European agencies as engines of regulation?
On different architectural strategies of the regulatory state

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1. Introduction

It is by now almost a truism that the European Union (EU)[1] has developed as the prototype of a regulatory state with regulatory agencies among its distinct institutional features. Whereas European law demands regulatory agencies at national level to enforce the liberalization of various internal market sectors (e.g. by the new directive on energy), a growing number of agencies at European level are engaged to regulate by information in different areas (Majone 1997). Although they do not operate like full-fledged regulatory agencies with strong regulatory competencies, these EU agencies are likely to have a significant impact on regulation in the EU by encouraging member state administrations to harmonize their regulatory processes and by increasing the transparency of EU regulatory processes (Kelemen 2004, p. 133). However, in addition to such indirect influences on national policies, EU agencies might also directly enforce polity changes within member states, namely domestic administrations. Thus, the paper will address two questions:

1. To which extent are EU agencies influencing member state administrations? (= dimensions of change)
2. How do EU agencies impose the change of member state administrations? (= mechanisms of change)

To answer these questions, the creation and operation of two European agencies – the European Medicines Agency (EMEA) and the European Food Safety Agency (EFSA) – will be analysed regarding their effects on two member state administrations (United Kingdom and Germany) from the early 1990s until present. Both national administrations are supposed to differ in various ways. Next to the different administrative systems of a unitary and a federal state with its distinct features, one can also distinguish the cultural orientation of public administration between the British 'public interest' approach and the German *Rechtsstaat*. Against, the policy fields pharmaceuticals and food safety can be subsumed under the wider field of health policy and share some relevant characteristics: they are politically highly sensitive and bear much of risk for politicians, they reflect an integral conflict in their policy goals between citizen protection and a free market (enhanced by an inherent need for scientific advice) and in both policy fields community's harmonization upholds enormous economic consequences. The newly created EU agencies are likely to have an impact on member state administrations, but it might vary across countries and policy sectors. Thus, other relevant factors – especially at national level – must be taken into consideration for a preliminary assessment on the effects of the creation and operation of EU agencies on national administrations.

The plan of the paper is as follows: In section two an analytical framework will be developed to study the impact of European agencies on member state administrations. Section

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[1] Although the EU came into existence in 1993 and did not replace the European Community, throughout this paper the term EU is synonymously used to simplify matters.

three describes the regulatory regimes in both policy fields at EU level, particularly the creation and operation of the two European agencies. In section four the changes in both national administrations across the two policy fields will be exposed to illustrate whether and how European agencies affect the national level and which relevant factors shape such processes. In section five, the analytical framework will be tested against these preliminary empirical findings. The last section discusses the capacity of EU agencies to self-define their role within such adaptation processes in order to assess whether these bodies pursue a new strategy of the European regulatory state.

2. Toward an Integrating Framework for Analysis

The analysis of interrelations between administrative changes at the European level, particularly the increasing number of EU agencies, and changes of national administrations addresses two different, but connected research agendas. On the one hand, under the umbrella term 'Europeanisation' authors discuss a wide range of phenomenon including national polity changes caused by or causing European integration. On the other hand, within discussions on the 'rising regulatory state' EU agencies are identified as a new type of regulatory agencies with apparent outcomes at national level. Although these literature strands may discuss in separation, obvious connections exist. The following section will briefly present both research agendas (1) on Europeanisation and (2) the regulatory state, in particular their contributions on changes of administrative structures, to adopt an integrating perspective for the analytical framework of this paper.

(1) Although Europeanisation is widely discussed, the term still provides no clear definition on what Europeanisation actually means. Instead, there is a lot of confusion within the literature – of methodological issues, sound empirical evidence as well as theoretical concept building. Several analytical adjustments can be distinguished; for the purpose of this paper mainly two perspectives are interesting.

First, a number of studies on Europeanisation discuss from a top-down perspective the impact of the EU level on developments in its member states. Initially, research was mainly focused on changes of national policies (Hanf/Jansen 1998; Weale et al. 2000) and politics (Goetz/Hix 2001; Greenwood/Aspinwall 1998; Mair 2000; Mazey/Richardson 1993). Comparatively little attention was given to the polity dimension, although EU enlargement processes offer a new empirical research area (Grabbe 2005; Hughes et al. 2004). Several authors stress the non-existence of a European model of public administration which could impose converging national administrative structures (Olsen 2003; Page/Wouters 1995). Additionally, even in implementing European policies, member state administrations are not challenged: EU policies are neither disturbing national administrative structures, nor their distinct approaches and procedures (Jordan 2003). Hence, most authors follow early assessments by Wallace (1971; 1973) that changes of national administrations due to European developments are modest, incremental and mostly path dependent.

Within this research on Europeanisation, many authors emphasize the degree of "fit" between the European and the national level (Börzel 1999; Green Cowles et al. 2001; Héritier et al. 2001). On the one hand, these authors underline the variation within the 'European pressure' by differentiating the levels of obligation – considering not only legally binding

(hard) EU law but also soft law requirements (Senden 2004; Snyder 1994). On the other hand, they highlight the importance of mediating factors at national level to explain the empirically evident differences between member state responses to European pressure.

Primarily, many authors argue that the national political institutional capacity to respond is crucial and point to the number of veto players and their positional influence on attempts to introduce EU related change (Börzel/Risse 2003; Giuliani 2003; Schmidt 2002). They suggest that a low number of veto points facilitate processes of adaptation to European demands by reducing the internal decision-making costs and favouring the flexibility and promptness of the national level (Immergut 1992). Similarly, the degree of fragmentation within the politico-administrative system influences the likelihood of change at national level: the more comprehensive and fragmented decision-making competencies, the more difficult it is to attempt change (Knill 1998). Next, Buller and Gamble argue, that the timing of European pressure is virulent: "…those governments who have or are in the process of experimenting with policies also being introduced at European level, will find it easier to adapt to such European pressure as and when it materializes" (Buller/Gamble 2002, p. 14). Finally, the belief systems or paradigms of national governments also have an impact on member state adaptation to European demands (Barberis 1994; Haverland 2000). Those governments with a strong commitment to the "European idea" may find it easier to adopt change than those countries with different political cultures (Buller/Gamble 2002).

Second, developments at national level are analysed as explaining factors and driving forces for progress at European level. With a bottom-up perspective various ways are identified to 'upload' national models by defining the scope of issues before they reach the European arena. Several authors analyse the formulation of national preferences for upload or rather the national coordination of EU policy (Bulmer/Burch 1998). Strong incentives to co-ordinate action "arise from the general characteristics of the EU, from specific duties and obligations incumbent on the member states, and from the politicisation of European matters in domestic political life" (Kassim et al. 2000, p. 6). Another form of upload has been identified in the involvement of national officials within the comitology system (Trondal 2000; Trondal/Veggeland 2003). Besides, the implementation of EU policies by national administrations and their room for discretion reveals differences and might therefore influence future developments at EU level – as the member states meet again at the European arena where they can discipline failing members. Finally, in recent years new advisory groups were established by community legislation, e.g. the "Working Party on the Protection of Individuals with regard to the Processing of Personal Data" in one of the telecommunications regulations (Regulation 95/46/EC, art. 29), which enhance the development of European-wide expert networks with prospective influence at the European level (Coen 2005).[2]

(2) Whereas the regulatory state has been extensively discussed within the US-american literature, the following paragraphs will focus on research against the background of the EU. Due to the amount of literature this overview must be very selective and will for the purpose of this paper focus on contributions to the 'European regulatory state'.

[2] Although such networks can be exploited by EU institutions, particularly by the Commission (see Fleischer 2005b).

The notion of a European regulatory state was initially addressed by Majone (1994), identifying the EU as the prototype of a regulatory state with two characterizing features. First, due to its *sui generis* character as a political system – particularly the limited powers at EU level and the restricted fiscal options of EU institutions – community policies are mainly formulated with regulatory instruments. These institutional weaknesses of the EU system are combined with a strong constitutional ideology – the principle of subsidiarity (Moran 2002, p. 402) – which allows the Commission to apply regulatory powers but shifting the costs of implementation to the member states (Majone 1996, p. 66). Second, the distinct institutional arrangements to formulate these regulatory policies at EU level are characterized as regulatory agencies – in particular the Commission with its responsibilities in completing the internal market via 'economic regulation' (Pollack 1997) as well as the recently created EU agencies to correct possible market failures by accomplishing a 'social regulation' (Dehousse 1997; Kreher 1997; Majone 2003). Whereas the first feature of the European regulatory state entails the mutual agreement of member states on the delegation of competencies to the European level and its institutions, the second feature implies more actors, at least because the creation of EU agencies follows procedures which include several legislative actors.

Meanwhile, many authors focus on the diffusion of the European regulatory state at national level. Although the concentration on regulatory policies wields much less power than constituent policies (Lowi 1972) – which have a greater impact on organizations and might end up with changes of the whole system – these authors suggest that European regulatory policies also have a strong impact on member states and might result in convergent national regulatory patterns. Here, empirical applications – similar to research on Europeanisation – used a top down perspective to study differences between the various fields of EU regulation as well as interrelations between European and national regulatory policies in different sectors, notably telecommunication, utilities etc. (Bulmer et al. 2003; Héritier 2002; Schneider 2001) and in areas like environmental policy or consumer protection (Demmke 2001; Vogel 2003).[3] Within this research, polity structures at national level are widely examined, particularly the creation and operation of national regulatory agencies (Geradin/Petit 2004; Gilardi 2001, 2004; Thatcher 2000, 2001, 2005).

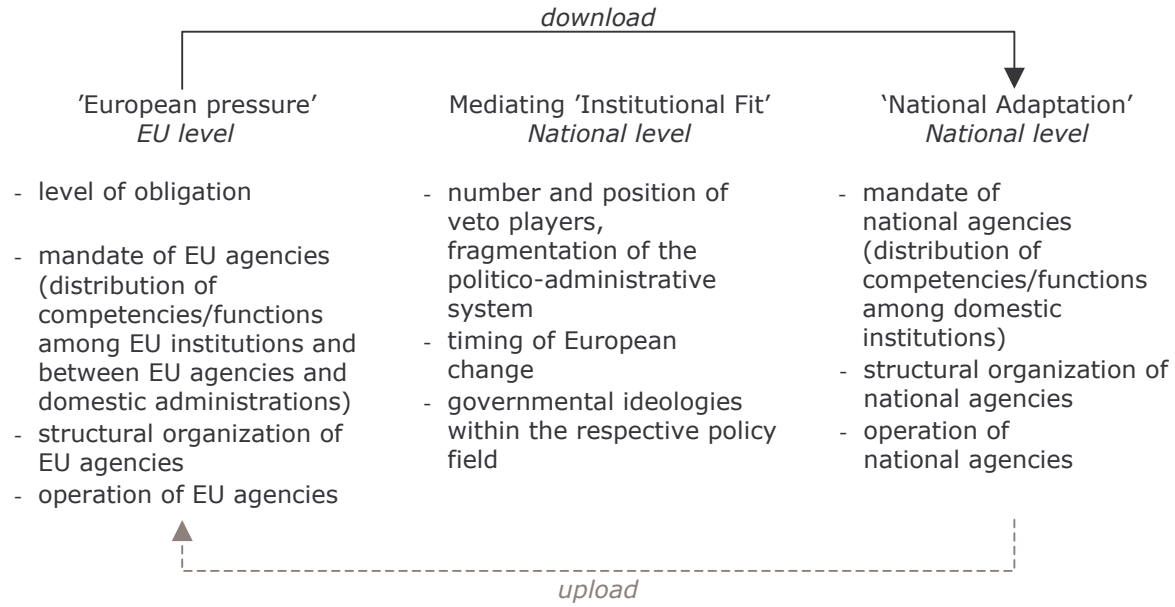
To sum up, both research agendas follow similar conjunctures of questions, methods and explanations and offer origins to analyse interrelations between the creation and operation of agencies at EU level and changes of member state administrations. Thus, the analytical framework of this paper will integrate both (see figure 1). First, the European pressure will be considered as such EU legislation that relates to the two EU agencies in both policy fields. This includes the stipulated level of obligation and distribution of competencies and functions – not only horizontally among EU institutions but also vertically between EU agencies and national administrations. The change of member state administrations will be explored regarding the national institutional arrangements or rather national authorities, specifically along three dimensions: In addition to their mandate as expressed in their delegated competencies and functions as well as their organizational structure, the operational practice of these national bodies will be scrutinized.

[3] Additionally, other market sectors are examined (e.g. Busch 2003; Lütz 2004) (for an intersectoral comparison across countries see Sturm et al. 2002) or even areas between market and society like sport (Meier 2005).

To explain this three-dimensional change of member state administrations, mediating factors will be considered, which are likely to influence the impact of European agencies. First, distinct institutional characteristics of the member state (e.g. veto points and level of fragmentation) may affect decision-making processes on the creation of national authorities including their mandate and structure. It is also reasonable to assume indirect effects on their operational practice, because the authorities' mandate may shape the position within the politico-administrative system and operational orientations. Second, the timing of European pressure compared to changes at national level reflects a temporal perspective and may therefore be more explanatory for the decisions to create national agencies (with a respective mandate and structure), but less relevant for their daily operation – unless European pressure is actualised and holds new demands which have to be managed. Finally, for the purpose of this paper the general governmental attitudes toward the European Union will be analysed as part of the distinct governmental ideologies within the respective policy domain, which are likely to influence not only the decisions on mandate and structure of national bodies, but in particular their operational practice.

In addition, one can assume, that the creation and operation of EU agencies – by framing mutual cooperation among national authorities – offer opportunities for uploading national models and thus indirectly change domestic polities. Although this paper will exclusively focus on the direct (top-down) impact of EU agencies on national authorities, contrary bottom-up processes will be mentioned where they are observed.

Figure 1: Analytical framework



3. The regulatory architecture for pharmaceuticals and food safety at the EU level

Both fields of regulation – pharmaceuticals and food safety – assess a 'risk regulation' and can be subsumed under the wider field of health policy. A great deal of community legislation on pharmaceuticals and food safety has been produced, but the following paragraphs will mainly focus on such pieces of EU law on (1) pharmaceuticals and (2) food safety, which are mostly relevant for and related to the creation and operation of EU agencies in both policy fields.

(1) The regulation of pharmaceuticals has been strongly attended at European level for a long time. Already the thalidomide scandal in the 1950s made effective pharmaceuticals regulation evident. Against that background of high pressure on politicians the Commission started discussions on a harmonization strategy for pharmaceuticals regulation and applied various strategies (Kingham et al. 1994). First, in 1975 a 'multi-state procedure' was introduced for market authorisation (Directive 75/319/EEC, revised in 1983), which created a system of parallel or sequential reviews of national applications by national authorities and therefore supported mutual cooperation. Besides, in case of no mutual agreement, a 'reasoned objection' was required to be delivered to a special EU advisory committee – although its opinion was non-binding. Second, in 1987 a 'concertation procedure' was initiated (Directive 87/22/EEC), which required for specific pharmaceuticals ex ante assessments and evaluations by particular scientific committees at EU level before national authorities finally decided – again their recommendations were not compulsory. Nevertheless and despite the committee system at EU level, differences in national regulatory decision-making behaviour prevailed and impeded attempts to introduce a uniform authorisation procedure. Thus, a centralisation of market authorisation at EU level was politically inconceivable for a long time.

However, in 1993 a legal reform was accomplished,[4] which introduced *inter alia* new authorisation procedures for medical products and replaced the procedural predecessors. Thus, three different procedures for market authorisation within the EU were realized (Hansen et al. 1996): the 'national procedure' for marketing in one country only, where regulatory decisions are taken at the national level from the respective national authority; the 'mutual recognition procedure' for marketing in more than one member state, where national authorities decide and in case of disagreement the decision is taken at EU level and the 'centralised procedure' for specific categories of pharmaceuticals and obligatory for products derived from biotechnology, where the decision is always taken at EU level. The establishment of two procedures which involve the EU level is said to reflect industrial requests to avoid a single authorisation procedure modelled on the US-american Food and Drug Administration, which in their view was very bureaucratic and excessively slow (Matthew/Wilson 1998). Additionally, the defined substantive criteria for a market authorisation of pharmaceuticals on which assessments have to be based left very little discretion for member states (Krapohl 2004).

In combination with these new procedural arrangements, a new European Medicines Evaluation Agency was established (Council Regulation (EEC) No. 2309/93). The long duration to formulate the founding regulation was caused by debates between the legislative actors on the new procedures and the functions and competencies of EMEA, whereas quite little attention was given to structural matters of the new agency (Lyon 2000, p. 25). The EMEA is headed by a dual structure of an executive director and a management board, which consists of representatives from the Commission and the member states and is responsible for appointing the director and adopting the work program and the draft budget (Council Regulation (EEC) No. 2309/93, art. 56). Additionally, two scientific committees[5] were

[4] Council Regulation (EEC) No. 2309/93; Directive 93/39/EEC, 93/40/EEC and 93/41/EEC.

[5] These are the 'Committee for Medicinal Products for Human Use' and the 'Committee for Medicinal Products for Veterinary Use' as well as two other committees established in 2001, namely the 'Committee on Orphan

integrated into EMEA, including one expert appointed by every member state, which assemble the real core of decision-making (ibid., art. 52, 53). Political oversight and control are mainly traditional and are based on annual reports and the permanent opportunity for all involved actors (Commission, EP as well as the member states) to intervene via EMEA's internal organs (Fleischer 2003).

The EMEA is responsible for the evaluation and supervision of pharmaceuticals within the centralised procedure and acts as the arbiter for the mutual recognition procedure. Besides, EMEA is engaged in public information and pharmacovigilance. Within the first responsibility, the EMEA (or rather the respective committee) evaluates the pharmaceuticals applied for authorisation and adopts an opinion, which is sent to the responsible DG Enterprise to be transformed into a single market authorisation valid for the EU.[6] That the EMEA is not allowed to adopt this legal authorisation independently and thus to perform full-fledged regulatory functions is caused by the application of the powerful Meroni principle,[7] which as an "anti-delegation doctrine" (Vos 2003, p. 129) precludes the delegation of autonomous decision-making powers between EU institutions. In practice, one of the member states and its scientific resources and competent authorities is responsible to carry out assessments and evaluations as *rapporteur* for the distinct product. Hence, companies choose those country most sympathetic to their own interests; i.e. those *rapporteurs* with the quickest approval procedures – which has led to the UK, Sweden, France and the Netherlands being either first or second-choice *rapporteur* in the majority of cases (Abraham/Lewis 2000).

Some criticism appeared that the changes within the procedures and the creation of EMEA put not enough effort on resolving problems of mutual recognition between member states. To react and strengthen the industry's confidence in the new system, heads of national agencies held a meeting in early 1996 to review the EU medicines licensing systems (Lewis/Abraham 2001, p. 67). Until now the "Heads of Agencies (HoA) meetings" are held twice within each presidency of the Council and are supported by an executive structure, additionally the member states' authorities build up working groups on certain issues, e.g. clinical trials or homeopathic medicines (HoA homepage). As several authors argue, not only the centralised procedure but also such mutual collaboration arrangements have facilitated a vivid competition between national authorities – although the common benchmark is under discussion (Dehousse 1997; Feick 2005).

Although some member states argued, that responsibilities in medical devices should also be placed at EU level – among others the French government remembering its initiative from 1997 to create a European Medical Device Agency (Altenstetter 2003) – the revision of the pharmaceutical regime in 2004 (Regulation (EC) No. 726/2004 of the EP and of the Council) changed the prior system not radically – at least neither a new EU agency nor EMEA received any responsibilities for medical devices. Nevertheless, some changes were made: First, the centralised procedure is now compulsory for orphan medicinal products (ibid., Annex. 4), in

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Medicinal Products' (Regulation (EC) No. 141/2000 of the EP and of the Council of 16 December 1999) and a 'Committee on Herbal Medicinal Products' (Directive 2001/83/EC).

[6] The Commission decision is subject to a regulatory comitology procedure, but until now all of these decisions have been according to EMEA' draft opinions.

[7] Case 9/51 High Authority vs. Meroni [1957-58] ECR 133 and case High Authority vs. Meroni 10/51 [1957-58] ECR 157.

addition the operation of all authorisation procedures was improved. Second, the EMEA was renamed in European Medical Agency (Regulation (EC) No. 726/2004 of the EP and of the Council, art. 55) and several administrative amendments were made, e.g. introducing neutral experts in EMEA's management board who are appointed by the Council and the EP (ibid., art. 65). Third, EMEA's responsibilities were enlarged, especially in the field of pharmacovigilance (ibid., art. 57.1). Besides, the Commission started considerations to concentrate the future system of national authorities which support and accompany the EMEA on a lower number of "centres of excellence" serving as EMEA's first bodies to turn to (BMGS 2004a, p. 1).

(2) The regulation of food safety in EU food law was for a long time interpreted as the reduction of trade barriers – namely labelling and composition requirements (Kelemen 2004, p. 134). Initially, the EU tried to reorient its approach by harmonizing foodstuffs legislation across member states in the form of directives – though it was leaving member states much room to decide how to achieve the harmonized outcome. In 1984 a rapid-alert system was introduced to deal with food safety emergencies and a small veterinary inspection service was created within the DG Agriculture (Council Decision 84/133/EEC), replaced in 1991 by the 'Office of Veterinary and Phytosanitary Inspection and Control' (OVPIC), which was in 1997 renamed 'Food and Veterinary Office' (FVO) and moved to Ireland to enhance its independent position.[8] Under the rapid-alert system several scientific committees at EU level were responsible to notify the national authorities and coordinate national or EU-wide restrictions. Within these committees particularly British experts could insert a strong "British thinking" on the Commission and the direction of the emerging regulatory policy which can be interpreted as an attempt to upload a national, namely British model of food safety (Strünck 2001, p. 10; Vos 2000, p. 230).

Within the 1980s several food scandals, particularly British BSE-contaminated beef, produced a political crisis, which broke national uploading processes. Many politicians as well as the Commission were persuaded to enhance European efforts in food safety (Vincent 2004). Reflecting new attitudes to foodstuffs in several member states, the Single European Act of 1987 (particular art. 37, 95, 153, 154) already committed EU institutions to protect the health of member states citizen and their consumer rights within the completion of an internal market. Additionally, due to its long-rooted tradition at national level, food law constituted strong trade barriers and was therefore among the priorities for harmonization after the decision to create this internal market (Vos 2000, p. 228).

The BSE-scandal showed most radically, that the committee system at EU level failed to acquire consumer protection. Under the pressure of a parliamentary scrutiny on the Commission's handling of the BSE-crisis, in 1997 a major reform on the management of food health issues started (Vincent 2004). Among its main changes were the creation of a strong 'DG for Health and Consumer Protection' (DG SANCO) and the decision to functionally separate risk analysis. Following an approach which was initially applied at the WHO (1995) three elements were differentiated, namely risk assessment, risk management and risk communication: Whereas risk assessment is defined as a "scientific evaluation of hazards and

[8] Although some authors argue, that the decision was merely caused by the "pork-barrel" share-out of EU agencies between member states (Chambers 1999).

the probability of their emergence in a given context", risk management includes the "assessment of all measures making it possible to achieve an appropriate level of protection, which will include the evaluation of policy alternatives resulting from scientific assessment and the desired level of protection" and risk communication compromises the "exchange of information with all parties concerned" (COM(1997)183final). Hence, the assessing FVO was transferred to the strengthened DG SANCO, while the DG Agriculture was still responsible for risk management (Ugland/Veggeland 2005, p. 17).

After the Santer Commission resigned, the new Prodi Commission took up several plans from its predecessors and issued in 2000 a White paper on food safety. In 2002 a legal reform followed,[9] which stipulated general principles and requirements of EU food law and introduced new procedures in matters of food safety. First, a central feature of European environmental law was imported into EU food law as a guiding principle (Cazala 2004): The 'precautionary principle', which was rooted in German law as the *Vorsorgeprinzip* since the early 1970s (Rehbinder 1987), should ensure a consumer oriented approach with the promotion and protection of public health as its essential requirement (Ugland/Veggeland 2005, p. 14). Such an inclusion of a traditional German policy-driving principle can be interpreted as a successful form of uploading. Second, the authorisation of genetically modified food and feed products is now carried out at EU level, where also ex ante evaluations on their risks are assessed. As to the other requirements, the regulation remains quite vague, since it stipulates that food shall not be placed on the market, if it is unsafe, meaning if it is injurious to health or unfit for human consumption (Regulation of the EP and the Council (EC) 178/2002, art. 14). Here, member states have discretion to decide whether and how their food is 'unsafe' (Krapohl 2004).

However, this EU legislation also includes the creation of a new European Food Safety Authority, explicitly modelled after the EMEA (Krapohl 2004; Vos 2003). The EFSA is also headed by a dual structure of an executive director, and a management board whose 14 members are appointed by the Council and EP according to their expertise and competence; four of them must be member of respective interest organisations. The management board is responsible to adopt the draft budget and the work program, appoints the director as well as the members of the scientific committee and the scientific panels (Regulation of the EP and the Council (EC) 178/2002, art. 25). This scientific committee as well as the panels, which include independent and neutral scientists appointed following an open call for expression of interest (ibid., art. 28), assemble the most of EFSA's work. The first executive director of EFSA Geoffrey Podger was prior chief executive of the British food agency and in the words of Stuart Slorach, the first chair of EFSA's management board "the right person for the job [with] the knowledge and experience that we need, having led the development of a national food agency" (Press release EFSA, 02.12.2002). Additionally, an 'Advisory Forum' was created to insert representatives from national food agencies within EFSA's structure, who work within this consultative body for the director and advise on scientific matters, priorities and the work program (ibid., art. 27). Again, the political oversight and control mechanisms are mainly traditional and rely on annual reports and the permanent opportunity for all involved and relevant actors to intervene through EFSA's internal organs.

[9] Regulation of the EP and the Council (EC) 178/2002.

In case of the EFSA the Meroni-principle was as well strictly interpreted. As a result the EFSA (or rather its scientific committee and panels) is responsible for providing scientific expertise for EU institutions on food and feed safety matters including emerging risks, gathering scientific data and information, assisting the EU institutions in crisis management and ensuring collaboration with stakeholders, national and European institutions and international bodies, particularly enhancing coordination of member states' food agencies (ibid., art. 23). In addition, within the newly established authorisation procedure, one of the scientific panels is assessing products relating to genetically modified organisms and delivers his opinion to the public and the Commission, which finally grants the authorisation (Brosset 2004). Thus, in correspondence to the EU approach on separating risk analysis, EFSA is responsible solely for risk assessment and risk communication – risk management remains the prerogative of DG SANCO (Buonanno 2003). In its operational practice, the EFSA works closely with member states and its scientific resources and competent authorities – under certain provisions of EU law, the EFSA has the formal duty to get information from national authorities. As the Geoffrey Podger puts it: "some decisions end up with us because we are the final court of scientific opinion" (Podger 2004). In addition to the advisory forum, the EFSA established as well a "heads of agencies meeting" to enhance mutual cooperation among national authorities and towards the EFSA (EFSA Homepage).

To sum up, EU regulation on pharmaceuticals and food safety vary in their 'tightness': Whereas EU law on pharmaceuticals is – due to its long tradition at EU level – already highly specified, with detailed and mandatory obligations; the legal requirements on food safety are rather vague via voluntary obligations. Nevertheless, in both areas particular pieces of EU law establish a European agency to carry out several functions at EU level and to replace and integrate the former institutional arrangements of scientific committees in both policy fields (for an overview see Vos 1999). Although these agencies are not required to perform strong regulatory functions, their founding regulations stipulate mutual cooperation with respective national authorities. Hence, member states are required to appoint national administrative authorities with a correspondent mandate to act as counterparts and stipulate a European wide network of respective authorities in both policy areas.

4. The administration of regulating pharmaceuticals and food safety in Britain and Germany

4.1 No bitter pills at all? British and German administrations for pharmaceuticals regulation

The regulation of pharmaceuticals at national level was imposed for the first time by the pharmaceuticals scandals during the 1950s and 1960s. Hence, although institutional structures at national level have existed since decades, the following paragraphs will focus on changes of the (1) British and (2) German administrative arrangements from the early 1990s, when the new centralised procedure and the EMEA were established, until present, when the revision at EU level in 2004 may have caused adjustments.

(1) In 1987 political concern was rising, that the responsible division for drug approval within the Department of Health (DH) was showing signs of work overload, provoking the conduction of a major review of the effectiveness of the system (Evans/Cunliffe Report 1987). The main conclusion of the report was to transform the division into a Medicines

Control Agency (MCA), which was pursued in April 1989. Corresponding to the radical reforms of the British Civil Service under the 'Next Steps Programme', the MCA was turned in July 1991 into an 'executive agency' of the DH with apparent outcomes for structure and operation (Ceccoli 2002).[10] Hence, a management board was created, which supported and advised the installed chief executive who – as head of agency – was responsible for the performance and management of the MCA. The result-oriented performance was formulated within a framework document signed between MCA and DH which stipulated goals and performance targets. Thus, in addition to several advisory committees for the formulation of pharmaceuticals policy in UK, an independent ministerial advisory board was set up (comprising stakeholders from UK government and industry) to advise the Secretary of State for Health on the strategy and objectives of the MCA and the setting and achievement of performance targets (MCA Business Plan 2001/2002). The MCA was responsible on behalf of the 'Licensing Authority'[11] to control medicine for human use in the UK and to ensure appropriate standards of safety, quality and efficacy for all human medicines on the UK market, to apply relevant controls and provide information. When the centralised procedure was introduced at EU level in 1993, the MCA also started to assess pharmaceuticals within these procedures as contractor to the EMEA (Harman 2002a).

Similar, in September 1994 the former directorate for medical devices within the DH was launched as an executive agency, named Medical Devices Agency (MDA). Thus, it was also dual structured with a chief executive and a management board, accompanied by a framework document which entailed performance targets. The MDA was responsible for the post marketing surveillance of medical devices including the designation and audit of UK based notified bodies, which audited manufacturers of moderate to high-risk devices under the European Medical Devices Directive (Council Directive 90/385/EEC). The MDA hold lively contacts to other national authorities, e.g. it also audited the performance of notified bodies on behalf of the Danish Ministry of Interior and Health (NBOG 2003, p. 7). Separately, the MDA had responsibilities for the approval and monitoring of clinical trials and run evaluation programmes for equipment to be used in the National Health Service (Harman 2002b; Jeffereys 2001).

Due to continuous demands by their stakeholders, the DH carried out in 1999 a study to examine options to merge these two agencies. From the perspective of the majority of British pharmaceutical industry a merger was favoured because of the increasing convergence of both fields and to maintain high standards – rather than organisational structures (Press release BIVDA, 13.06.2002). In contrast, some argued, that in case of a merger medical devices regulation would be surpassed by the larger medicines control work or, even worse, the regulatory systems and processes would be merged as well. However, the recommendation of the study was, on balance, against a merger. While accepting that recommendation, ministers also said that the case should be reviewed again – the retirement of the first MCA chief executive in October 2002 provided an opportunity for looking again at that issue.

[10] In April 1993 its financial basis was changed to a trading fund.

[11] The Licensing Authority consists of the Secretary of State for Health and ministers from devolved administrations and is a legal entity responsible under the Medicines Act 1968 and relevant EU directives. Thus, the MCA dealt on behalf of the Licensing Authority with every EU law that have been transposed in UK law.

In June 2002 the Secretary of State for Health announced that the MCA would merge with the MDA in April 2003, establishing a new Medicines and Healthcare products Regulatory Agency (MHRA). Because the statutory basis for the regulation of both remained, no legislative change was needed to bring about the merger. Thus, both functional parts of the MHRA maintained in their responsibilities, even in financial matters: pharmaceutical companies' fees are not used to pay for the costs of medical devices regulation, and vice versa (Press release DH 13.06.2002). The main reason for merging the MCA and the MDA was in the "increasing convergence in the fields of pharmaceuticals and medical devices. As technology develops, there are likely to be growing numbers of products that cross the borderline between medicines and devices" (Press release DH 13.06.2002). The first chairman of MHRA adds another important point: "It was not the policy of the MCA or MDA to adopt a high public profile and few healthcare professionals, let alone members of the public, understood their role. One of the aims of the MHRA is to increase the public understanding of the concept of risk and benefit with respect to medicines and medical devices and to raise the level of public debate on matters of patient safety" (Breckenridge 2004, p. 573).

The MHRA is created as an executive agency of the DH with trading fund status. The merger offered the opportunity to introduce some organizational modifications: a new post of a non-executive chairman was created, who serves as a public authoritative character and the agency board consists now despite the chairman of six non-executive members and the chief executive to reflect the agency's independence. Although the government was considering to remove the MHRA a bit further from the minister by creating an agency board which takes a position between chief executive and minister and holds the responsibility for the final decision; finally a 'normal' chief executive was installed, who is still responsible for service, delivery and resources – and makes the final recommendation to the minister, who remains legally accountable for making the final decision (J-K Carruthers Ltd. 2003, p. 7). The executive board, consisting of MHRA's directors, takes overall responsibility for day-to-day management. Although the structures of the administration to regulate pharmaceuticals changed, the functions and core activities of the two former agencies have not been materially affected. Thus, the MHRA is responsible for market authorisations of pharmaceuticals, monitoring medical devices as well as post-marketing surveillance of new medicines.

However, the operation of MHRA situates an inherent conflict already observed within MCA: Besides its mission to protect public health, the MHRA also should support British pharmaceutical industry and its section on pharmaceuticals is also entirely funded by drug company fees. Because activities such as safety monitoring and public information serve wider interests than those of the industry, the DH tries to reflect a clear focus on improving public health within the formulation of performance measures, although a complete diminution of this conflict has not been accomplished so far (HC 505, Session 2002-03). Similar, objectives of transparency and public information are not met yet – as a report of a parliamentary committee concludes: The MHRA "has tended to take a narrow view of its role as a provider of information and has no public profile to help it put across safety messages" (ibid., pp. 3-4).

Additionally, a strong orientation towards the EU level can be identified throughout the operation of MHRA and its predecessors. First, as the chairman admits, the revision in 2004 at EU level "poses both challenges and opportunities for the UK. One challenge is to work

more closely with European colleagues to make the new enlarged system function well and to give strong support to the London-based EMEA" (Breckenridge 2004, pp. 572). That MHRA helps several accession states to ensure they are effective partners in European pharmaceuticals regulation also relates to a second observation: A strong ambition within the MCA, which prevailed the merger in MHRA, to be "the lead player, based on scientific expertise or excellence, in Europe" (MCA Business Plan 2001/2002, para 4). Hence, the British agency for pharmaceuticals authorisation traditionally has "comparably short approval times and cultivated this tradition and image through public management reforms and marketing efforts" (Feick 2002, p. 44). Besides and driven by influential stakeholders, the policy community agrees, that a strong UK medicines regulatory agency is needed to protect public health although much more licensing work may be carried out via the centralised procedure after the revision in 2004 (NAO 2002, p. 2).

(2) In Germany, the regulation of pharmaceuticals and food safety was prior 1994 administered by several institutes subsumed under a single authority: The Federal Sanitary Board (*Bundesgesundheitsamt*, BGA), established in 1975 as an agency (*Bundesoberbehörde*, BOB) under the supervision of the Ministry of Health (*Bundesgesundheitsministerium*, BMG) was responsible for all areas of public health, food safety and consumer protection along with market authorisation of pharmaceuticals. The German pharmaceutical industry relentlessly criticised, that it took not only to long for the BGA to approve drugs, but also that it was hostile to industry (BCG 2001; Hohgräwe 1992). Additionally, after the introduction of the centralised procedure, the BGA faced critique by the Commission to adopt regulatory review procedures that could meet EU timetables for assessment (Lewis/Abraham 2001). Nevertheless, no administrative changes were considered – at least not until a public scandal arose in summer 1993 when the media accused the negligence regarding the safety of blood products, which revealed serious coordination problems among the different institutes of the BGA as well as between BGA and BMG. As a consequence, the Health Minister announced in October 1993 the abolition of the BGA, replaced by three bodies (Ganhahl/Hasskarl 1994, p. 757): The Robert Koch Institute as the central federal institution responsible for disease control and prevention, the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, BfArM) for tasks within pharmaceuticals authorisation and the Federal Institute for Consumer Protection and Veterinary Medicine (*Bundesanstalt für gesundheitlichen Verbraucherschutz und Veterinärmedizin*, BgVV) for responsibilities in food safety and consumer protection.

The common agreement of all politicians (and all political parties) to react that radical can be traced back to a new approach in German pharmaceutical regulation towards more industry-oriented service delivery, which could be more easily introduced into new structures and to the fact, that the standing of the BGA within the politico-administrative system was weak – at least after a dispute between BGA and BMG on the decision to remove the BGA to Bonn (Döhler 2004, pp. 160). The BfArM was established as an agency (BOB) under the supervision of the BMG,[12] hence it is headed by a President, appointed by the BMG. It is mainly responsible for marketing authorisation and postmarketing surveillance of human medicines within the national regulatory procedure and monitoring risks after the market

[12] After the general election in 2002: *Bundesministerium für Gesundheit und Soziales* (BMGS).

authorisation. The BfArM also serves as the national counterpart in licensing procedures for medicinal products within the centralised procedure although the majority of authorisations are applied for the national procedure. Moreover, the BfArM monitors medical devices and determines occasionally the causes for risks to recommend corresponding measures for risk prevention.

In its duties concerning market authorisation for pharmaceuticals, the BfArM has been constantly criticised not only by industrial stakeholders (BCG 2001). Likewise, German politicians are suspicious about the service output of the BfArM – thus, the Health Minister established in 2003 a task force within the ministry under the chairmanship of a Permanent Secretary of BMGS to explore the opportunities of Germany as a location of pharmaceutical industry (BMGS 2004b). Their report concluded, that the BfArM had to catch up in terms of procedural efficiency with other member states' authorities and to invest more resources in the European approaches than in the purely national procedures (Feick 2002, p. 44). Nevertheless, the BfArM is still rejecting such comparisons and benchmarks for its operation; instead a BfArM official fears a race to the bottom effect (Tagesspiegel, 15.02.2005). Evidently, the German government followed industrial opinions in taking a benchmark perspective and repeated concerns about the competitiveness of BfArM among the respective authorities in the EU. Simultaneously, when the EU announced the new system of centres for excellence, the German government was obviously alarmed perhaps not to be within the club (Döhler 2005). Thus, the German government opposed the opinion of the BfArM, which can be interpreted as an evidence for the continuously declining standing of the BfArM within the politico-administrative system.

Consequently, only recently in April 2005, the German cabinet passed a statutory bill for a German Agency for Pharmaceuticals and Medical Devices (*Deutsche Arzneimittel und Medizinprodukteagentur,* DAMA) which will transform the BfArM (DAMA-Errichtungsgesetz, Entwurf):[13] Besides its new name, the legal basis of the former BfArM will be changed into an agency under public law (*Anstalt des öffentlichen Rechts*) (ibid., art. 1, § 1). Hence, a president and a management board will lead the new authority. The president will be appointed by the BMGS and the Ministry of Finance (ibid., art. 1, § 7). The management board consists of eight members, appointed by the BMGS, including three members as representatives from other ministries (ibid., art. 1, § 8).

For the first time in German administrative history, an explicit requirement is included within the legal basis to sign a performance contract with distinct targets between the BMGS and the director (ibid., art. 1, § 4). Additionally, the bill stipulates that the responsible BMG will be limited in its competencies regarding oversight and control to enhance neutrality and credibility of DAMA (ibid., art. 1, § 7) – even if the very same article offers exceptional cases from this rule. All these changes are said to ensure a better quality compared to other member states authorities as well as more engagement within the centralised procedure (Press release BMGS, 13.04.2005).

In sum, the changes of national administrations concerning the regulation of pharmaceuticals are in the British case attributable to occasional events, as reorganizing a work overloaded ministry, or caused by the successful influence of stakeholders, which

[13] At present, the bill is under parliamentary consideration, but will probably be adopted in its current form.

resulted later in the merger of two authorities. The German case reveals comparable causes, namely a combination of stakeholders' influence and public scandal, which lead to the creation of a new authority – recently under reform, because industrial complaints succeeded. According to their functions, differences to the EMEA can be observed, as both national agencies are responsible according to their mandate for pharmaceuticals and medical devices – a combined approach, which could not been achieved during the revision at EU level in 2004. In structural terms both authorities were established along national traditions or rather national administrative reforms: Whereas the British agency and its predecessors were created according to the next steps reforms as an executive agency with some modifications during the merger which are likely to ensure independence from its parent department, the German agency reflects in its legal basis an authority type, which has been selected since the 1880s and limits discretionary action. Nevertheless, the recently announced reform reflects a change of the German administrative model toward more independence as well as more service delivery and results, which can indirectly be traced back to the operation of EMEA and the centralised procedure – as the emerging competition among national agencies persuaded German politicians to accomplish more compatibility with correspondent authorities. Whereas the British agency acknowledged in their operational practice the European network of authorities as a virtual competition and is strongly oriented toward leadership, the German agency's operation is almost rejecting such a perspective, even though German government obviously tries to insert competitive thinking.

4.2 Same menu, different plates? British and German administrations to enhance food safety

The regulation of food safety at national level was already forced by the food scandals during the 1980s and 1990s. Thus, the creation of national authorities with tasks in food safety started eventually earlier than 2002, when the new EU agency was established. Hence, the following paragraphs will give an overview on developments within the (1) British and (2) German administrations from the early 1990s until present, when changes might be more directly linked to the creation and operation of the EFSA.

(1) The outbreak of the BSE-crisis generated "one of the most damaging science-based political crises that have ever occurred in the UK" (Millstone/van Zwanenberg 2002, pp. 601-602). This external shock exposed several institutional problems of the British regulatory regime of foodstuffs (Rothstein 2003:4). First, the Ministry of Agriculture, Fisheries and Food (MAFF) pursued a mission with competing goals in its responsibilities for food safety policy, consumer protection and promoting farmers' and food industry's economic interests. These conflicts of interests along with the obvious risk of regulatory capture by industrial interests were identified among the main reasons for the crisis (Philips Inquiry 2000, vol. 1, para 1171-1173). Second, as the crisis showed, the different administrative units were poorly linked – horizontally between MAFF and DH as well as vertically, where relations between the policy-making central level and the law enforcing local level were nearly non-existent (ibid., para 1225pp., 1239pp.; Gerodimos 2004). Third, the decision-making processes were merely opaque by including several advisory committees, but offering marginal access for external actors. Thus, some radical reforms were accomplished.

The Labour Party manifesto for the 1997 general election featured a Food Standards Agency (FSA) and while still Leader of the Opposition Tony Blair asked for a report which sets out a proposed blueprint for such an agency (James/Mackenzie 1998). The so-called 'James report' was delivered on the very day when Blair came into office and recommended, that the FSA should be established as a non-departmental public body (NDPD) to ensure the highest possible level of independence (James 1997, para 6.2). Additionally, an interdepartmental working group should be established to progress the creation of the agency. Hence, Blair established in June 1997 along with his decision on cabinet committees an interdepartmental Ministerial Group on Food Safety (PA News, 09.06. 1997). Besides, in July 1997 the Secretary of State of MAFF announced the set up of an interdepartmental working group between MAFF and DH headed by Geoffrey Podger (later FSA's first chief executive), to assemble those parts of the two departments that were likely to form the operational core of the new agency (Hansard Debates, 14.12.1999: Cm. 145). The James report was followed by a Government's White Paper in January 1998 and the draft Food Standards Bill in January 1999 passed in late 1999 as Food Standards Act. That the Parliament asked the Minister of State for Food Safety at MAFF, Jeff Rooker, after the reasons for such a long time period can serve as evidence, how broadly accepted and supported the idea of a Food Standards Agency was (HC 276-II, questions 1pp.).

Although the James report recommended that the FSA should "monitor the whole of the food chain, from the farm to the shop or restaurant" (James 1997, para 1.6); the final Food Standards Act rejected this full-fledged approach. Instead, MAFF was still responsible for several veterinary and agricultural aspects and therefore the FSA was focused in its work "from the farm gate to the plate" (Millstone/van Zwanenberg 2002, p. 602). Hence, the FSA is responsible for "developing policies (…) relating to matters connected with food safety (…), providing advice, information or assistance in respect of such matters to any public authority (…) [as well as] to the general public" (Food Standards Act 1999, art. 6). Besides, the FSA may "carry out observations (or arrange with other persons for observations to be carried out on its behalf) with a view to obtaining information" (ibid., art. 10) and is in charge for "monitoring the performance of enforcement authorities in enforcing relevant legislation" (ibid., art. 12). Thus, the FSA is responsible in all elements of risk analysis: risk assessment, risk management and risk communication.

The prime objective to establish the FSA was "to dislocate food standards and safety out of the ministry that sponsors food and farming" (HC 276-II, question 5). This argument of separating regulation and sponsorship to restrain capture by industrial stakeholders is also reflected in its organizational structure and operation – although no politician ever acknowledged that under the former regime such capture had occurred (Millstone/van Zwanenberg 2002). The agency became effective in April 2000 as a NDPD, which is not a government department, or part of one, and which accordingly operates to a greater or lesser extent at arm's length from ministers (Pliatzky Report 1980) – thus, this legal basis should ensure independence from DH and MAFF. The FSA is accountable to Parliament through the Minister of Health. It is led by a board, consisting of a chairman, a deputy chairman and not less than eight or more than twelve other members which are appointed by the Secretary of State and ministers from devolved administrations. The board should act collectively in the public interest instead of representing particular sectors (Henry 2000, p. 239) and is

responsible for overall strategic direction, ensuring the agency fulfils its legal obligations. The board holds meetings in public, and publishes its agendas, papers and decisions to enhance transparency and openness. The chief executive is responsible for (among other things) securing that the activities of the agency are carried out efficiently and effectively (Food Standards Act 1999, art. 3). Additionally, the board agreed in 2000 to establish a 'Consumer Committee' reflecting a wide range of consumer interests to advise FSA (Webster 2002).

The James Report linked the creation of the FSA directly to European developments – but rather to European policy formulation: "[the] creation of the Agency at a time when the European Commission is reorganising its food standards, quality and safety activities provides an opportunity for the UK to play a major role in shaping future European food policy" (James 1997, para 3.10). Here again, the ambition to upload a British model on food safety policy can be observed. Although "[s]taff of the agency will therefore be the appropriate experts to represent the United Kingdom at working level in negotiations in the EU, (…) ultimate policy responsibility for negotiations with the EU must rest with Ministers" (ibid., para 3.11). However, in practice several concordat papers between FSA and other departments express equality: First, a "need to work together constructively in relation to common interests in the formulation, negotiation, implementation and enforcement of EU and international policies, agreements, rules and legislation" is recognized, followed by the agreement, that "[T]he lead department will provide the other with comprehensive information, as early as possible, on all relevant new developments and initiatives including notifications of relevant meetings" (Concordat with the DH 2002, para 14-16).

That the FSA will host a meeting of EFSA's advisory forum in November 2005 cannot only be traced back to the British presidency of the Council during these six months, but might also benefit from the fact, that EFSA's executive director in his duty as chairman of the advisory forum has a close personal relationship to the FSA – and will return in taking up the post as chief executive of the British Health and Safety Executive in November 2005 (Press release EMEA 29.07.2005). Besides, this meeting is due to EFSA's functions limited to "networking between EFSA and the national food agencies and authorities working in fields of risk assessment and communication" (FSA Homepage).

Another major reform was accomplished when with the foot-and-mouth disease crisis the next big food scandal occurred: In June 2001 the MAFF was replaced by a new Department for Environment, Food and Rural Affairs (DEFRA) to promote an integrated rural policy (Barling et al. 2002).[14] Although this change should solve the apparent conflict of interests within MAFF, new conflicts arose: As the DEFRA retained the responsibility for veterinary and agricultural aspects but took on environmental issues, struggles between promoting British farmers' interests and protecting British environment from possible damage from agricultural activities can be observed (Millstone/van Zwanenberg 2002, p. 605). In addition, not all responsibilities in food safety were put into the portfolio of DEFRA, instead DH retains responsibilities in foodborne diseases and the handling of emergencies. Thus, the FSA has framework agreements with both departments (Flynn et al. 2004).

[14] Environmental matters were previously located in the former Department of the Environment, Transport and the Regions.

(2) The BgVV started in July 1994 after the split-up of the BGA as an agency (BOB) under the supervision of the BMG. It was headed by a President, who was appointed by the BMG. It proceeded several functions within the whole chain of risk analysis (Böschen et al. 2002:11). Nevertheless, due to the German postulate of executive federalism with allocating competencies between the federal and the *Länder* level (art. 85 GG) and allowing only in exceptional cases the execution of administrative tasks by federal bodies (§ 4.2 GGO), the responsibility for risk management followed a fragmented approach with responsibilities between the federal level and the *Länder* level whose authorities are also responsible to enforce law.

The BSE-scandal shocked the German regime on food safety – at first mostly because of the high level of citizen's beef consumption – resulting in a strong German involvement in achieving a ban on British beef at EU level. After years of denial that BSE could also be an original German problem, the discovery of the first BSE infected cow in November 2000 and the subsequent constant rise in the number of BSE cases led to a massive loss in consumer confidence (Boschert/Gill 2004, p. 19). Hence, the German administrative authorities came under public pressure: Due to the executive federalism not only the BgVV, the Ministry of Agriculture (*Bundesministerium für Landwirtschaft*, BML) and BMG at federal level, but also authorities at *Länder* level were publicly accused for several cases of disinformation within and among them as well as vis-à-vis the public.

As a result, Chancellor Schröder announced in his New Year's Eve address of 2000/2001 that he had commissioned the President of the German Federal Court of Auditors (*Bundesrechnungshof*, BRH) Hedda von Wedel in her second function as "Federal Commissioner for Efficiency in Public Administration" (*Bundesbeauftragte für Wirtschaftlichkeit in der Verwaltung*)[15] for an analysis on the weaknesses of the German regulatory regime in food safety.[16] As the public concern and pressure increased, Chancellor Schröder used the window of opportunity together with his Green coalition partner to radically reorient German agricultural policy towards more consumer protection and a diminution of agricultural interests – underlined with the catchphrase "Agrarwende" (Feindt/Ratschow 2003). Hence, Schröder abolished in January 2001 the BML and established a new Ministry for Consumer Protection, Food and Agriculture (*Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft*, BMVEL), which was strengthened by adding responsibilities in consumer protection, formerly carried out by the BMG and the Ministry of Economics and Technology. Simultaneously, Schröder used this reshuffle to dismiss the (even within cabinet) unpopular Minister of Health (as well as the former Minister for Agriculture), which were made responsible for the identified information mismanagement. That the appointed minister for the new ministry is a lawyer not only broke off the tradition to have a farmer on that post and reduced risks for regulatory capture, but also underlined the new approach in German agricultural policy, which stimulated a general

[15] The federal commissioner is legally separated from the BRH-president, although since 1952 every BRH-president combines both functions.

[16] One can assume, that this unusual move not to ask the involved BML and BMG at first but to select an external actor was caused by the low reputation of both ministries at that time against the high reputation of an independent federal commissioner.

reorientation toward more consumer protection and at least the creation of a new policy field in its own right (Janning 2004).

In July 2001 von Wedel submitted a report, which entailed several recommendations, one of them very influencing and elementary: With reference to the EU approach a separation of risk assessment and risk management was suggested – although the report did not explicitly mention two different authorities for both tasks (Steiner 2003; von Wedel 2001).[17] Following this report and another internal report from a task force within the BMVEL, the 'Consumer Protection and Food Safety Bill' was formulated, passing German cabinet in March 2002. Already its explanatory statement refers to the European structure – in particular to the functional separation of risk assessment and risk management (Annex 1 cabinet submission of the BMVEL 314-1320-7/1, pp. 1). Nevertheless, the German interpretation of this functional separation resulted in a very exceptional solution: Two new bodies were created by one law to replace the BgVV,[18] namely the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*, BfR) and the Federal Agency for Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*, BVL).[19]

The BfR became effective in November 2002 as an agency under public law within the remit of the BMVEL to enhance its independence. Hence, it is headed by a president appointed by the BMVEL and a board, which consists of the president, the vice-president and the heads of department (BfRG 2002, § 6). The BfR is responsible for "the preparation of scientific opinions on food safety and consumer protection (…), for scientific advice to the federal ministries and to the BVL (…), it carries out own scientific research closely related to its activities (…), may serve as a national reference laboratory (…) and informs the general public about health risks and other findings and work results" (BfRG 2002, § 2 para 1.1-1.12). Thus, the BfR is engaged in risk assessment and risk communication. Explicitly and already ranked third within the enumerative description of its tasks, the BfR is responsible for the cooperation with the services of the EU, in particular the EFSA (BfRG § 2 para 1.3). Although the BfR is by statute independent when it comes to its scientific assessments and its research (BfR 2005, p. 1), meaning it is not technically supervised (*Fachaufsicht*) by the BMVEL, several provisions allow direct control and influence by the department (o. A. 2001:10f.)(BMVEL 2001, p. 17).

The BVL has been operative since November 2002 as an agency (BOB) under the supervision of the BMVEL and is headed by a President, appointed by the BMVEL. In addition, two scientific committees on food safety and on oversight mechanisms were set up within the agency structure including representatives from the BfR and the *Länder*. These committees compensate *Länder* requirements, since according to the German executive federalism they are responsible for merely all law enforcement and thus contribute to risk management (Döhler 2005). The BVL is responsible for "risk management in terms of food safety, public health and consumer protection (…) [and] the harmonization of control

[17] Another sign for a strong EU orientation of von Wedel and her supporting group can be the case, that next to the qualified federal and *Länder* representatives also an expert on European affairs was attending this task force.
[18] Thus, the law includes in its first two articles the statutory laws for both authorities, namely the BfR statutory law (*Gesetz über die Errichtung eines Bundesinstituts für Risikobewertung*, BfRG) and the BVL statutory law (*Gesetz über die Errichtung eines Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit*, BVLG).
[19] The relations between BfR and BVL are not completely settled yet, but several features are identified, which might cause problems in the future (Henning 2005).

standards of the *Länder* and crisis management (BVLG 2002, § 2, para 1.1, 1.2). In practice, the BVL formulates (according to EU law requirements) administrative regulations to coordinate the control efforts of the *Länder* authorities and to enhance a uniform application of European standards and EU law. It remains to be seen how the BVL will cooperate with the *Länder* authorities, since *Länder* officials argue, that the BVL is not needed to enhance coordination between the federal and the *Länder* level and instead a more intensive use of existing institutions (like a meeting of the respective *Länder* ministers on the level of the German *Bundesrat*) would be more efficient (Böschen et al. 2002, p. 56). Additionally, the BVL serves as intercept for the European rapid-alert system and as national contact authority for the FVO (BVLG 2002, § 2, para 1.2). Hence, the BVL may play a transmission role between the control and oversight procedures commissioned at EU level (e.g. by the FVO) and control mechanisms, which are conducted at *Länder* level by respective authorities.

Overall, the administrative developments of both countries in the regulation of food safety can be traced back to the outbreak of the BSE-crisis as an external shock. While Blair used the crisis in Britain for his landslide victory as well as for the prompt and broadly supported creation of a new agency; only years after and caused by another food crises a strengthened ministry was created with a new portfolio to indicate a medium turn in agricultural policy. In Germany the reforms happened conversely, using the crisis to create first a strengthened ministry with a new portfolio and enforce a radical reorientation of agricultural policy, followed as late as 2002 with the creation of two different agencies with an announced strong relation to EU legislation. In terms of their mandate differences can be noticed: Whereas the British agency is responsible for all three elements of risk analysis, in Germany risk analysis is carried out by different authorities, in particular the BfR is limited to risk assessment and risk communication to explicitly imitate the functions of the EFSA. As for their structure, again both authorities were established along national traditions or rather national administrative reforms: While the British agency was created as a non-departmental body enjoying high independence from its parent department, the German agency reflects a traditional authority type, although its legal basis enhances independence from the parent ministry. In terms of their operational practice, although both agencies are just starting to establish cooperation with EFSA, the British agency exists longer and developed already close relationships to correspondent national authorities, against the only recently created German authority still begins to tangle networks.

Before testing the analytical framework against these preliminary empirical findings, the following table 1 summarizes the observed administrative changes across both policy fields in UK and Germany to underline similarities and differences. The highlighted cells signify an observable orientation towards the European agencies or rather the European approach.

Table 1: The download of European pressure: comparing the empirical findings

	Regulation of pharmaceuticals		**Regulation of food safety**	
	UK: MHRA	Germany: BfArM/DAMA	UK: FSA	Germany: BfR *(+ BVL)*
mandate	• national contractor of EMEA • integration of pharmaceuticals and medical devices → broader mandate than EU agency	• national contractor of EMEA • integration of pharmaceuticals and medical devices → broader mandate than EU agency	• national counterpart of EFSA • whole chain of risk analysis → broader mandate than EU agency	• national counterpart of EFSA • risk assessment and risk communication → similar mandate as EU agency
structure	• executive agency as trading fund + little modifications (e.g. non-executive chairman)	• agency (BOB), • planned reform: agency under public law + performance contract	• non-departmental public body	• agency under public law • *[agency (BOB), incl. two advisory committees]*
operation	• strongly oriented toward leadership within EU-wide competition	• nearly opposing EU-wide competition	• poorly assessable • first orientation toward close relations within an emerging EU-wide network	• poorly assessable • announced orientation toward EU agency

legend

- little orientation toward EU approach/agency
- medium orientation toward EU approach/agency
- strong orientation toward EU approach/agency

5. The impact of European agencies on changes of national administrations

In comparison, no converging administrative arrangements developed after the creation of both European agencies. Instead, differences can be observed on all dimensions of change concerning the mandate, structure and operation of national authorities. In assessing the analytical framework, first the European pressure will be considered; afterwards the explanatory mediating factors will be scrutinized.

In general, although the level of obligation differs between the regulations on pharmaceuticals and on food safety, those pieces of EU law, which relate to the two EU agencies, represent regulations with an obligatory character. Indeed these founding regulations address national administrations – although varying along the three analytical dimensions: First, reflecting the principles of the executive federalism within the EU (Lenaerts 1991), they require explicitly national authorities with a respective mandate to carry out functions within European procedures at national level. Second, they demand mutual cooperation, which can be considered as a less explicitly requirement on the operation of national bodies, though a certain provision to orient the operational practice toward the European level can be assumed. Third, in terms of the structure of national authorities both EU regulations do not include any obligations or even a voluntary suggestion. Thus, the hard

law requirements entail no structural model, although one might assume, that their mandate as well as their operational practice (especially their cooperation with other member states' authorities) might give an indirect incentive to adjust structures. However, structural decisions on national authorities may also be influenced by other reasons, e.g. those widely discussed in debates on administrative reform. In sum, as the European pressure is only virulent for two of the three analytically distinguished dimensions of administrative change, the mediating factors can only be tested against changes of the mandate and operation of national authorities. Thus and in addition to the considered qualification of these mediating factors as outlined in the analytical framework only partial and preliminary causal explanations can be made. Besides, an assessment of the three mediating factors reveals differences in their explanatory strength, as the following paragraphs will expose.

First, the national institutional characteristics, namely the number and position of veto points and the degree of fragmentation, impose different effects across all cases. In the UK the low number of veto players and the little fragmented system supported a prompt creation of agencies and the delegation of far-reaching competencies in both policy fields. Besides, the two agencies enjoy – also benefiting from their powerful mandate – a strong position within their policy fields and against their parent ministries. Thus, their proactive operational orientation within the EU-wide networks of national authorities is not much interfered by any national institutional obstacles. However, in the German system with its many veto players (especially the *Länder*) and high fragmentation two different courses of change can be observed: The establishment of an agency in the field of pharmaceuticals was hasty, supported by all political parties and resulted in a delegation of merely wide competencies; in contrast, the establishment of the agency in the field of food safety needed a longer time for compromise and the delegated competencies bear not only several conflicts – especially since a second agency was set up simultaneously – but can also be assessed as limited. Nevertheless, the German agencies in both policy fields share a less powerful position in their operational practice: The agency for pharmaceuticals regulation lost its standing continuously, as the arguments of the German government for the recently initiated reform demonstrate, and may therefore not be able to influence an EU-wide network of agencies with strong own interests and a formulated strategy. The new agency in food safety regulation has to operate with a restricted mandate within a complexity of competencies at national level, leaving little discretion to manoeuvre within the emerging EU-wide network of corresponding authorities. Thus, the number of veto points and the level of fragmentation cannot be taken into full explanatory assessment for the influence of EU agencies on changes of national administrations: Whereas the mandate (e.g. the designated functions) of national agencies is not very mediated by the national institutional context, their operational practice is likely to be shaped by these institutional contextual features, because they determine the agency's position within the politico-administrative system and therefore their possible engagement and contribution to the EU-wide networks of correspondent bodies.

Second, timing draws a similar unclear explanatory picture – as again the cross-country comparison across two policy fields reveals differences for the respective authorities. The creation of both British agencies in the two policy fields was completed years before the European agencies were established, which therefore could not be exploited by national politicians to enhance reform. Instead, their work experience offered capacities to influence

the formulation of new regulatory strategies at EU level in future EU regulation and to upload a British model, in particular in the field of food safety. Hence, even after several changes at EU level, adjustments within the mandate of British agencies were minor. In contrast, German politicians established in both cases national authorities parallel with European developments – although in pharmaceuticals regulation actually the public scandal triggered political action and European developments were not even used as a political justification, whereas the mandate of the separated agency in food safety was announced as a direct imitation of the EU agency. In addition, a closer look on the case of pharmaceuticals regulation shows, that in both countries the mandate of the respective authorities combines the regulation of pharmaceuticals and medical devices, whereas the European agency is only responsible for the former. Here, the timing of national administration's change can be characterized as 'in advance', since a potential functional combination at EU level was during the creation of the British agency in 1989 not virulent at the European agenda and during the establishment of the German agency in 1994 not formulated into the mandate of the then newly established EMEA. Against, for the field of food safety methodological restraints must be considered for timing as a mediating factor, since in this policy field all levels (EU level as well as the two member states under scrutiny) were highly influenced by the outbreak of the BSE-crisis at merely the same time. In sum, the timing of changes at EU level seems to be only partial explanatory, indeed it is likely to be relevant for uploading national models, but for downloading the European approach the timing could not be measured as equally relevant or rather supportive across all four cases.

Finally, governmental ideologies as distinct policy legacies expose more explanatory power – probably because they are related to respective sectoral traditions. The regulation of pharmaceuticals follows broadly speaking different approaches in both countries: Whereas the British approach is primarily interested in the functioning of the market, the German approach highlights somewhat more citizen protection and public health – although the German government seems to turn toward competition in recent times. Thus, the European legislation in the field of pharmaceuticals regulation with its mandatory procedures and the role and competencies of EMEA are interpreted from the British perspective as a competition among national authorities – as can be observed in the operation of the MHRA. Against, the German approach in pharmaceuticals regulation is associated with transparency and starts only recently to consider competitive elements – nevertheless, the outcome of the initiated reform of BfArM (new: DAMA) cannot be assessed so far, but it is expected, that the German agency is changing not only in its structure but also in operational practice to become one of the new centres of excellence. In the field of foodstuffs the British approach points especially to transparency and independence, not rejecting that mutual coordination among national authorities must be established to secure food safety and consumer protection. However, the German approach follows a similar logic, adding a strong commitment to the – legally deeply rooted – precautionary principle. That the recent EU regulation in food safety is from a British perspective seen as mutual collaboration within a EU-wide network can be observed not only in the emerging relations to EFSA, but also to other national authorities – where the first attempts show a similar strategy like the MHRA to get a leadership position. For the German case assessments are difficult at the moment, but the announced strong orientation toward EFSA makes it reasonable to doubt that the German agency will take an ambitious position

within the EU-wide network of national authorities. Instead a similar development as the BfArM is more likely; where in a few years another "competitive adjustment" by the German government might be needed. Thus, governmental ideologies shape not only decisions to delegate certain functions to national authorities, but influence strongly their operational orientation. However, governmental ideologies always include a momentum of national interpretation – especially in such cases where the European approach is merely compulsory – and therefore can be quite easily used not only for national politicians as justification for symbolic changes or rather as a "smokescreen for domestic policy manoeuvres" (Buller/Gamble 2002:15) but also for scholars as a residual variable which should be taken by caution.

Within these operational practices one can also assemble further informed guesses on processes of uploading national models after the creation of European agencies, which are likely to go further than influencing European policies (like the British experts in comitology committees or the German precautionary principle) toward an influence of member state polities – and maybe up to the European polity, in particular EU agencies, as well. In general, in both policy fields the stipulated cooperation among national authorities create 'epistemic communities' (Haas 1992). On the one hand this mutual cooperation may cause an apparent impact on the operational practice of these bodies: Whereas the British agencies for pharmaceuticals (and for food safety starting as well) are highly motivated to push both systems towards the competitive paradigm and thus are strongly engaged in both networks of national agencies, the German agencies in both policy areas are not (yet) using the established or emerging network of national agencies to upload German regulatory patterns that are tried and tested. Rather, as the case of the BfR shows, a reliance on the orientation towards the European agency is announced. In addition, the first chief executive of FSA who took later the position as first chief executive of EFSA points to another opportunity for uploading national models – this time directly to the European level, namely the respective EU agency. With the recruitment of Geoffrey Podger, explicitly linked to the creation and set up of EFSA, it is more than likely that a British management style will be imposed at EFSA with an apparent 'British-open' operational practice. Nevertheless, one can argue that these differences in uploading national models are fostered by the national politico-administrative system, since agencies in the UK are in particular cases widely accepted as political actors, whereas the German agencies at federal level exist in the shadow of the policy-formulating ministries and are not seen as self-interested actors within a policy field.

On the other hand, these forms of regulatory competition – as already established in the pharmaceuticals regulation but still in its infancy in food safety regulation – are likely to have an indirect impact on structural changes of the corresponding national authorities, in particular their political oversight and control. Due to the increasing relevance of policy credibility within the European procedures as well as the network, these agencies are based on legal types, which ensure a certain independence from national ministries and room for discretion. Whereas the British agency for pharmaceuticals regulation already reflects an independent body, enhanced by the position of a non-executive chairman, the announced reform of the respective German agency is directly linked to the emerging competition among member state agencies and also challenges traditional oversight mechanisms by introducing for the first time a performance contract within the German federal administration. Similar,

the British agency for regulating food safety reveals with its legal type already high independence from the parent department. That the German agency is not structured with an innovatory oversight regime including contract management could be attributed not only to the strong orientation in the German *Rechtsstaat* toward the principle of law as the general 'non-contractual' oversight mechanism but also to the merely voluntary European approach in food safety and the current absence of competition among the respective national authorities.

In addition, the persistence of the structures of national authorities also reflects the relevance of national traditions or administrative reforms. Hence, the divergence between the British agencies in both fields compared to the respective EU agencies can be explained with the applied radical reforms of the British civil service during the late 1980s and early 1990s, delegating tasks of central administration to agencies – a concept that spread throughout Europe and caused an "agency fever" (Pollitt et al. 2001). This 'agencification' compromised not only the delegation of tasks to independent bodies but also the contract management between agency and parent department (Pollitt/Talbot 2004). However, the German administration was until the announced reform of BfArM resistant against such reforms (Döhler 2004) and therefore rested upon traditional agency types when new bodies were created. Similarly, the European level is not very engaged in agencification, instead EU agencies are entangled in hierarchical relations to the responsible DG without a contract (Fleischer 2003, 2005a). Thus, EU agencies share some structural characteristics with German agencies, which might have had a confirming touch for German politicians when they decided upon the structure of these authorities.

6. Conclusion: The EU agencies as engines of the regulatory state?

The paper advances evidence that the creation and operation of agencies at EU level have an impact on national administrations. Nevertheless, not only the kind of European pressure but also particularly mediating factors at national level affect, to which extent and how change occurs. According to the different levels of obligation due to the respective EU law in the policy field, distinct dimensions of national authorities are challenged. The explicit demand of national bodies with a corresponding mandate (delegated functions and competencies) to the European agencies is neither highly interfered by the central characteristics of the national institutional context (e.g. the number of veto players and the level of fragmentation) nor by the timing of European pressure, sehr wohl but by governmental ideologies for the respective sector. The merely implicitly requirement of EU-wide mutual cooperation in the operational practice of the corresponding national authorities is strongly mediated by the national institutional context as well as governmental ideologies within the respective policy field, whereas the timing seems to be extraneous. Thus, evidence shows a distinct download of the European approach in both policy fields by both countries. In addition, preliminary observations of uploading could be made, which seem to be more indirectly and address primarily corresponding bodies of other member states within the EU-wide network of authorities instead of the respective EU agency.

These results offer a first judgment on the role of European agencies as a new architectural strategy of the regulatory state. First, it is indeed a new and additive kind of regulation compared to other forms at EU level. In addition to observations on the policy dimension whereby these EU agencies pursue a regulation by information to harmonize

regulatory policies (Kelemen 2004; Majone 1997), these agencies exercise in a similar way a set of compulsory requirements on the polity dimension of regulation. In particular the EU-wide networks of member states' agencies in both policy fields and their emerging competitive character are likely to initiate continuative polity changes, which go further than the initial creation and delegation of functions to a respective national authority. At the same time, the relevance of national governmental ideologies as mediating factors exposes a merely weak position of EU agencies within these networks – as national agencies seem to be more important for the direction and intensity of possible competition.

This leads to the capacity of EU agencies to self-define their role within the European regulatory state: Even though several studies show, how the Commission is institutionalising EU agencies to explore new fields for regulation and expand its own competencies (Fleischer 2005a; Krapohl 2004), the member states may have the opportunity to respond via these networks of national authorities. Thus, although EU agencies can be characterized as among the 'engines' of the European regulatory state with an impact on national administrations, it is questionable who actually is the engines' driver – the answer is also influencing their success as promoters of the European regulatory state: Whereas the Commission may be more interested in exploring new market failures and enhance its regulatory competencies; the member states have veritable interests to protect their own administrations. Hence, the possible impact of EU agencies on member state administrations is likely to be shaped by these contradictory objectives – leaving a blurred picture of the future role of EU agencies within the European regulatory state.

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