of misusing EFSA’s scientific advice to push through authorization of GMOs in view of economic motives. Nowadays, the Commission even demands that the agency presents risk management options and takes into account the feasibility of particular measures (Vos and Wendler 2006). In response to the criticism of member states and NGOs, the Commission has usually shifted the blame to EFSA, accusing it of not sufficiently considering contextual factors.

To establish a reputation for independent science, its first director has actively asserted the agency’s autonomy from the Commission, proactively setting its tasks. For example, so as to provide scientific and technical assistance beyond assisting panels and having questions answered, the agency attracted scientists for its own scientific expert services. The build up of in-house expertise was halted by an internal reorganization following the 2005 external evaluation of the agency, reflecting the perceived need to work more closely with national agencies, not part of the agency’s decision-making structures by design.

Through its composition, EFSA’s management board has played an important role in safeguarding the agency’s independence vis-à-vis the Commission and the member states but also the Parliament. Interviews reveal that the relations between the agency and the board have generally been easy. Most of what the agency proposed to the board has been followed. When the board made objections, however, these have often come from the side of the Commission. The other board members then usually followed the Commission representative, which is not entirely surprising, in view of the Commission’s information lead, particularly on staffing and budgetary matters, and given the board’s obligation to ensure that EFSA’s work programme is consistent with the Commission’s priorities. Whereas board members’ nationality has not played a role in the board’s decision making, the absence of member state representation has in fact in some cases increased the Commission’s role.

Even though its budget showed a steady growth, EFSA has suffered from several financial setbacks in its early years. The Parliament, locked in a power struggle with the Council, used its power to put a substantial part of the agency’s budget in reserve, and, right at the time when the agency’s workload was rapidly increasing as a result of new legislation, the Council decided to reduce the budget heading under which EFSA operates. Yet, neither the Commission nor the agency have considered compensating for the budgetary shortfall through the introduction of a fee system an option until now: the Commission is afraid it will result in skewed priorities towards the needs of companies, whereas the board fears it will introduce an element of uncertainty in the agency’s resource allocation and planning which can have a negative impact on the scientific advice EFSA delivers.
5. Developmental trajectories: the early years of EMA and EFSA

5.1 EMA: cooperation by co-optation

EMA’s relatively high level of actual autonomy from the Commission and the member states is at least partly due to the way procedures and rules are written by the agency’s founders. It is argued that EMA can act autonomously because political actors are wary of deviating from opinions in light of the possibility that pharmaceutical companies take legal action (Gehring and Krapohl 2007). They therefore typically follow the committees’ opinions and rely on judicial supervision. Also the high level of consensus among experts, as a consequence of which political actors do not have to deviate from opinions, is to some extent designed into the system. Experts use the same criteria for the evaluation of medicinal products, as laid down in two Community Codes and elaborated in numerous additional guidance documents. The adherence to these criteria is said to add to the credibility of the authorization system and the reputation of the agency (Gehring and Krapohl 2007).

At least as important for the agency’s actual autonomy, however, is the way political actors and notably member states’ medicines authorities are involved in the work of EMA. Although the agency

Table 2: Actual autonomy

<table>
<thead>
<tr>
<th></th>
<th>EMA</th>
<th>EFSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tasks</td>
<td>From pre-marketing ‘medicines evaluation’ to pre- and post-marketing ‘science, medicines and health’</td>
<td>Separation between risk management, assessment and communication continuously contested</td>
</tr>
<tr>
<td>Powers</td>
<td>De facto binding value of opinions</td>
<td>Some normative effects, but opinions not undisputed</td>
</tr>
<tr>
<td>Board</td>
<td>Interests of national authorities dominant in board decision making when it comes to fees</td>
<td>Commission representative dominant in board decision making</td>
</tr>
<tr>
<td>Director</td>
<td>Entrepreneurial approach</td>
<td>Confrontational approach</td>
</tr>
<tr>
<td>Staff (in-house)</td>
<td>Exerting influence over evaluation process through administrative and procedural tasks</td>
<td>From scientific expert services to scientific cooperation and assistance</td>
</tr>
<tr>
<td>Experts (in committees and panels)</td>
<td>Consensus-oriented</td>
<td>Balancing independence and excellence</td>
</tr>
<tr>
<td>Budget</td>
<td>Competition for funding between agency and national authorities makes both dependent on industry</td>
<td>Dependent on Commission as main client</td>
</tr>
</tbody>
</table>
coordinates the centralized procedure, it does not centralize authorization. As Metcalfe (2000: 135) notes: [i]f an entirely new and separate organization had been created without any involvement of the Member States it would probably have been perceived as a threat by national regulatory authorities and found it difficult to secure their cooperation.” Indeed, both interviewed practitioners and academic observers consider the partnership between the agency and national regulatory authorities a key factor influencing the development of EMA.

Decentralizing its core activities in a network of national agencies contributes to EMA’s support in a number of ways (Everson et al. 1999). First of all, it protects the interests of national agencies in terms of organizational survival. They are ensured of income through their evaluation work for EMA. It also gives them ownership of the agency, or at least the impression that they exert some control over its activities. Furthermore, it confers credibility on the agency’s scientific work, as being involved at the evaluation stage makes it difficult for the member states to question agency opinions during the decision-making phase. This makes the agency look more trustworthy and silences its potentially most critical adversaries (Feick 2002; Broscheid and Feick 2005; Gehring and Krapohl 2007).

But national authorities were not immediately willing to cooperate within the EMA framework. They shared a similar distrust of the new system upon its introduction where it concerned their own positions. Indeed, the creation of EMA helped foster a degree of mutual understanding and trust among national authorities. Realizing that they could only maintain their positions by cooperating to resolve the problems that had hampered the regulatory system before, the heads of the national medicines agencies decided to create an informal network. Through their interaction in the new authorization system, suspicion among national agencies gradually disappeared and they learned to trust each other (Metcalfe 2000).

EMA was initially not invited to take part in the meetings of the national agencies’ network, but the agency’s director quickly understood that he would have to make this network part of existing transnational structures, for otherwise it would pit the heads of national agencies against EMA. Whereas the informal network of national agencies started off as the result of a defensive strategy, it has over time developed into a cooperative structure. Most national authorities have supplied the agency with the expertise required to fulfill its mission and have also used it as a forum for discussion on scientific issues with regard to pharmaceuticals regulation. Notwithstanding the continuous bickering over fees, this support has contributed to the agency’s effectiveness.

Before EMA’s creation, it took four to six years to get a drug authorized. The mission of the agency’s first director, a Frenchman trained as a pharmacist and a lawyer who had worked with both the French ministry for health and the Commission’s DG Enterprise, was to bring this down to twelve months. As the agency quickly reduced the approval time for new medicines, it demonstrated its value to both pharmaceutical companies seeking to market their medicinal products and patients groups pressing for speedy approval of innovative medicines. In turn, this support, as also reflected in the limited number of legal challenges and the fact that the science underlying EMA’s opinions has never been successfully challenged, made it (even more) difficult for the member states to question EMA’s evaluation work.

The fact that the member states have generally followed the agency and have not interfered in its work also indicates that political considerations are often already taken into account by the expert committee. Member state representatives in the comitology committees are often senior officials from the same national medicines authorities that have been involved through their experts in the evaluation stage. So whereas the experts in the scientific committees operate independently from their national agencies, they also depend on these agencies for their position and are unlikely to issue opinions that are not in line with the position of their
national authorities. Hence, “opinions adopted by the [Committee on Human Medicinal Products] are […] likely to include not only purely scientific, but also normative (national-flavoured) elements” (Vos 1999: 226).

Indeed, Hauray (2006), based on the observation of expert discussions in the Committee for Human Medicinal Products, finds that experts implicitly take into account non-scientific factors. Opinions comprise assessments of the necessity and acceptability of a treatment, with regard to the size of the patient group and the importance of the disease for patients’ and public health. National experts in the agency’s committees know their domestic regulatory cultures and traditions and are thus not only able to assess the risks related to the authorization of new medicines from a scientific perspective but can also judge whether the degree of risk is politically acceptable in their home countries (Krapohl 2004).

There is nonetheless a strong incentive for committee members to come to agreement amongst themselves on the basis of scientific arguments. When committees are unable to reach agreement, the Commission and the member states are likely to resort to negotiations and bargaining, the outcomes of which are uncertain and may well reflect purely political arguments (Feick 2002). Moreover, although experts come from different national cultures and have been trained in different traditions, they have similar professional backgrounds, many of them being pharmacists, chemists, medical doctors or veterinarians. Interaction among them in the framework of the agency is even said to further their cosmopolitan orientations or supranational identities (Majone 2000; Broscheid and Feick 2005).

Yet, health policy being an area of shared competence between the supranational and the national level, the member states eventually decide on reimbursing and pricing medicines approved by EMA. This has made it possible for controversial medicines such as Viagra to be approved without member states objecting in the decision-making process. So even if the advice rendered by the scientific experts contradicts the preferences and interests of political actors, they can still decide not to reimburse a particular medicine or make it expensive.

As for the Commission, notably its DG Enterprise which had been pushing for a medicines agency in the first place, it would not be in its interest to question the agency’s opinions. At least, as long as the agency’s activities still emphasize industry interests. Furthermore, because one of the reasons to create the agency was to more clearly separate science from politics, interference by the Commission, even occasionally, could undermine the legitimacy of EMA and the credibility of the authorization system (Everson et al. 1999). What is more, the Commission does not have the scientific expertise required to determine whether EMA’s advice is scientifically sound, the idea behind the creation of EMA being that the Commission would focus on policymaking while relying on the agency for scientific expertise.

Ultimately, however, the Commission and the member state representatives in comitology (or, in case of disputes, the Council) decide, so the agency’s expert committees realize that they better reach opinions that are acceptable to the Commission and a majority of member states. While autonomous from the Commission when deciding on authorizations, the agency thus “does so in the shadow of threatened intervention by the Commission and/or the Standing Committee” (Gehring and Kraphol 2007: 217).

5.2 EFSA: between isolation and interference

A paradoxical situation applies to EFSA’s actual autonomy from the member states and their national authorities: precisely because member states are formally not represented in the management board and their national authorities are not directly involved in the scientific process, as in the case of EMA, they tend to regard the agency’s advice with much more suspicion and are more inclined to disagree. Hence,
the comitology committee usually meets to discuss proposals or drafts of the Commission and the Council often controls whether Commission proposals based on EFSA’s advice make it into legislation and policy (Krapohl 2004). Indeed, member states regularly bring in political considerations, questioning EFSA opinions and deviating from them, just like they did before the establishment of EFSA.

Even as there are criteria for the authorization of food, regulatory policymaking in the food safety area continues to be politicized, rather than driven by scientific evidence. This politicization is most clear in the assessment of GM and other novel food products as several authors have shown (Chalmers 2005; Buonanno 2006; Borras et al. 2007). EFSA’s advice to authorize GM food products has been criticized by some member states. Under increased member state pressure, the Commission admitted that GMO assessment needed improvement, calling directly on EFSA to consider member states’ concerns in the scientific evaluation phase or give better reasons for not doing so. Otherwise the Commission could intervene, suspending the procedure and referring back the question for further consideration by EFSA. Whereas the Commission maintained that it was not putting up for debate the working practices of EFSA or its earlier opinions, it openly questioned the quality of scientific opinions rendered stating that opinions “relied exclusively on information provided by companies that look at short-term effects” and that “EFSA cannot give a sound scientific opinion on long-term effects of GMOs.” The controversy between EFSA, the Commission and the member states helped opponents of biotech food products to intensify their anti-campaign and inadvertently made it easier for environmental groups to cast even more doubt on the safety of GMOs and to further reduce the credibility of the EU regulatory framework, including the position of EFSA therein (Levidow and Carr 2007).

The examples of GMOs and cloned food show that, while on paper risk assessment and risk management may be clearly separated, in practice there is often no sharp distinction between science and politics. Science is not objective: when assessing risks scientists take decisions on the use of particular methodologies and techniques, which potentially affect their conclusions. And even if science would be objective, politicians and the general public are not always willing to accept conclusions that only take into account purely scientific factors. Too much emphasis on their separation might even be counterproductive from the agency’s point of view, as it allows the Commission and the member states to distance themselves from EFSA and use it as a scapegoat, which is why the agency is now also answering, more broadly, concerns raised by member states and NGOs.

In spite of the structural arrangements designed to enable the interaction between EFSA and the Commission, in particular its DG SANCO, the relation between the two in the early years has been conflictive. Unlike in the case of EMA, most tasks performed by the agency were previously carried out by or under the control of the Commission. The experts left in the Commission found it difficult to accept their changed role, no longer being responsible for science. They felt threatened by EFSA, and, afraid of losing even more tasks, thus attempted to retain their influence over the new agency’s work. According to respondents the Commission was often seeking scientific opinions to underpin its policies and legislation rather than really being interested in receiving independent advice. The agency has therefore been trying to demonstrate through self-tasking that it is not simply a means to legitimize the Commission’s policies, issuing several opinions without having been requested to do so by the risk managers. This, in turn, led the Commission to complain about delays in the provision of requested advice.

Much of the tension between the Commission and the agency has also been due to the agency’s unclear remit regarding risk communication, as illustrated in the introduction. Particularly in the early years “there [was] a certain irritation, especially at the Commission, about EFSA’s focus seemingly biasing towards topics with high media
interest rather than often more complex assessment work which is essential to underpin policy and legislation.”10 The agency’s constant emphasis on its formal independence, its director for instance often starting his speeches saying that “EFSA is completely divorced from the Commission,” inhibited interaction. In recent years, the agency has acknowledged that, in order for its science to be accepted it depends on the Commission, and that it cannot solely focus on “objectively analyzing and scientifically interpreting the facts,” as an interviewee put it. The Commission, in turn, has gradually become used to the agency’s existence and realizes that an independent EFSA is not necessarily a threat.

Also in the agency’s relationship with the member states credibility does not automatically follow from objective scientific expertise. When scientific expertise does not or is not perceived to build on knowledge in the member states, the member states are less inclined to accept such expertise and more likely to question it. One of the main recommendations of the 2005 external evaluation of EFSA was that the member states and their national authorities would have to be involved more closely in the agency’s work, especially its scientific activities. At the time of EFSA’s creation the conditions for cooperation were not particularly favorable: mutual trust and understanding still needed to develop as most member states were in the process of restructuring existing agencies or creating completing new ones. Hence, the agency focused on the quality of its own science. The expectation was that a high level of quality would convince national authorities to cooperate, and that they would eventually realize that they do not necessarily have to perform all risk assessments themselves anymore.

Whether increased involvement of national agencies in EFSA’s scientific work leads to more political acceptance and less interference from politicians remains to be seen. Several respondents pointed to the lack of contact between member state politicians and their national authorities who are involved in the work of EFSA through the advisory forum, on paper a platform for the exchange of scientific information among national agencies and between them and EFSA but in practice a communication channel for EFSA. Members of this forum are often representing risk assessors at the national level, which do not necessarily connect with national risk managers such as ministries. As a result, national representatives in the relevant comitology committee or the Council might adopt a position that differs from the position adopted by the representative of national agencies in the advisory forum. Realizing this, EFSA in 2007 established a network of national focal points to facilitate the flow of information and dialogue between the agency and national food safety authorities, research institutes, consumers and other EFSA-related stakeholders.

6. Discussion and conclusion

This paper set out to explore why in practice the European Medicines Agency (EMA) seems to have developed a higher level of autonomy than the European Food Safety Authority (EFSA), whereas on paper EMA appears to be less autonomous than EFSA. This variation is difficult to grasp by only looking at the reasons underlying their creation and their formal design features.

My investigation shows that the historical origins of both agencies and their design have certainly had an important effect on their development. EMA’s creation was relatively uncontroversial and its design inclusive, whereas EFSA’s creation was sparked by a number of highly politicized food crises and with independence as a characteristic feature of its design as well as a guiding principle in its early development. Contrary to what one would perhaps have expected, EFSA’s eventual design has hardly been affected neither by EMA’s design nor by its
development. In fact, if used as a model at all, EMA has been used as a ‘counter-model’ in view of the different circumstances under which EFSA was created and the different preferences and interests of the actors involved in its creation.

But the paper attempted to show that, in order to understand differences in their de facto autonomy, also agencies’ (early) development needs to be taken into account. In-depth investigation of EMA and EFSA cases, guided by literature on the developmental trajectories of other bureaucratic organizations, leads me to the following conclusions with regard to the conditions affecting such trajectories in the case of EU agencies.

First of all, EU regulatory agencies that develop a reputation for effectiveness and demonstrate their unique capacity in their early years, are likely to be supported by actors in their environments, which has a positive effect on their autonomy (cf. Sapolsky 1972; Carpenter 2001). EMA quickly developed a reputation for effectiveness, showing a growing number of high quality opinions and a reduced authorization time, thus distinguishing its work from that of agencies under national systems. This has led to support from pharmaceutical companies and patients groups, which convinced the Commission and the member states of EMA’s effectiveness. EFSA also demonstrated that it was capable of providing expertise. It delivered opinions that are generally judged to be of high quality. A key difference with EMA, however, is that EFSA’s opinions are not always accepted by the member states and its claims are sometimes challenged by NGOs, which has also led the Commission to question the agencies’ science and vice-versa. So whereas EFSA perhaps has the capacity to deliver, it lacks a reputation for effectiveness.

Furthermore, continuously emphasizing their formally autonomous position may hamper EU agencies’ interaction with actors in their environments and thus have a negative effect on agency autonomy (cf. Sapolsky 1972). In contrast to EMA, the first director of which came from the ranks of the Commission, EFSA fought tough battles with its ‘parent DG’ in the Commission. Given the historical background to its creation and as formally autonomous entity, EFSA tried hard not to be seen as an extension of the Commission. A certain amount of conflict with their parents is often considered necessary for regulatory agencies and adopting a conciliatory approach in their very early years could mean their demise as independent agencies in the long term. Yet, even if agencies’ added value is in their autonomous position, forcible demonstrations of their autonomy usually backfire, as EFSA experienced. Constant reiteration of its autonomous position in the early years led to hostility from the Commission, while cooperation with the member states’ remained limited because they were not co-opted in the agency’s decision-making structures. That the Commission as well as member states questioned EFSA’s opinions not only damaged the agency’s reputation, but also put the credibility of the regulatory process at risk. This is something which the Commission, or rather the particular Commission DG, had been more clearly aware of in the case of EMA and from which it had refrained, while the member states were reluctant to criticize agency outputs as they were closely involved in the different stages of its work.

Moreover, if EU regulatory agencies cooperate with potential bureaucratic contenders, taking their preferences and interests into account, this may have a positive effect on the support for the agency and, thereby, on its degree of autonomy. EMA, in spite of the conventional wisdom that this would decrease its autonomy, entered into partnerships with other
organizations, notably national agencies. Indeed, in order for EU agencies to add value to already existing organizations, they do not have much choice other than to take the interests of such organizations into account and to enter into relationships with them for most EU agencies were not created in a vacuum. Even agencies, such as EMA or EFSA, that have a certain degree of isolation from other actors by the technical nature of their tasks, could not simply isolate themselves from the environment, not even in the early years (but see Selznick 1957). They came into being in an environment replete with other organizations, in particular national authorities, on which they rely for professional expertise and with which they thus have to establish cooperative relations right from the start.

Thus, similar to other bureaucratic agencies, EU agencies, whilst ‘speaking truth to power’, are not free from politics. Quite the opposite. Their creation and design reflects the political struggle among the different EU institutions, and as soon as they are created, agencies become, using Moe’s (1989: 282) words, “political actors in their own right.” In order to develop a level of support not only from political actors, but also from national agencies, EMA established cooperative relations, whilst distinguishing itself from these agencies by its expert capacity. By so doing, the agency developed a level of trust among actors that before the creation of the agency mistrusted each other, and became accepted itself as a trustworthy actor in the network. In the case of EFSA, national food safety authorities, represented in the advisory forum and not on the management board, felt left out of the agency’s work, thereby decreasing the acceptance of its work. What is more, in its early years, EFSA substantiated its actions solely on the basis of the scientific findings of its ‘own’ experts, rather than also taking into account the science of agencies with a different regulatory philosophy (but see Shapiro 1997; Everson 2001). Afraid of compromising the independent character of its scientific activities, the agency did just that by eliciting the interference from the Commission and the member states.

The aim of this paper was not to make sweeping general statements on the basis of a comparison of EMA and EFSA. For that purpose the cases simply differ too much when it comes to their creation and design, while they are also not representative enough of a larger population. Yet, EMA and EFSA are more similar than most other EU agencies, which allowed for at least a partial comparison and formulation of the above conclusions. Other researchers may use these conclusions as propositions to study the development of EU regulatory agencies such as the Office for the Harmonisation in the Internal Market, the European Aviation Safety Agency, the European Chemicals Agency or the new agencies in the financial area. Such studies will have to improve and refine our knowledge of the conditions under which these agencies, all created with a level of formal autonomy from political actors, develop into actually autonomous agencies, thus helping us to understand the actual practice of EU regulatory agencies and their autonomy.
ENDNOTES

1 Earlier versions of this paper were presented at UC Berkeley’s EU Center, the Penn-Temple European Studies Colloquium, the University of Washington’s Political Science Colloquium, and Harvard University’s Minda de Gunzburg Center for European Studies. The author is grateful to Chris Ansell, Todd LaPorte, Mark Pollack, Orfeo Fioretos, Peter May, Peter Hall, Andy Martin and Madalina Busuioc for their constructive comments.


3 EFSA, EFSA Provides Update on Avian Influenza and Food Safety, Press Release, October 26, 2005.


7 See for instance Regulation 1829/2003 on genetically modified food and feed.

8 EFSA, Letter from Professor P. Wall, Chair of the EFSA Management Board, to R. Madelin, Director-General, Health and Consumer Protection Directorate, European Commission, Consultation on fees, MB 27.03.2007-7.


10 FPA Market and Management Advice, Assessment of the Current Image of the European Food Safety Authority, Interviews with Interested Parties and Stakeholders, March-April 2004 (also known as the ‘Paeps report’).
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