The London School of Economics and Political Science

Eva M. Heims

Managing European Risks without a European State:

Transnational Coordination between Regulators in the European Union

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Declaration

I certify that the thesis I have presented for examination for the MPhil/PhD degree of the London School of Economics and Political Science is solely my own work other than where I have clearly indicated that it is the work of others (in which case the extent of any work carried out jointly by me and any other person is clearly identified in it).

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Abstract

Governmental authorities are known for zealously protecting their 'turf', which is usually seen to inhibit them from coordinating their work with rival authorities. In the EU, however, national regulators often engage proactively in coordination with sister authorities in the forum of EU regulatory bodies. This is puzzling if one considers that this means that national authorities actively support EU bodies –potential rivals- in their work. The thesis hence examines what determines the coordinative behaviour of national regulators at a transnational level in the European Union. It analyses the engagement of UK and German authorities in transnational coordination in the regulatory regimes of drug safety, maritime safety, food safety, and banking supervision.

The study demonstrates that coordinative behaviour is driven by strategic considerations of national regulators that want their coordination activities to add value to their own work, rather than being determined by their professional norms, functional pressures or the 'shadow of hierarchy', as stipulated in the EU governance literature. Their strategic assessments of whether they are getting something out of transnational activities are informed by the interpretative filters of the social relations they are embedded in at the domestic level. They are also fundamentally shaped by the institutional frameworks provided by the tasks of the EU regulatory bodies in which national regulators come together. This explains variation of coordination patterns across policy areas and national regulators, which the EU governance literature has not accounted for.

The argument of the thesis implies that the engagement with coordination can be linked to an enhancement –rather than a loss– of bureaucratic autonomy. By identifying the determinants of coordinative behaviour at a transnational level, this thesis hence also seeks to contribute to our understanding of the conditions in which transnational administration functions. This, in turn, is vital for understanding of how capacity to manage cross-border risks is created in the absence of a 'European' state.

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Contents

List of Abbreviations

ADR	Adverse drug reaction
AMG	German Medical Act ('Arzneimittelgesetz')
BaFin	Federal Financial Supervisory Authority
BfArM	Federal Institute for Drugs and Medical Devices
BfR	Federal Institute for Risk Assessment
BMELV	Federal Ministry of Consumer Protection, Food and Agriculture
BSE	Bovine spongiform encephalopathy
BTSF	Better Training for Safer Food
BVL	Federal Office for Consumer Protection and Food Safety
CEBS	Committee of European Banking Authorities
CHMP	Committee for Medicinal Products for Human Use
COREP	Guidelines on Common Reporting
CRD	Capital Requirements Directive
CRR	Capital Requirements Regulation
Defra	Department for Environment, Food and Rural Affairs
DSRU	Drug Safety Research Unit
EBA	European Banking Authority
EBC	European Banking Committee
ECB	European Central Bank
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMSA	European Maritime Safety Agency
EP	European Parliament
ESAs	European Supervisory Authorities
ESRB	European Systemic Risk Board
EU	European Union
FINREP	Guidelines on Financial Reporting
FSA	Financial Services Authority
FSA	Food Standards Agency
FVO	Food and Veterinary Office

GP	General Practitioner
GPRD	General Practice Research Database
HELCOM	Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area
IMO	International Maritime Organization
LCR	Liquidity Coverage Ratio
MAFF	Ministry of Agriculture, Fisheries and Food
MANCP	Multi-Annual National Control Plan
MaRisk	Minimum requirements for risk management
MARPOL	International Convention for the Prevention of Pollution from Ships
MCA	Maritime and Coastguard Agency
MCA	Medicines Control Agency
MDA	Medical Devices Agency
MEPC	Marine Environment Protection Committee
MHRA	Medicines and Healthcare products Regulatory Agency
MSC	Maritime Safety Committee
NGO	Non-governmental organisation
NSFR	Net Stable Funding Ratio
Paris MoU	Paris Memorandum of Understanding on Port State Control
PEI	Paul-Ehrlich-Institute
PEM	Prescription-Event-Monitoring
PhVWP	Pharmacovigilance Working Party
PRA	Prudential Regulation Authority
PRAC	Pharmacovigilance Risk Assessment Committee
QM	Quality Management
SCFCAH	Standing Committee on the Food Chain and Animal Health
SSM	Single Supervisory Mechanism
STCW	Convention on Standards of Training, Certification and Watchkeeping for Seafarers
UK	United Kingdom
WHO	World Health Organization

Chapter 1

Introduction

Coordination between governmental authorities is key to the functioning of public administration (Wilson, 2000, [1989], p. 268f). The capacities of public administrations can often only be realised if authorities coordinate their work with each other. Indeed, the efforts of public authorities will often be ineffective if inter-connected issues are administered by separate organisations (Hood, 1976). If, for example, a policy problem cuts across the jurisdiction and expertise of a variety of agencies, coordination is usually needed. An instance of this can be found in relation to the integrated market of the EU, in which a 'single' market is administered by separate regulators in each Member State. In the absence of hierarchical capacity of EU institutions to manage cross-border risks, specialised EU regulatory bodies have been created as a means to coordinate the practices of national regulators at the transnational level. These EU bodies lack formal authority and expertise. Despite these potential limitations, they have developed into significant regulatory actors which create transnational capacity to regulate through coordination between national regulators. That national regulators apparently coordinate their practices –and thus support EU regulatory bodies in their work is– puzzling if one considers that coordination between public authorities is known to be perennially problem-ridden: Government authorities are keen to protect their 'turf' and the engagement with coordination processes is costly for them, especially since it usually

represents an auxiliary activity to their main line of work. This thesis hence poses the question of what determines the coordinative behaviour of national regulators at the transnational level. The answer to this question is crucial for elucidating the conditions for transnational administration. Section 1.1 elaborates on the motivation for this research project.

The relevant literature on EU governance has mainly focused on the professional norms of regulatory officials, functional pressures, and the 'shadow of hierarchy' in order to explain what determines coordinative behaviour of national regulators at the transnational level. This thesis argues that –whilst each approach points out crucial factors that are likely to affect coordinative behaviour– they remain too restricted in their assumptions, and their ability to account for variation in coordination processes across policy sectors and national regulators. They also neglect the potential extent of coordination problems that has been pointed out by the public administration literature. Section 1.2 expands on this discussion of the relevant literature.

In this light, the thesis suggests that the coordinative behaviour of national regulators at the transnational level is in fact determined by strategic concerns of national regulators that the auxiliary activity of engaging in coordination needs to add value to the main regulatory work they fulfil 'at home'. National regulators' perception of their own interests, in turn, are formed in the setting of the social relations they are embedded in, as well as during the process of carrying out tasks in the forum of EU bodies: National regulators evaluate whether the task carried out by a given EU body 'adds value' through the filter of the social relations they are embedded in. These conceptualisations are then also affected by the act of carrying out specific tasks in EU bodies. The variation in tasks fulfilled by EU bodies and the differences in the social relations that national regulators operate in have the potential to explain variation in coordination patterns across different policy areas and national regulators. Section 1.3 discusses this argument at greater length.

1.1 Managing European Risks without a European State?

The establishment of specialised EU regulatory bodies –in which national regulators come together to coordinate their practices– has been seen as a means to counter-act the so-called 'capacity gap' between the highly differentiated regulatory responsibilities of the EU and its administrative capacity (see Section 1.1.1). These EU bodies, however, lack formal authority and expertise: In order to carry out their regulatory tasks they are reliant on the willingness of national authorities to come together in their forum to coordinate their practices with their sister authorities. Despite these circumstances, the specialised EU bodies have developed into regulatory actors to be reckoned with (Section 1.1.2). This is puzzling since governmental authorities are usually better known for the zealous guarding of their turf, rather than their proactive support of a potential rival agency and coordination with other governmental authorities. The thesis thus poses the question of what determines this coordinative behaviour of national authorities at the transnational level (see Section 1.1.3.).

1.1.1 Specialised EU Regulatory Bodies as Answer to the Capacity Gap of the EU?

In order to manage policy problems such as risks,[1] governments need to set standards about accepted safety levels, whilst also being able to gather information on whether these standards are met and modifying behaviour if

[1] Risk as a problem of public administration has traditionally been seen as calculable entity. In this regard, the 'classic' technical definition of risk and uncertainty has been provided by Frank Knight (1921, see especially pp. 197-232). In his conception, 'risk' can be calculated, whereas uncertainty is immeasurable: 'To preserve the distinction […] between a measurable uncertainty and an unmeasurable one we may use the term "risk" to designate the former and the term "uncertainty" for the latter' (p. 233). Risk as a calculable property in this case is defined as the probability of the occurrence of an event taken times the potential harm of this event (Royal Society, 1992, p. 2f). The meanings of risk and uncertainty, however, have become blurred: Many forms of 'risk management' are indeed 'uncertainty management' in the Knightian definition since governmental authorities are faced with possible future events of which no calculable probability exists. Uncertainty is indeed a key factor attached to risk, which renders it into a particularly difficult problem for government: We do not have information on the long-term effects of recent risk-producing technologies, such as the effects of genetically-modified organisms. Risk, then, has a strong connotation with calculability (see Knight's definition) *and* uncertainty (which Knight separated strictly from risk as calculable property). This has led to the paradoxical situation in which risk and 'risk management' are now often associated with the 'calculation of uncertainty' (which, according to Knight, is an impossibility). Risk can thus be said to represent an (adverse) future event, of which the incident is uncertain (although sufficient experience and data might allow the minimisation of uncertainty through the calculation of statistical probabilities in some cases).

practices on the ground are not in line with these safety standards (Dunsire, 1978; Hood, Rothstein and Baldwin, 2001). Whilst the EU sets regulatory standards and has the responsibility to manage cross-border risks in its integrated market –which should entail information gathering and behaviour modification- its administrative capacity is far too small to fulfil this duty (Eberlein and Newman, 2008; Kelemen, 2005, p. 173f; Majone, 2000; Van Boetzelaer and Princen, 2012, p. 819), and national administration remain responsible for the implementation of EU law (Versluis, 2007).[2] In this regard, the 'single' market of the EU is administered by separate entities (*f.* Hood, 1976, p. 17), i.e. the authorities of each Member State. The resulting "capacity gap" has been associated with the EU and international organisations alike (Eberlein and Newman, 2008; also see Abott and Snidal, 1998):

> One of the most obvious defects of the EC regulatory system is the mismatch between the Community's highly complex and differentiated regulatory tasks, and the available administrative instruments (Majone, 2000, p. 279).
>
> The demand/supply equation for international coordination [...] rarely clears as nation-states tend to jealously guard their sovereignty. International organizations, then, often lack the tools and skills to monitor and oversee the development and implementation of international rules (Eberlein and Newman, 2008, p.25).[3]

Whereas the EU has been entrusted with the management of cross-border risks, the resources and expertise to control risks continue to exist mainly at the national level: National officials –not EU officials– have the administrative capacity to verify the safety of ships on the ground. National

[2] How to define and evaluate administrative capacity remains highly difficult: For example, the EU accession process requires candidate countries to possess the necessary administrative capacity to implement the EU's body of law. However, the European Commission has reportedly not found a means to judge the quality of an administration (Dimitrova, 2002, p.179f). At its heart, however, the concept seeks to capture administrations that are able to address the problems for the handling of which they have been created (Nelissen, 2002, p.12f). Limitations in this regard might not only be institutional, but also be about how legitimate a regulator is seen to be and how their work ties in with political issues (*ibid.,* p.13). At the most general level, administrative capacity entails running the machinery of a political or economic system, a government, and its international or global affairs, executing policy decisions, and translating political or collective will into actions and management (Farazmand, 2009, p.1016, also see p.1016ff for an in-depth discussion of the various angles of the concept of administrative capacity).

[3] In order to describe this mismatch between regulatory tasks and administrative capacity, Eberlein and Newman (2008) borrow Keohane's notion of the 'Governance Dilemma' (2001).

experts –rather than EU experts– have the resources and the knowledge to monitor and evaluate whether a medicine on the market is indeed safe to use. As Majone notes "regulation is not achieved simply by rule-making; it also requires detailed knowledge of, and intimate involvement with, the regulated activity" (Majone, 2000, p.280). This 'intimate involvement' is found in national administrations –rather than in supranational bodies– in the regulatory regimes of the EU. The ensuing capacity gap has not only been noted to threaten the legitimacy of the EU (Eberlein and Newman, 2008; Majone, 2000), but also to question its very governability (Scharpf, 1999).

Indeed, the integrated market of the EU –and the cross-border risks associated with it– are a prime example of a "situation where different parts of inter-connected systems are separately administered in such a way as to render the total administrative effect ineffective or counter-productive" (Hood, 1976, p. 17), which characterise the limitations of government to realise its capacities: One set of rules supposedly applies to the internal market of the EU; however, the implementation and enforcement of these regulatory standards are administered by national regulators in each Member State. If, for example, food control authorities in France do not carry out effective controls, health risks from unsafe food could quickly spread to all EU countries, thus rendering regulation ineffective. If authorities in one country do not enforce rules –or interpret them in a lax manner– regulatory loopholes are created that can render the given EU-wide regulatory regime counter-productive.[4]

This has provided (perceived) functional pressures for action (Majone, 1996), which political actors in the EU have responded to within the framework of the dominant norm of 'the need' for delegation to non-majoritarian institutions that has been observable across the globe (Gilardi, 2005; McNamara, 2002): Specialised EU regulatory bodies –such as agencies, committees and offices– have mushroomed over the past decades (Busuioc, Groenleer and Trondal, 2012; Dehousse, 1997; Kelemen, 2002,

[4] Hood refers to such a situation as multi-organisational sub-optimisation (1976, p. 17).

2005; Maggetti and Gilardi, 2011; Majone, 1997; Levi-Faur, 2011 Rittberger and Wonka, 2011). As expressed by *The Economist* in 2001, "the idea took hold that no area of EU business was complete without its agency or authority".[5] In the field of economic and social regulation, the number of such bodies has been continuously on the rise, especially since the early 2000s. Whilst the European Medicines Agency was already established in 1995, other policy areas soon followed suit, such as the founding of the Committee of European Banking Supervisors in 2004, which was then surpassed by the European Banking Authority in 2011. Equally, we saw the emergence of the European Maritime Safety Agency and European Food Safety Authority in 2002, whilst the European Chemicals Agency started working in 2007. In total, the EU currently has 35 of these so-called 'decentralised agencies'. In 1990, only three of such bodies had existed. By 2000, this number had risen to twelve, and by 2005 this number had reached 25.[6]

Some commentators have described this as an exercise in "bureaucratic self-aggrandizement" on part of the European Commission (Kelemen, 2002, p.98). The formal authority and regulatory capacities of these EU bodies, however, are in fact miniscule. Instead of building a regulatory interface with the regulated industry, EU regulatory bodies

[5] 'The EU: Wider still and wider'. *The Economist,* 2 August, 2001.

[6] See the following list of EU decentralised agencies and the years in which they were created (i.e. the year of the ratification of the legal text establishing them; also note that many of these agencies evolved from previous 'committees').
1975: European Centre for the Development of Vocational Training (Cedefop), European Foundation for the Improvement of Living and Working Conditions (EUROFOUND; *1990*: European Training Foundation (ETF); *1993*: European Environment Agency (EEA), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); *1994*: Translation Centre for the Bodies of the European Union (CdT), Community Plant Variety Office (CPVO), European Agency for Safety and Health at Work (EU-OSHA), Office for Harmonisation in the Internal Market (OHIM); *1995*: European Medicines Agency (EMA); *1998*: European Police Office (EUROPOL); *2000*: European Police College (CEPOL); *2002*: European Union Institute for Security Studies (EUISS), European Food Safety Authority (EFSA), European Maritime Safety Agency (EMSA), The European Union's Judicial Cooperation Unit (EUROJUST), European Union Satellite Centre (EUSC); *2003*: European Aviation Safety Agency (EASA); *2004:* European Railway Agency (ERA), European Defence Agency (EDA), European Agency for the Management of Operational Cooperation at the External Borders (FRONTEX), European GNSS Agency (GSA), European Centre for Disease Prevention and Control (ECDC), European Network and Information Security Agency (ENISA); *2005*: European Fisheries Control Agency (EFCA); *2006*: European Institute for Gender Equality (EIGE); *2007:* European Chemicals Agency (ECHA), European Union Agency for Fundamental Rights (FRA); 2009: Body of European Regulators for Electronic Communications (BEREC); *2010*: European Banking Authority (EBA), European Insurance and Occupational Pensions Authority (EIOPA), European Securities and Markets Authority (ESMA), Agency for the Cooperation of Energy Regulators (ACER), European Asylum Support Office (EASO); *2011*:European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice (eu-LISA).

create an interface with the relevant authorities in the Member States (Eberlein and Grande, 2005). As a result, EU regulatory bodies are usually not involved in risk management 'on the ground'. This remains the responsibility of national regulators that represent the operative arm of this transnational bureaucracy (see Wilson, 2000 [1989], pp.31-110). Indeed, other commentators have argued that the proliferation of EU regulatory bodies equates to a strengthening of Member States since national officials hold crucial positions in these EU regulatory bodies (Kreher, 1997, p. 226): National officials constitute the executive boards and expert committees of EU agencies and other regulatory bodies. This means that the decisions emanating from these bodies effectively represent the coordinated views of national authorities. In fact, EU regulatory bodies –themselves highly restricted in their formal authority and resources– have been described as hubs of transnational networks of national regulators (Chalmers, 2005, p. 649; Dehousse, 1997; Eberlein and Grande, 2005; Majone, 2000). In order to be able to fulfil their tasks, EU regulatory bodies hence need to closely bind national authorities into their work to make use of their resources and expertise (Eberlein and Grande, 2005; Majone, 1997; Sabel and Zeitlin, 2008, 2010, 2012): In the absence of proactive engagement with their tasks on part of national counterparts, they can usually not carry out their work (Busuioc, Curtin and Groenleer, 2011).

In this regard, then, transgovernmental ties have been established through the direct interactions between national authorities (Slaughter, 1997, 2004, 2011; also see contributions to Djelic and Sahlin-Andersson, 2006).[7] Slaughter goes as far as to proclaim that these ties represent a "new world order" in which regulators that coordinate their actions need to be seen as the "new diplomats" (2004). In the context of the EU, the establishment of these transgovernmental links has been described as an instrument of capacity-building through the coordination of practices

[7] The majority of research on transogvernmental networks originates from the governance literature, which is rooted in public policy approaches. Slaughter's work on transgovernmental networks, however, departs from an international relations angle. Her work demonstrates that research on this topic is of relevance beyond the interest of governance and government since it studies how sub-units of governments establish relationships that might indeed be decoupled from the diplomatic and political relationship between the given countries.

between national regulators at a transnational level (Dehousse, 1997; Hobolth and Martinsen, 2013).

1.1.2 Capacity Building through Transnational Coordination Processes

Despite their limitations in resources and authority, EU regulatory bodies have developed into influential regulatory bodies that have come to fulfil a variety of crucial regulatory functions. Some of them assess risk. For instance, the European Food Safety Authority and the European Medicines Agency are responsible for formulating scientific opinions on questions of safety and risk emanating from particular products and materials.[8] Other EU regulatory bodies –like the European Securities and Markets Authority– are responsible for the setting of detailed technical standards that govern the behaviour of national regulators and the regulated industry. Bodies like the European Aviation Safety Agency and the Food and Veterinary Office, in turn, inspect the regulatory practices of national authorities. In other words, EU regulatory bodies are heavily involved in key regulatory tasks, such as the setting of safety standards and the monitoring of whether these are adhered to (see Hood *et al.,* 2001).[9] In taking decisions on whether a given

[8] Please note that these agencies do not take legally binding decisions. Rather, the European Commission decides on the basis of these scientific opinions. This is so because powers cannot be fully delegated to specialised EU regulatory bodies. If, for example, and EU agency has the task to authorise products for the market –such as the European Medicines Agency- the European Commission remains formally in charge of authorisation on the basis of an expert opinion of the specialised agency. This is a result of the so-called *Meroni* doctrine established in case law: It does not allow for a delegation of decision-making powers to independent EU agencies in order to keep the 'institutional balance' between EU institutions intact (*Meroni SpA v ECSC High Authority (Meroni I)* [1957 and 1958] E.C.R. Spec. Ed. 133, and *Meroni SpA v ECSC High Authority (Meroni II)* (10/56) [1957 and 1958] E.C.R. Spec. Ed. 157). For further commentary see, for example, Griller and Orator (2010). Recently the European Court of Justice seems to have lifted these restrictions on agencies. The consequences of this ruling are unclear at the time of writing. For an analysis, see Chamon, 2014. In practice, the European Commission generally 'rubber-stamps' the decisions of EU regulatory bodies.

[9] In this thesis, regulatory regimes are conceptually viewed as *control systems*: Inspired by cybernetics, each control system (i.e. regime) is assumed to have the capacity of *directing* (i.e. standard-setting), of *detecting* (i.e. information-gathering), and of *effecting* (i.e. behaviour-modification) (Dunsire, 1978, p. 59; Hood, 1983). This analytical view helps us to direct our attention from multi-level conceptualisations of bureaucracies in the EU –and the inevitable categorisation of their nature in relation to supranationalism and intergovernmentalism- to the organisations that are all involved in the pursuit of the same objective (i.e. the management of a given risk). Hood *et al.* conceptualise regulatory *regimes* as entailing a variety of actors dispersed over private and public organisations and different levels of government, which all work towards the control of the same risk (2001, p. 8f). Please note, however, that this does not mean that this thesis indeed regard government to be 'machine-like' in practice: Any governmental system is bound to have flaws (Hood, 1976).

product is safe, or which rules regulators and industry in the EU should follow, they perform powerful regulatory activities.

That EU regulatory bodies have developed into forces to be reckoned with is visible in how they are viewed by national governments and EU institutions alike: For example, a review of the powers transferred to Brussels by the Dutch government has –amongst other issues- focused on EU agencies. In this review, the Dutch government voices stark concern about the need for EU agencies to take the view of national governments into account when taking decisions or devising regulatory guidelines (Ministerie van Buitenlandse Zaken, 2013, p.2 and 4f). The potential influence these bodies can wield has indeed been the subject of numerous parliamentary inquires in the Member States.[10] Also, the European Parliament has on occasion refused to sign off the accounts of several EU agencies.[11] These bodies are thus regarded as important players that need to be constrained by political actors. Overall, then, they appear to have developed into powerful regulatory bodies that facilitate European capacity to regulate through transnational co-ordination.

The *de facto* capacities of these organisations can only be understood as a result of the active participation of national regulators in their activities. Take the European Banking Authority, for example: It is responsible for the setting of technical regulatory standards aimed at ensuring the financial soundness of banks.[12] It has roughly 120 members of staff and an annual budget of around €20,000,000.[13] In comparison, the German Federal Financial Supervisory Authority (BaFin) has around 3200 staff members and a budget of approximately €224,000,000. Whilst direct comparisons need to be treated with care –after all tasks and responsibilities are never identical across different regulatory bodies– it is clear that the administrative capacity and regulatory expertise continues to reside with

[10] A case in point is the British House of Lords Inquiry about the EU regulatory bodies concerned with financial regulation (see House of Lords, 2009).
[11] As a result of concern about the influence of industry on the work of EU agencies, the European Parliament delayed its approval of the past expenditure of the European Food Safety Authority, the European Medicines Agency and the European Environment Agency for the year 2010.
[12] See Regulation No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC.
[13] EBA, 2013, p.12 and 73.

national authorities despite the emergence of EU regulatory bodies. The small administrative capacity of EU regulatory bodies becomes especially visible in comparison to their US counterparts. In order to manage risks from foods and medicinal products in a market of around 320,000,000 consumers, the US Food and Drug Administration employs around 14,500 people and has an annual budget of roughly €3.2billion ($4.3billion).[14] In comparison, the combined number of staff and annual budgets of the European Food Safety Authority and the European Medicines Agency add up to around 1,100 people and €328,000,000 per year in order to regulate a market of a population of around 510,000,000.[15]

How similar regulatory demands can be fulfilled despite this stark difference in resources can only be understood if one takes into account that national regulators devote resources and expertise to the regulatory activities of EU regulatory bodies. Without this engagement of national authorities, EU regulatory bodies would not be able to fulfil their responsibilities.

1.1.3 What Determines Coordinative Behaviour at the Transnational Level?

EU regulatory bodies are usually able to fulfil their responsibilities, although they are reliant on the willingness of national regulators to engage with their work and to coordinate their practices with sister authorities. That national regulators indeed seem to engage in coordination in the forum of EU bodies is puzzling given that coordination between governmental authorities is perennially riddled with difficulties. Indeed, coordination among public authorities has been described as one of the most pervasive problems of government (Wilson, 2000, [1989], p. 268f; also see Hood, 1976, p. 17ff). The need for coordination in interdependent settings –and the difficulty of maintaining coordination processes– have been described as one of the central limits of administration (Hood, 1976, p. 17ff).

Coordination between governmental authorities is often problem-

[14] Up-to-date numbers can be retrieved from the Distribution of Full-Time Equivalent (FTE) Employment Program Level and the Annual FDA Budget Summary.
[15] See EFSA, 2013, p.21; EFSA, 2013b, p.3; and EMA, 2013b, p.17f.

laden as a result of the tendency of bureaucratic actors "to get and to keep as much [turf] as they can" (Wilson, 2000 [1989], p.28). Protecting their turf equates the maintenance of their autonomy –for example vis-à-vis the governments that there are accountable to– is usually seen as a key motivation for bureaucratic behaviour (*ibid*., p. 179ff): In order to maintain their organisations, public authorities are known to strive for autonomy from other actors since this allows them to define their work in their own terms. This, in turn, helps to establish a sense of mission within an agency, which is usually helpful in order for the organisation to stay in control. For example, this helps executives to ensure that officials throughout the organisation are carrying out their work as required, which again feeds into the authorities' ability to maintain its autonomy vis-à-vis potential rivals and political actors (*ibid.,* p. 26; p. 183f).

The protection of autonomy –or 'turf'– is hence inextricably linked to public authorities' strategic aim to survive. In this respect, the proactive engagement of national regulators with transnational coordination efforts is particularly intriguing since bureaucratic actors are usually more likely to attempt to limit the influence of any rivals that fulfil similar tasks to them: Governmental authorities are usually seen to want to be the only 'sheriff in town'. In coordinating, however, national regulators in the EU create capacities for an EU regulatory body that can potentially rival them in their field, thus supporting them actively in their work, rather than trying to limit their influence. In light of what we know about the importance of the protection of turf on part of governmental authorities, it is puzzling that national authorities seem to proactively help to maintain potential rivals (i.e. EU regulatory bodies).

Coordination between governmental authorities –or organisations and organisational units more generally– is also known to be particularly difficult if the aims of this exercise are not clear to the involved organisational units, when there is a high turnover of participants that are involved in the coordination process, and if these participants have limited time and resources since they have other issues to handle than the coordination process (see Cohen, March and Olsen, 1972). Considering the

high number of officials involved in an EU of 28 Member States and the great variation in the contexts they are embedded in at home, transnational coordination in the EU seems to be affected by such unfavourable circumstances at least to some degree. Also, national authorities' primary task is usually the regulation of a particular industry in their home country. Engagement with transnational coordination in EU regulatory bodies to support their work is hence indeed an auxiliary task in relation to national regulators' 'main line of business'. Time and resources devoted to the engagement with transnational processes cannot be devoted to the main regulatory work of an authority in their home country.

That transnational coordination between national authorities seems to function is also particularly interesting since these efforts often come closer to 'positive coordination' than to 'negative coordination'. Scharpf has coined the term of positive coordination in order to describe coordination processes which entail proactive participation by a variety of actors to agree on mutually beneficial rules or practices (1993, 1994). Negative coordination, on the other hand, does not involve the proactive engagement of all potentially affected actors. Rather, potentially affected organisational units only become involved if a reached agreement is seen to obstruct their practices, in which case they block the coordination process. In comparison to negative coordination, positive coordination is rare because it requires an extraordinary willingness of the involved actors to invest their time and resources to coordination processes (*ibid.*). Transnational coordination in the EU is mandated, hence not rendering the involvement of all affected actors surprising as such. What remains puzzling, however, is the willingness of national authorities to *proactively engage in coordination* despite the strains these activities can put on their resources. In this regard, the engagement in 'positive coordination' requires the willingness to overcome collective action problems.

Even though national authorities might have a common interest under conditions of interdependence, conflicting interests might persist at the same time, rendering it difficult to solve such collective action problems. Under the assumption of limited resources, active engagement with positive

coordination is costly for national regulators. Costs are not only accrued by investing time and resources in the coordination process itself. Rather, as an outcome of engaging in coordination and defining new working practices, national authorities will need to invest resources into modifying their own practices: They may have to change the computer systems they use to collect data, change their organisational set-up or retrain staff (etc.). Since their existing practices are usually based on underpinning regulatory philosophies, administrative traditions and norms these changes can run into resistance within national regulators (Van Boetzelaer and Princen, 2012, p.821).

The thesis is hence devoted to the research question of what determines the coordinative behaviour of national regulators at a transnational level. At its heart, this question is of immediate importance for understanding the capacity of the EU to manage cross-border risks despite the absence of supranational capacity as such (Egeberg, 2006; Trondal and Peters, 2013, p.299f and p.303), as well as for setting out the conditions for transnational administration. Capacities to manage cross-border risks in the EU are being established through transnational coordination without supranational capacity, and this thesis is devoted to the study of the functioning of transnational administration. This means that we need to understand which conflicts arise in coordination processes, through which mechanisms they are resolved and why national regulators are willing to engage with coordination activities despite the potentially material and immaterial costs of doing so.

1.2 Discussing Previously Identified Determinants of Coordinative Behaviour

The literature on EU governance offers three dominate lines of thought in order to account for the coordinative behaviour of national regulators at the transnational level. Whilst constructivists argue that the norms of their professional communities drive the coordinative behaviour of regulatory actors (see Section 1.2.1), the functionalist school of thought stresses the

pressures of interdependence as determinant of coordinative behaviour at the transnational level (see Section 1.2.2). Rational choice institutionalists, in turn, focus on the strategic behaviour of national regulators within the framework of the institutional framework of the EU (i.e. 'the shadow of hierarchy') (Section 1.2.3).

Each of these three schools of thought identifies crucial factors that affect coordinative behaviour. However, they all neglect the potential problems associated with coordination between government authorities pointed out in the public administration literature (as discussed in the previous section). Moreover, as is the case in any literature their assumptions restrict their analysis in some regards. Whereas the assumptions of the constructivist and functionalist accounts do not allow enough room for the political (i.e. actors' interests and power struggles), the rational choice institutionalist approach assumes interests to be exogenously given, and hence neglects the multiplicity of factors that inform interest-driven behaviour beyond the institutional framework of the EU. Overall, these three approaches over-characterise coordination processes at the transnational level, which results in a lack of observance of variation in how coordination functions in varied settings. This thesis suggests that we need to be able to account for variation of how coordination functions if we are to explain what determines coordinative behaviour.

1.2.1 The Constructivist Lens: Professional Norms as Determinants of Coordination?

The constructivist lens emphasises that the coordinative behaviour of regulatory actors is determined by the norms of their professional and epistemic communities. In this view, professionals are keen to exchange practices, learn from each other and maintain their professional reputation amongst their colleagues (Eberlein and Grande, 2005; Slaughter, 2004, p.59; Sabel and Zeitlin, 2008, 2010; Trondal, 2010, p.22). Regulators coordinate because this means 'acting professionally' to them and learning and

deliberation are used to solve coordination problems (Majone, 1997, p.271ff; 2000, p.295ff).[16]

> […] an agency that sees itself as part of a transnational network of institutions pursuing similar objectives and facing analogues problems […] is more motivated to defend its policy commitments and/or professional standards against external influences. This is because the agency executives have an incentive to maintain their reputation in the eyes of the other members of the network. Unprofessional or politically motivated behaviour would compromise their international reputation and make co-operation difficult to achieve in the future (Majone, 1997, p.272).

The constructivist literature hence draws our attention to the importance of the norms of professional communities of experts that regulatory actors are embedded in as drivers of transnational coordination. In this view, coordination processes are determined by the peer pressure exerted in professional communities, such as the perceived need to enhance and maintain reputation amongst expert colleagues. Information as valuable resource is seen to play a key role in driving coordination: Although EU regulatory bodies do not have the formal authority to induce coordination between national authorities, they are seen to possess crucial information through which they can exercise regulatory control and promote coordination (Majone, 1997; Eberlein and Grande, 2005, p.100). In a similar vein, the literature on EU comitology committees has emphasised that coordination between highly specialised national officials happens through persuasion and deliberation in an expertise-based and consensus-driven problem-solving mechanism (Joerges and Neyer, 1997; Joerges and Vos, 1999; Rhinard, 2002). Trust between regulatory actors is usually described as facilitating factor of coordination in this context (Eberlein and Grande, 2005, p. 103; Börzel and Heard-Lauréate, 2009, p.143).

In doing so, the constructivist lens of the EU governance literature neglects that regulators are embedded in wider social relations –such as the national regulatory regimes they form part of– which also inform their

[16] Please note that Majone would commonly be classified as a 'functionalist', rather than a 'constructivist' scholar. However, it is put forward here that in relation to his arguments about the determinants of coordination he needs to be including in the 'constructivist' line of thought in the EU governance literature due to his focus on professional norms. This does not mean, however, that his way of thinking about the rationale for the establishment of EU agencies is not decidedly functional.

interests. Whilst professional norms certainly play a crucial role in shaping the attitude of regulators, it is likely that their interests –and hence behaviour– are shaped by more complex settings of social relations. Moreover, the focus on consensus-driven deliberative forms of coordination disregards that differing regulatory tasks of EU regulatory bodies set up different relations between national regulators: Technical standard-setting, for example, is likely to cause more contention between regulators than regulatory tasks focused on information exchange. The generalised focus on professional norms hence disregards important sources of variation in coordination patterns across different policy areas and different national regulators. Since professional norms are not seen to vary across Member States and policy areas in the constructivist literature, coordination processes are seen to be alike in very different settings. Also, the focus on trust does not help us to understand why the same set of actors coordinate in relation to one aspect of their work (thus ostensibly trusting each other), whilst not doing so in other areas of their work (for an example, see the case of banking supervisors in Chapter 6 of this thesis).

The deliberative approach has also argued that national officials engage in deliberation, mutual exchange and learning in order to define common ways of doing things because they know that a centrally imposed solution would be 'unworkable' on the ground: By engaging in coordination, national officials can find common solutions which they can adapt to the circumstances in their own country (Sabel and Zeitlin 2010, p.15; also see Eberlein, 2010).[17] This idea takes into account the national contexts of regulators, without, however, considering that the circumstances across countries might shape regulators ideas and interests to a considerable extent, rendering agreement on common solutions difficult.

Overall, the assumption that regulators are inherently interested in exchanging practices and in learning from each other underestimates that engaging in transnational processes is a resource intensive and time-

[17] Sabel and Zeitlin capture this idea in the concept of the 'penalty default': If national officials do not engage in coordination they know that the European Commission (potentially in conjunction with the European Parliament and the Council) will impose a harmonised standard on them. In the diverse setting of the EU, in turn, such a centrally imposed solution is seen as unworkable by Sabel and Zeitlin (and in their view national officials also this as an untenable outcome) (Sabel and Zeitlin, 2010, p.15).

consuming process for national authorities. As such, then, the constructivist lens of the EU governance literature underestimates the nature of the coordination problems that can arise between governmental authorities, as highlighted by the public administration literature (see Section 1.1.3). Whilst national authorities might indeed have an inherent interest in exchanging views with their peers, the realities of getting their day-to-day work done under time-constraints and their aim to keep existing practices intact render it more questionable whether professional norms are indeed a primary determinant of coordinative behaviour of national regulators. In this regard, it has been put forward that regulators need a stronger incentive to coordinate their work. In other words, they need to 'get something out of' coordination (Van Boetzelaer and Princen, 2012, p.822).

1.2.2 Functional Explanations: Does Interdependence Drive Coordinative Behaviour?

Functional explanations focus on the interdependence of regulators as driving force of coordinative behaviour. In this view, regulators proactively engage with coordination processes since they cannot carry out their work effectively if other regulators fail to do their job in a context of interdependence.

> The aim is not altruism. It [engagement with coordination] results from the recognition that a global regulatory system based on transgovernmental networks is only as strong as its weakest link (Slaughter, 2004, p.57).

These explanations hence emphasise that rationally acting regulators have an interest in coordinating their actions: Due to the cross-border nature of risks they cannot successfully pursue their regulatory goals without coordination. This approach usefully highlights that regulatory authorities are interested in carrying out fruitful work: They would like their regulatory activities to be effective, as a result of which they coordinate. Research has demonstrated that the higher the perceived level of interdependence between regulators in the EU, the more intensive their cooperative efforts in EU agencies and committees (Van Boetzelaer and Princen, 2012).

(Perceived) interdependence is seen to provide the involved regulatory actors with the necessary incentive to commit resources to coordination. This approach argues that the main potential benefit of the engagement with transnational coordination is an increase in the homogeneity of risk management practices. National regulators hence do not receive an added value from coordination in cases where national authorities are not directly affected by the activities of authorities in other Member States. In such cases –it is put forward– the coordination activities of national regulators mainly benefit the European Commission, rather than the national regulators engaged in coordination. Thus, in such cases of low (perceived) interdependence national regulators lack an incentive to engage with transnational processes (*ibid.,* p.822). This perspective highlights that regulators would like to go about their work effectively and in order to do so, they coordinate. This approach hence makes a crucial contribution in demonstrating that regulators care about the results of their work, which –under conditions of interdependence– are necessarily linked to the work carried out by sister authorities in other countries. This idea is also present in public administration literature on the motivations of bureaucratic behaviour, which has found that officials would like to 'do their jobs well' (Brehm and Gates, 1997).

Whilst perceived interdependence might hence be crucial for providing national authorities with a sense of purpose when coordination is concerned, this approach struggles to explain cases in which regulators fail to coordinate despite (perceiving to be) interdependent. Also, this approach tends to neglect that national regulators can potentially gain other 'added values' from transnational coordination than the approximation of regulatory practices that directly affect them. Although functional accounts usefully point out that regulators have a reason to care about the effectiveness of the work of their sister authorities, they neglect the possibility that they also care about the their regulatory work 'at home': After all, they are the operative arm of this regime that carry out the day-to-day work of risk management within the institutional contexts of their home countries. Similarly to the constructivist approach they neglect the

possibility of politically motivated behaviour of regulators. National authorities are likely to form their preferences in wider settings of social organisation –such as their relations to actors within their national regimes in which they carry out their primary work. In this regard, the functionalist approach underestimates the problems that usually associated with coordination between governmental authorities identified in the public administration literature. Overall, this theoretical lens provides for an overly general explanation since functional pressures are deemed to induce coordination regardless of the formal rules that structure interaction between national regulators (i.e. the regulatory tasks of EU bodies) and the specific (national) contexts national regulators operate in. Similarly to the constructivist approach, then, the functionalist account overstates its argument in relation to the neglect of variation of coordination patterns across vastly different institutional contexts of regulatory actors across different policy sectors.

1.2.3 Rational Choice (Institutionalist) Approaches: Interest-driven Coordinative Behaviour?

Rational choice institutionalists suggest that national regulators' behaviour at the transnational level is strategically driven. The 'shadow of hierarchy' view of the EU governance literature emphasises that in principal-agent relationships national officials coordinate if there is a threat that coordination will otherwise be replaced by hierarchical intervention (i.e. intervention by the principal) (Héritier and Lehmkuhl, 2008, 2010; Eberlein, 2010b; also see Börzel, 2010; Rhodes, 1996; and Scharpf, 1997). This idea usefully highlights that despite the lack of formal authority of EU regulatory bodies, 'hierarchy' is not necessarily absent when coordination between national authorities in the EU is concerned and might hence indeed be a determinant of coordinative behaviour: After all, these interactions take place within the framework of a legal system in which hierarchical authority is present in the form of the legislative process of the EU, as well as the European Commission and the European Court of Justice as 'guardians' of the European legal order. Nevertheless, these approaches tend to neglect

that the EU regulatory bodies that bring together networks of national authorities are largely a result of the lack of capacity on part of the EU's central institutions to formulate technical regulatory standards, guidelines and behavioural standards (Dehousse, 1997; Eberlein and Grande, 2005; Eberlein and Newman, 2008; Majone, 1997).[18]

As such, it is unlikely that the 'shadow of hierarchy' can fully explain the coordinative behaviour of involved actors: In many regards, it is the lack of sufficient hierarchical capacity which brings national regulators together to coordinate their practices in the first place. The assertion that these hierarchical 'threats' shape behaviour have been largely based on assumptions underpinning theoretical principal-agent modelling, rather than empirical substantiation. It assumes that actors' behaviour is shaped by the formal rule frameworks in which they operate, rather than by the immediate activity they have been tasked to carry out, which differ widely across EU regulatory bodies. Regulatory actors across all policy sectors and Member States are embedded in this larger formal rule framework, whilst coming together to fulfil a variety of activities at the transnational level. The assumption that actors consider the large scale implications of their actions in relation to the 'grand' institutional framework they are embedded in remains questionable, especially since it has difficulty capturing variation in transnational coordination patterns. Regulators are also embedded in micro-level frameworks that govern their immediate interactions with other actors (such as the tasks of EU bodies). These are also likely to be of concern to involved actors, which the rational choice institutionalist approach tends to neglect. Nevertheless, this approach helpfully points out that the larger formal rule framework that regulatory actors operate in (such as the legal system of the EU) cannot be neglected.

Importantly, this approach counteracts the weaknesses of the constructivist and functionalist lenses by acknowledging that regulators can have political interests, such as power and the accumulation of resources. This is crucial since it takes into account that national regulators are unlikely to be only motivated by professional norms. However, rational

[18] In the literature on coordination, Lindblom has also pointed out that the coordination of complex policies is too difficult for a central decision-maker (1959, 1965).

choice institutionalist approaches tend to focus on material and instrumental interests. In this regard, this approach seems to regard the interests of national regulators to be exogenous to the institutional framework of the system of the EU. Interests, however, are arguably formed in complex institutionalised settings, which include –but go beyond– the professionally motivated seeking of reputation, 'power' or resources within the incentive structures of the EU system (in relation the role of social relations in informing views of what is 'rational', see Wildavsky, 1987, 1992).

In this regard it is also worth mentioning rational choice approaches since they explicitly acknowledge the importance of interest-driven behaviour of bureaucratic actors. (To the author's knowledge, however, these have not been applied to transnational coordination between regulators in the EU so far). The rationalist budget-maximising approach, for example, stipulates that bureaucratic actors are motivated by the aim to maximise their organisation's budget as a means to increase their own power (Niskanen, 1994 [1971]). This approach directs our attention to the rational behaviour of regulators as operative arm of an emerging transnational bureaucracy (Trondal, 2010; also see Wilson, 2000 [1989], pp.31-110): Since the engaging in the solving of coordination problems is costly, national regulators are likely to want to receive some kind of added value from transnational processes. Yet, such approaches leave little room for the different incentive structures provided by differing formal rules – such as the regulatory tasks of EU regulatory bodies– that structure relations between national regulators in specific ways. They also over-emphasise the material and instrumental nature of preference formation at the expense of interests that are shaped by institutional contexts (for example, Wildavsky, 1994). In this respect, they cannot adequately explain how national regulators are able to perform cost-benefit analyses that would enable them to decide whether or not to coordinate. For example, how they define and weigh potential collective gains against potential losses of reputation as a result of engaging at the transnational level is arguably impossible to understand without taking into account the settings of social

relations that regulatory actors are embedded in: Regulators are likely to apply interpretative filters that enable them to conceive of such costs and benefits in ways that correspond to their way of seeing the world (*ibid.*).

On the empirical level, this rational choice inspired framework also does not necessarily hold up well in relation to transnational coordination of regulators in the EU. If national regulators in the EU are budget-maximising, we can expect them to engage extensively in transnational processes because the additional task of coordinating with their colleagues endows them with extra resources. Indeed, in some cases national authorities receive EU funds to partake in the work of EU agencies: For example, national food risk assessors receive money from the European Food Safety Authority for their contribution to transnational coordination.[19] Also, drug and food safety experts receive remuneration for scientific assessments they prepare for the European Medicines Agency and the European Food Safety Authority.[20] In the former case, however, these contributions are relatively small amounts, which are reportedly insufficient to cover the costs of even the most formalised coordination activities.[21] Indeed, national regulators usually experience a (perceived) loss of resources through their experts' involvement in the work of EU agencies since their experts are often busy with 'European businesses' instead of doing their job at home. In other cases, national experts heavily involved in EU working groups do not receive any remuneration, such as in the case of the European Banking Authority.

It hence seems difficult to explain engagement in coordination purely from a budget-maximising perspective. Even though medicines regulators receive relatively substantial remuneration for their work in the European Medicines Agency, national officials in other policy sectors receive little or no financial reward for their efforts. This, however, does not correspond to the absence or presence of engagement with coordination on the empirical level. Nevertheless, such a rationalist perspective reminds us that regulators

[19] Financial contributions are attached to the so-called 'Focal Point Agreements' that EFSA concludes with each national authority individually. These payments, however, do not have an official legal base and remain informal in character (EFSA, 2013c, p.16ff).
[20] For example, see MHRA, 2013, p.6.
[21] EFSA, 2013, especially p.23.

are likely to want to see some kind of 'pay-off' from their engagement with coordination processes.

Overall, these three theoretical strands point towards important underlying motivations for coordination: Professional norms, instrumental rational action, and the pressures of interdependence are all likely to play crucial parts in shaping coordinative behaviour. However, all three approaches neglect that the coordinative behaviour of national regulators is likely to be shaped by the context of social relations they are embedded in, as well as the specific relations that are set up between them by the regulatory tasks of EU bodies. These insights are reflected in the next section of the Chapter that elaborates the theoretical framework of this study and the central argument of the thesis that is derived from it.

1.3 Defining the Determinants of Coordinative Behaviour: Social Relations and Tasks

Whilst previous literature has put forward that regulatory actors' coordinative behaviour is determined by professional norms, (perceived) functional necessity, or the shadow of hierarchy, this thesis argues that coordinative behaviour is determined by strategic behaviour of national regulators that is aimed at 'getting something out of' coordination. Interests of national regulators, however, are not seen to be determined by professional norms, material utility or perceived functional pressures alone. Rather, national regulators' perception of their own interests are formed in the complex setting of the social relations they are embedded in (see Section 1.3.1), as well as during the process of carrying out tasks in the forum of EU bodies (see Section 1.3.2). National regulators evaluate whether the task carried out by a given EU body is desirable through the interpretative filter of the social relations they are embedded in, which are usually the national contexts in which they carry out their main regulatory work. These conceptualisations are then also affected by the act of carrying out specific tasks in EU bodies: Tasks provide specific institutional frameworks for

strategic interaction. A particular task hence requires interests of national regulators to be expressed in a particular way and sets out a particular calculus of reward. This study hence argues that coordination patterns found in transnational processes vary significantly since the tasks of EU regulatory bodies and the social relations national regulators are embedded in vary across policy areas and countries. Although the discussed literatures explain important aspects of the coordinative behaviour of the involved regulatory actors, they fail to account for the variation that this thesis argues fundamentally characterises transnational coordination processes.

The thesis takes an analytical outlook that is aligned with an actor-centred institutionalist approach (Mayntz and Scharpf, 1995; Scharpf, 1997, 2000). This means that the strategic interactions of actors are placed at the heart of understanding what determines coordinative behaviour. However, strategic interactions are shaped by the specific relations set up between actors through the tasks they are performing in EU bodies and the social relations national regulators are embedded in.[22] The thesis applies a cultural institutionalist understanding of social organisation. This theoretical approach emphasises that actors' perception of their own interest is shaped by how they see the world as a result of being embedded in particular forms of social organisation (Douglas, 1986; Douglas and Wildavsky, 1982; Wildavsky, 1992; Thompson, Ellies and Wildavsky, 1990).

1.3.1 Social Relations Inform Coordinative Behaviour

Regulators are embedded in social relations beyond the EU, which act as interpretative filters and as vehicles for interest formation since they inform the way these actors view the world. National regulators are effectively involved in a multi-level game, in which transnational coordination with their colleagues only represents one (often rather small) aspect of their work. The social relations that actors are embedded in represent their main frames of reference in relation to which they structure their behaviour. In

[22] Scharpf has referred to the former aspect as 'actor constellation', whilst calling the latter factor 'actor orientations' (Scharpf, 2000, p. 775ff), which, in this thesis are defined in a socio-cultural manner. In contrast to his formulation of actor-centred institutionalism, however, these factors hold greater importance in the approach of this study than he has ascribed to them.

engaging in transnational coordination, then, national regulators assess the value they can derive from this process in relation to the social relations that matter most to them in their regulatory work. These are usually found in the national arena (whilst not being restricted to this). This thesis hence argues that the assessment of the value of tasks carried out by EU regulatory bodies –and whether proactive engagement with them is seen as desirable by national regulators– are informed by factors outside the EU framework of coordination.

Social Relations Represent Interpretative Filters

National regulators evaluate the task carried out by an EU regulatory body through the interpretative filter of the social relations they are embedded in. This thesis hence takes a theoretical outlook that emphasises that actors create meanings through interactions: They interact with other actors in frameworks of social relations –i.e. patterns of interpersonal relations– and cultural biases –i.e. shared values and beliefs– which inform the way in which they view the world (Thompson, Ellis and Wildavsky, 1990).[23] Social relations and biases fundamentally frame how regulatory actors approach, view and evaluate a particular situation or activity. These include (but are not limited to) formalised relationships with other (governmental) actors in or beyond their country, informal relations –such as their relation to the media or other societal actors– as well as the professional norms of their expert communities. How confined national regulators are in the framework of the social relations they are embedded in (such as the institutional ties they have to other governmental authorities in their home country) and

[23] This thesis is hence based on a theoretical framework of cultural institutionalism. Without taking into account the social relations and cultural biases which inform how actors create meanings and interpret the world, we cannot understand how formal rules systems come about or how actors make use of these formal systems, such as the regulatory tasks that are deemed to structure coordination at the micro-level in this thesis (see next sub-section). The cultural theory of institutions emphasises that meaning is constructed by social actors through their experience of everyday life, their interactions with other actors, their interpersonal (or organisational) relations, values and beliefs (for example, Douglas, 1986, 1992; Douglas and Wildavsky, 1982; DiMaggio and Powell, 1983, 1991; Meyer and Rowan, 1977; Thompson e*t al.,* 1990; Wildavsky, 1987).[23] These aspects form the basis of institutions, which, in turn, structure how actors confer meaning upon situations, events, relations and objects (Thompson *et al.,* 1990). Cultural theory approaches as defined by Mary Douglas, Wildavsky and Thomposn *et al.* hereby bear the crucial advantage that they clearly include formal and informal forms of social organisation in their theoretical understanding of institutions and make these tangible through their definitions of social relations and cultural biases.

how much their thinking is informed by particular biases (such as the norms of their professional communities) affects how they evaluate the tasks carried out by EU regulatory bodies (compare to Thompson *et el.,* 1990, p.5f).

Social Relations as Vehicles for Interest Formation

As rational actors, national regulators seek to offset the costs related with engagement with transnational coordination with the potential benefits that are attached to it. Engagement with transnational coordination is costly for them: They invest time and resources in these processes and other costs are potentially associated with the support of the work of an EU regulatory body, such as a potential loss of their own sphere of influence or professional reputation as a result of the presence of an EU body in 'their field'. However, whether such costs indeed exist –or are perceived as such– by a particular national authority is framed by the interpretative filter or the social relations they are embedded in: The conceptualisation of actors' interests can only be understood in the framework of social relations in which they create meaning. For example, whilst the particular national context an authority is embedded in might render proactive engagement with the work of an EU body costly in terms of reputational losses in its home country in favour of the EU body, in a different national context a national regulator might perceive the work of an EU body as beneficial for bolstering its own reputation within its home country. How regulators assess the costs and the benefits of transnational coordination is hence context dependent in that it is filtered through the lens of the social organisation a national regulator is embedded in (see Wildavsky, 1987, 1992, 1994).[24] Congruent with the thinking of actor-centred institutionalism, then, actors' interests include subjectively defined material and immaterial interests (Scharpf, 1997, p. 19-22). Since these 'cost-benefit analyses' can potentially vary from regulator to regulator as well as from policy area to policy area to the extent that regulators are embedded in

[24] As put forward by Mary Douglas, we need to "treat cultural categories as the cognitive containers in which social interests are defined and classified, argued, negotiated and fought out" (1988, p.473): Any meaning can only ever be constructed *socially.*

different forms of social organisation, we can expect engagement with coordination to vary across country and policy area.

Social Relations Inform what Regulators Value

National regulators perceive transnational coordination through the interpretative filter of the social relations they are embedded in beyond the EU framework. Through this prism they conclude whether –and in which way– the task carried out by a particular EU regulatory body is of value to them. This thesis puts forward that this evaluation takes place in relation to the social relations that constitute the primary frame of reference of a given actor, i.e. the social relations at which an actor primarily aims its practices. In relation to the EU, this is mainly –but not necessarily only– the national context in which national regulators are embedded. The social relations at the national level have usually shaped regulators' administrative capacities, regulatory philosophies and administrative traditions over decades. These factors all inform the practices and ideas that regulators bring to the transnational level and constitute the interpretative filter for evaluating whether they can gain an added value from the tasks performed by EU regulatory bodies. Effectively, national regulators are embedded in multi-level games: Transnational coordination in the forum of EU regulatory bodies is not a closed system in which only the directly involved actors shape the functioning of the coordination process. Rather, whether national regulators see a value in the task carried out by an EU body –and hence whether they are willing to engage with this task proactively– depends on whether they see this to be desirable in relation to their main regulatory work, which usually takes place in the context of their home country, but is also often framed by other aspects, such as the importance of international regulatory bodies to the involved national regulators.

National regulators' coordinative behaviour is hence informed by parameters outside the EU framework, which reflects that national authorities are the operative arm of this transnational bureaucracy: Their main line of work is not to coordinate their actions with sister authorities from other EU countries. Rather, their main duty is usually the carrying out

of regulation 'on the ground' in their home countries. Auxiliary activities such as transnational coordination are hence evaluated in relation to this primary frame of reference which is constituted of the social relations that are most crucial for national regulators in their day-to-day regulatory work. These are essentially the 'situational imperatives' that the operative arm of a bureaucracy is embedded in: Wilson has drawn our attention to the fact that the behaviour of bureaucratic actors 'on the ground' is informed by the situations with which they have to cope on a day-to-day basis (2000 [1989], pp. 36ff). In this respect, key insights from public administration research can help us to refine our understanding of the determinants of regulatory actors in the EU.[25]

1.3.2 Tasks Shape Coordinative Behaviour

Whilst the wider social relations national regulators are embedded in act as interpretative filters for evaluating the work of an EU agency, the assessment of its desirability is also shaped by the tasks that national actors carry out in the forum of EU bodies. EU regulatory bodies fulfil specific tasks within transnational regulatory regimes: Some EU bodies have the task to set technical regulatory standards. Another task carried out by national officials in the forum of EU regulatory bodies is the generation of new knowledge about specific risks (such as food safety risks). Others have the task to take decisions on the safety of specific products before they enter the market or to inspect the regulatory practices of national authorities. This thesis argues that regulatory actors define and re-define their own interests while they are in the process of carrying out particular tasks in EU regulatory bodies. This means that their conceptualisation of their interest is not unwaveringly fixed when they enter the transnational arena. Rather, their own interpretation of their interests –conceived of through the filters of social relations– is affected by the tasks of EU bodies: These tasks represent the particular institutional framework that structures strategic interaction between the involved actors. Particular tasks hence require

[25] This is reflected in wider 'public administration turn' of EU studies (Trondal, 2010).

interests to be expressed in particular ways since they configure the involved actors into specific relations and set out a specific calculus for reward. In fulfilling a series of different control functions, tasks also set in motion different dynamic feedback loops that constitute coordination processes. National regulators hence evaluate whether the nature of the coordination *process* –which is structured by the task of a given EU body– is desirable in their eyes, rather than merely assessing the desirability of a given task at face value. This also means that tasks set specific frames for actions since regulatory actors define and re-define their evaluation of a particular task while carrying out the activities required by the task.

Tasks Represent Institutional Frameworks for Strategic Interaction

The regulatory tasks of EU bodies provide the institutional frameworks for interactions between regulatory actors at the transnational level. Tasks represent institutional frameworks that set up specific relationships between involved actors. They hence arrange the involved actors into particular constellations (Scharpf, 1997, p. 44ff; 2000, p.775ff). They arrange how, when, where and with whom actors meet for a specific purpose. An inspection task of an EU regulatory body, for example, arranges the involved actors into a constellation that has the EU body at the apex of all involved relations: It configures the main coordinative relation between the EU body and individual national authorities and sets out in which format their interactions take place (and hence to which extent this configures a top-down relationship between EU and national regulators). Depending on the task, then, horizontal or vertical relationships between involved actors are established through this institutional framework. Outside the framework provided by a particular task, the involved actors might have a different relationship with each other than when the carrying out of this particular task is concerned: Depending on the task, an actor meets fellow actors eye-to-eye or on a top-down basis. The institutional framework provided by an inspection task of an EU body, for example, sets up a vertical relationship between the EU body and national authorities whilst they are being inspected by the EU body. When, however, they come together outside

the institutional framework provided by this task they might meet as partners on a horizontal level.

Tasks hence also define the specific roles actors play in a particular process, which are mutually enforcing with the specific relations that are set up by a given task. This means that the very same actors might play different roles in the context of the carrying out of different tasks. Take standard-setting, for example: If an EU regulatory body has the task to set technical standards national regulators come together in its forum to formulate and decide on these rules. In that setting, their role is defined as one of being competitors in the seeking of influence on the end result. It defines their role to be one of adversaries in this particular context, even if the involved actors have very friendly relations with each other outside the context of the institutional framework provided by a standard-setting task.

These institutional frameworks also set up particular incentive structures for the strategic behaviour of involved actors. Standard-setting, for example, provides for an incentive structure to influence proceedings to the greatest degree possible. An inspection task of an EU body, in turn, sets up the incentive for national regulators to do everything in their power to appear compliant with the required norms. These incentive structures are mutually reinforcing with the relations and the roles that are established by tasks.

Moreover, tasks shape the interaction dynamics between actors by providing arenas for contention and agreement, which mutually reinforce the relations, roles and incentive structures created through the institutional frameworks which tasks represent. For example, one-off decision-making and standard-setting tasks both set up coordination patterns that are based on horizontal links between national regulators. However, by providing different incentive structures for strategic behaviour for regulatory actors the former presents an arena in which coordination is based on the seeking of agreement between regulatory actors: Since the decision that is taken does not constrain all further actions of national regulators the task provides an arena in which opinions can be openly exchanged and consensus sought. The latter, in turn, supplies a container for

coordination that is based on the resolving of contention between national regulators: After all, their further actions will be constrained by the decision taken.

This thesis hence suggests that tasks provide institutional frameworks at the micro-level, and hence provide specific incentives for strategic behaviour. Contrary to the dominant view in the constructivist literature, then, mutual exchange and learning is not necessarily on the cards when national regulators come together in EU bodies: National officials do not simply enter the room at the premises of EU regulatory bodies to be together and exchange views (even though this is likely to be part of their get-togethers). Rather, they carry out their actions in specific institutional frameworks that provide different incentive structures for strategic behaviour. Since the institutional frameworks provided by regulatory task differ across EU bodies, we can expect coordination patterns to vary as well. This approach can hence capture and explain variation that has been overlooked in the relevant literature.

Tasks Set in Motion Different Patterns of Control

The effects of tasks on behaviour are not static in nature: Tasks fulfil specific control functions in dynamic feedback loops of coordination, in which national authorities become aware of each other's practices, set (informal) standards for coordinated practices and modify their behaviour to match these standards (whilst then continuing the feedback loop of becoming aware of each other's practices, setting standards, etc.).[26] For example, the task of setting a shared norm for how much wine each group member needs to consume per week fulfils the function of setting a standard of acceptable group behaviour. In a dynamic conceptualisation, however, the coordinative process is not 'fulfilled' at this point. Rather, this is an on-going process: 'Coordination' of behaviour requires that group members gather information on whether their 'wine standard' is adhered to and if not change their behaviour accordingly (or re-wise their standard instead)

[26] Such a 'feedback loop can be conceptualised in cybernetic terms, whereby a control system needs to have a means to set standards of acceptable behaviour, of gathering information on whether this standard is met and of modifying behaviour if the standard is not met (Ashby, 1956; Beer, 1966; Dunsire, 1978; Hood *et al.,* 2001).

(Dunsire, 1978; Hood *et al.*, 2001). Coordination is usually referred to as a process ('coordinating') or/and an outcome ('is coordinated') (Alexander, 1995, pp.3ff; Chisholm, 1989, p.28; Mintzberg, 1979). A dynamic conceptualisation firmly emphasises its nature as *a process* and shows that tasks fulfil particular functions in feedback loops: Coordination is as a process that entails mechanisms of setting standards, gathering information on whether they are adhered to and modifying behaviour if there are not (Dunsire, 1978; Hood *et al.*, 2001). Whilst some tasks fulfil a standard-setting function in these cybernetic feedback loops, others fulfil information-gathering or behaviour modification functions (or a mixture of some of these control function).

Dynamic coordination processes entail the establishing of agreements on regulatory practices (standard-setting), the becoming aware of each other's practices (information-gathering) and a mechanism to change regulatory practices as a result of the newly emerged (informal) standards (behaviour-modification). Specific tasks, in turn, fulfil particular control functions in such a coordinative feedback loop and hence set in motion different forms of coordination patterns. For example, a task that mainly fulfils a standard-setting function (such as taking one-off decisions or technical standard-setting) sets a control loop in motion which puts standard-setting at the heart of interactions and hence requires information-gathering and behaviour modification to support the standard-setting function through formal or informal means. For instance, when regulators come together to set a technical standard, the discussions about which standard should be chosen can serve as an information-gathering exercise in which national authorities disclose their current practices, and try to persuade each other to change these practices. These aspects of the coordination process then form part of the assessment of the perceived value a given task is offering to a national regulator. For example, if that national regulator particularly values to receive information about the practices of other authorities this authority might see the task of the given EU body as desirable. Particular tasks hence fulfil specific control functions in the dynamic feedback loop of coordination. These functions need to be

complemented by the 'missing' control functions through mechanisms that complement the function carried out by a formal task. The (informal) mechanisms that develop as a result will form part national regulators' assessment of whether this task is desirable in their perception. Cybernetic insights from bureaucracy studies thus help us to re-define our understanding of what determines coordinative behaviour of regulatory actors in the EU.

Coordination is hence not an outcome that is 'achieved' and then stopped and evaluated by national regulators on such a static basis.[27] Rather, national regulators evaluate the *process* of coordination unleashed by a particular task of an EU body. This dynamic conceptualisation of coordination bears the advantage that it avoids the pitfall of describing coordination as an inherently desirable state of affairs that is either 'achieved' or 'failed to achieve' (Alexander, 1995, p.5ff) and thus evaluated by involved actors. This view was already present in Lindblom's pioneering work on coordination, in which he conceptualised coordination to produce positive outcomes to participating actors: Coordination in this view avoids negative consequences (Lindblom, 1965, p.23 and p.154).[28] If conceptualised as a dynamic process, however, coordination is a continuous feedback loop, rather than an outcome that has a beginning and an end. It is this process –rather than an outcome– that national regulators assess when evaluating whether the task fulfilled by an EU body is desirable in their view. As a result, national regulators discover –and potentially redefine– their assessment of a task of an EU body in the process of carrying out activities in the forum of this EU body.

[27] Indeed, this thesis suggests that this conceptualisation is most appropriate in a context in which a regulatory problem is likely to have altered by the time the regulatory response might be fully 'coordinated': In the context of permanently changing EU rules, industry structures, and regulatory problems, this process needs to be regarded as being permanently ongoing.

[28] Importantly, Lindblom clarified that coordination can happen through direct interaction between actors, but also through 'mutual adjustment': In this case, actors change their behaviour as a response to the actions of other actors with whom they do not interact directly, such as found in competitive markets (Lindblom, 1965, p.154). It has been noted, however, that such an all-encompassing definition of coordination runs the danger of almost making the concept meaningless (Alexander, 1995, p.5).

Tasks Set Frames for Action

Since regulatory bodies evaluate and re-evaluate the task of a given EU body in the *process* of coordinating, their own definition of their interest –and hence their coordinative behaviour– is *activity* related. Tasks hence set frames for action because the act of carrying out a specific activity affects how actors view the process in which they are involved. In this regard, the role of tasks in establishing institutional frameworks, in setting in motion different patterns of control, and in providing frames for action reinforce each other. Tasks do not just prescribe what EU regulatory bodies –with the support of national officials– should achieve. They also require specific actions of the involved actors and hence frame their strategic behaviour in specific ways. This means that regulators do not arrive at the transnational level with unwavering pre-determined interests that are not affected by the activities they perform when coordinating. Rather, they at least partially start to conceive of their own interests (through the filter of social relations) in the act of carrying out an activity (Cohen, March and Olsen, 1972, p.2). Regulatory actors hence "arrive at an interpretation of what they are doing and what they have done while in the process of doing it" (*ibid.*). Since different tasks require different activities of regulatory actors, we can expect coordinative behaviour to differ across EU bodies with different tasks. Whilst a standard-setting task, for example, requires strategically acting authorities to perform acts of bargaining and persuasion, an inspection task requires acts of immaculate self-presentation. Organisational theory literature –such as the just mentioned insight from the garbage can model– hence help us to re-conceptualise the determinants of coordinative behaviour from explanations based on norms and functional pressure to activity based explanations.

Overall, the theoretical approach taken in this thesis hence argues that actors act strategically (i.e. in their interest). Their strategic behaviour, however, is shaped by the particular task they are performing and informed by the social organisation they are embedded in. The remainder of this thesis is organised as follows: Chapter 2 sets out the research strategy of the

thesis which is aimed at the verification and substantiation of the above thesis argument. Chapters 3-6 then present the empirical findings of the study in the form of four case studies. This is followed by a concluding Chapter 7 which recaps the main results and expands upon the more general contributions of the thesis.

Chapter 2

Research Strategy

In-depth qualitative study of the involved regulatory actors and their interactions in individual regulatory regimes is most appropriate in the context of this study. It allows the analyst to study the perceived interests of actors emerging from their social relations, while also providing us with an opportunity to study the functioning of transnational coordination –as shaped by the task of a given EU body– in detail. Only if we ascertain the way in which coordination functions can we understand why national regulators evaluate the tasks carried out by EU bodies as desirable or not. In this regard, coordination in the field of drug safety, maritime safety, food safety and banking supervision, and the regulatory authorities of the UK and Germany are selected as cases for analysis (see Section 2.1). These cases are then used to verify and substantiate the observable implications that can be derived from the theoretical argument of this thesis that was developed in Chapter 1 (see Section 2.2).

2.1 Case Selection

The cases of drug, maritime, and food safety, as well as banking supervision are chosen since the given EU regulatory bodies have differing tasks,

ranging from technical standard-setting, over one-off decision-making, to knowledge generation and inspections. This allows us to gauge the effect of tasks on coordinative behaviour. The cases also provide us with relevant similarities and differences in relation to the social relations that the involved regulatory actors are embedded in. This gives us an opportunity to ascertain in which manner social relations inform coordinative behaviour (see Section 2.1.1). Moreover, the UK and German regulators are selected in order to study the engagement of national authorities with transnational processes in-depth. What specifically a regulator can 'get out of' transnational coordination depends on the social relations it is embedded in. The UK and Germany were selected to represent an interesting diversity in this regard (see Section 2.1.2).

2.1.1 Case Selection of Regulatory Regimes

Suitable case selection is vital in order to provide for analytical leverage: We need to have confidence that the chosen case studies indeed show something about the effect of the hypothesised determinants on the observed outcome (i.e. coordinative behaviour) (Gerring, 2006). Hence, the case selection needs to represent variation across the hypothesised explanatory parameters (and thus most likely variation in the observed outcome). Case selection according to this principle has been coined the *diverse case method* (*ibid.*, p.97ff). This ensures that the effect of the explanatory parameters is at least partially assessable (which is not given if the cases do not differ in the value of the explanatory factors). In other words, by choosing cases that differ on the value of the 'independent variables' we can expect the observed outcomes to differ in line with these different values. Whereas regulatory tasks can be clearly identified *a priori* by the analyst, the study of social relations that directly affect coordinative behaviour is less tangible. It was hence decided to select cases in which the tasks of EU bodies vary (see Table 2.1). This allows us to verify whether the institutional frameworks provided by different tasks indeed result in

different patterns of coordination (i.e. different types of conflicts and mechanisms to resolve them).

Nevertheless, an attempt was made to incorporate the interpretative filter provided by the social organisation that regulators are embedded in into the research design. A comparative framework was chosen in order to gain a better understanding of the way in which social organisation shapes the evaluation of the desirability of the tasks carried out by EU bodies on part of national regulators: Firstly, cases in which EU bodies have a similar task but the social relations of the studied national regulators differ were selected. This allows us to study how the different social relations that underpin different policy areas affect national regulators' evaluation of a similar task of an EU body. Secondly, cases were chosen in which the involved regulators have similar professional norms (or 'cultural biases'), but EU bodies have differing tasks. Since the relevant literature overwhelmingly emphasises the norms of professional communities as driver of coordinative behaviour, this comparison is vital in order to study whether the coordinative behaviour across these two cases differs despite their similar professional norms.

Table 2.1: Case Selection

	Maritime Safety	Drug Safety	Food Safety	Banking Supervision
Inspection Task	x		x[i]	
One-off Decision-making		x		
Knowledge Generation			x[ii]	
Standard Setting				x

[i] Food control (i.e. food safety inspections).

[ii] Food risk assessment.

In line with the argument of this thesis, coordination patterns should vary in line with the respective task, and national regulators should evaluate their value in relation to the social relations that represent their main frame of reference (i.e. usually national contexts). A further comparison aims at bolstering the argument of this thesis, which is a case in which the resources and authority of the EU regulatory body changed during the studied period whilst its tasks and the relevant social relations remained unchanged. We can hence analyse whether tasks and social relations indeed constitute the main drivers of strategic coordinative behaviour, even if the formal authority of an EU body is altered (see Table 2.2).

Table 2.2: Comparative Framework

	Maritime Safety	Drug Safety	Banking Supervision (CEBS)
Food Control	Most similar in regard of the task of the EU body (study of the effect of embedding in different social relations)		
Food risk assessment		Most similar in regard of professional norms (study of the effect of the tasks of the EU bodies)	
Banking supervision (EBA)			Most similar in task and social relations (study of the effect of formal authority and overlooked factors)

As a result of these case selection criteria, the regulatory regimes of maritime safety, food safety, banking supervision and drug safety were chosen (see Tables 2.1 and 2.2).

Cases of Regulatory Regimes

Drug Safety The European Medicines Agency (EMA) has the task to take one-off decisions on whether drugs can be deemed safe before they enter the market and when they are already in circulation. This offers a crucial comparison to coordination among food risk assessors. In both cases the experts involved form part of scientific communities that arguably share similar professional norms (or 'cultural biases'). Yet, the regulatory bodies in the two cases have differing tasks. This helps us to analyse to what extent different tasks and social relations at the national level –rather than professional norms– indeed drive coordinative behaviour.

Maritime Safety In the case of maritime safety, the EU regulatory body 'EMSA' (the European Maritime Safety Agency) has an inspection task: It has to inspect the practices of national maritime safety authorities in relation to their conformance with EU requirements. It hence represents a case of an EU body with an inspection task in order to study its effect on coordinative behaviour. This entails the study of whether national maritime safety authorities accept the oversight of an EU body over their work and if so why (i.e. how their evaluation of the desirability of this task is informed by the social relations they are embedded in). Also, the maritime safety case serves as a comparative case in relation to food controls: In the food safety regime the Food and Veterinary Office (FVO) has the task to inspect the practices of national authorities. However, the social relations national authorities are embedded in differ significantly: Whilst national maritime safety authorities have been cooperating for decades in the International Maritime Organization, food control authorities are widely dispersed and lack an overarching professional community. This comparison thus serves to further our understanding of the manner in which the social relations that

actors are embedded in inform the assessment of the task performed by an EU body.

Food Safety The food safety case allows us to study two EU regulatory bodies: Food risk assessment is the responsibility of the European Food Safety Authority (EFSA). The Food and Veterinary Office (FVO) is in charge of the realm of food controls (i.e. inspections of food businesses). As already mentioned, the FVO has the task to inspect the practices of national authorities (see above). EFSA, in turn, has the responsibility to issue risk assessments and provide scientific advice. In comparison to other EU regulatory bodies, its scientific panels are constituted of 'independent' experts, rather than representatives from national authorities. National officials, however, have the task to come together in the forum of EFSA to generate knowledge in order to support the European agency in its scientific work. The case offers a fruitful comparison to the drug safety case since the they two cases represent two different tasks under conditions of similar professional norms (see above).

Banking Supervision The case of banking supervision represents a case in which the EU regulatory body (the European Banking Authority, EBA) has the task to set technical standards**.** This means we can explore the form of coordination unleashed by such a task. The case is of special interest for two further reasons: The EBA also has the task to orchestrate information exchanges between banking supervisors in relation to their day-to-day supervision of banks. We can hence study whether the coordinative behaviour of the same set of actors indeed differs if they perform a different task (thus also being assessed differently by national regulators). Moreover, the EBA was preceded by the Committee of European Banking Supervisors (CEBS), which possessed less formal authority and resources than the EBA. This provides us with an opportunity to analyse whether the formal authority and resources of EU regulatory bodies have an impact on the coordinative behaviour of the involved actors.

2.1.2 Case Selection of National Regulators

In order to analyse and substantiate the theoretical propositions of the thesis adequately we need to analyse the social relations in which national regulators are embedded 'at home' (and beyond). We hence need to select cases of national regulators that potentially represent a significant variation in the social organisation they are embedded in.

National authorities represent the operative arm of the transnational bureaucracy that is under scrutiny in this thesis. They are the units of this administrative system that go about the day-to-day business of managing risks 'on the ground'. At the same time, they come together in EU regulatory bodies to coordinate their practices. This thesis suggests that we cannot comprehend national authorities' coordinative behaviour without incorporating the analysis of the social organisation they are embedded in, which is usually (but not only) the national context in which they operate. After all, the context of their 'home' regime can be expected to not only shape their perceptions of what an 'added value' is, but also shape what precisely national regulators seek to gain through coordination. In order to account for this, it is necessary to conduct in-depth analysis of national regulators and their regulatory regimes. Moreover, since the regulatory capacity of EU bodies is largely based on the active participation of the regulators that have the necessary capacity –i.e. the resources and the expertise– to contribute to transnational processes (Maggetti and Gilardi, 2011), the thesis suggests that it is most fruitful to study the engagement of 'high capacity' regulators. This is also sensible since it is more questionable what –if anything– 'high capacity' regulators can get out of transnational coordination in contrast to 'low capacity' authorities.

What specifically each regulator can 'get out of' transnational coordination depends on the social relations they are embedded in. The UK and Germany were selected to represent a variation in this regard. They are often described as having different regulatory philosophies and administrative traditions (Bekke and Van der Meer 2001, p.12ff and p.61ff; Knill, 1998; Knill, 2001; Pollitt and Bouckaert, 2011, p.47ff; also see Moran, 2003 and Müller, 2002). Administrative traditions capture administrative structures and styles, and the manner in which these are embedded in the

political-administrative and legal systems of a country (Knill, 2001, p.61). Germany's administrative system is decentralised as a result of its federal structure. Germany's administrative system is hence of a highly segmented character, which, however, is accompanied by hierarchical oversight structures. Moreover, it has a civil service culture focused on civil servants with legal training that serve life-long careers in specific parts of the administration. Actions of officials are usually guided by formal rules. The UK's administrative system, in turn, is far more centralised, which, however, is accompanied by relative autonomy of local government to act with large margins of discretion on a day-to-day basis. This is accompanied by a civil service culture that is more flexible in its expectations of the training officials should receive, and officials frequently rotate to various positions in the civil service. At the same time, administrative units responsible for given areas often have significantly more autonomy from other government actors than their German counterparts (for more a detailed elaboration, see, Knill, 2001, p. 61-84). In relation to differing regulatory philosophies a pertinent example of variation across Germany and the UK is the much higher level of up-take of 'risk-based' (as well as 'principles-based') approaches by UK regulators than by German authorities (Rothstein, Borraz and Huber, 2013). Such regulatory approaches are based on broad underlying principles, rather than detailed formal rules that guide regulatory behaviour.

Such differences in administrative structure and style can be crucial in the sense that national authorities assess the added value of participation with transnational activities in relation to these institutional ties, administrative cultures and regulatory philosophies. Overall, such (structural) differences render it likely that the national authorities of the UK and Germany are embedded in differing social relations that affect their evaluation of the desirability of the tasks of EU regulatory bodies in different manners. However, which social relations most crucially inform what a given regulator values can ultimately only be revealed in in-depth inductive research and these are likely to go much beyond the general differences that were briefly described here. Hence, the empirical chapters engage in

inductive analysis of the social relations that are of direct relevance for the assessment of EU bodies' tasks by UK and German authorities.

Regulators in both countries have important industries and a (long) history of regulation in all four chosen policy sectors (i.e. pharmaceutical industry, banking sector, maritime industry and coastline that foreign-flagged ships call at, and a food industry). This is crucial for understanding why they are deemed 'high capacity' in the context of this thesis: They have had the chance the build regulatory resources and capacities over decades (this is further substantiated in each case study chapter), not least because there is an economic interest in doing so in case of these industries. As a result, German and British regulators have *relatively* large administrative capacities in these areas in comparison to authorities from Member States with smaller industries and/or less differentiated public administrations.[29] It is crucial to note that 'high capacity' here is only used in such relative terms: Ultimately, it remains difficult to define what regulatory or administrative capacities indeed are. Here, they are regarded as a *relatively* high amount of resources (such as budgets and staff numbers) and regulatory expertise, which, for example, might develop as a result of the presence of a long-standing and large industry in a given field.

2.2 Empirical Study of Observable Implications

We can derive concrete expectations for observations on the empirical level from the theoretical argument developed in Chapter 1 and the selected cases elaborated in the previous section (see Section 2.2.1). These observable implications guided the empirical analysis in order to verify and

[29] For example, the Latvian Financial and Capital Market Commission has 124 staff members (FKTK, 2012, p.66) and a budget of approximately €5,779,000 (*ibid.,* p.72). In comparison, the German Federal Financial Supervisory Authority (BaFin) has around 3200 staff members and a budget of approximately €224,000,000. The Czech pharmaceuticals regulator employs around 340 people and its annual budget is around €88,800,000 (SUKL, 2013, p.72f). The British equivalent, in turn, has a budget of around €144,000,000 (MHRA, 2013, p.66) and it has around 930 members of staff (*ibid.*, p.16). However, capacity is not best addressed in quantitative measures alone. Rather, it also crucial whether a given regulator is usually seen as highly expert and competent by its peers in the EU and beyond, and whether its actual performance –rather its potential– is realised (Nelissen, 2002, p.13). In the end, administrative capacity might differ across tasks within the same regulator and whether it exists always remains an empirical question.

substantiate the argument developed in this thesis (see 2.2.2 for a brief overview of the empirical material that was analysed).

2.2.1 Observable Implications

This thesis suggests that the tasks of EU regulatory bodies structure the strategic interaction of regulatory actors in a specific manner and hence shape how coordination functions. National regulators' perception of the value of these tasks –and whether they should engage with them- are formed by the social organisation they are embedded in, i.e. the contexts in which they carry out their main regulatory work. We can derive observable implications about the functioning of the coordination processes across the different cases of regulatory tasks selected for this study from the premises of this theoretical argument. These observable implications are analysed and substantiated in the subsequent empirical chapters of the thesis.

Standard-Setting

The following observable implications will be analysed in relation to banking regulation and supervision: Standard-setting tasks of EU regulatory bodies can be expected to set up adversarial relations between national regulators. Decisions on standards impact all further behaviour of national regulators, as a result of which they can be expected to coordinate in order to influence the decision to the greatest degree possible. Their existing practices are likely to be an expression of their regulatory philosophies and the specific realities they face in the social organisation that inform what they value, i.e. usually the context they operate in 'at home'. As a result, it can be expected that national authorities will usually favour to agree upon a shared standard that supports their current embedding in the social organisation of their home country. A standard-setting task of an EU coordinating body, then, arguably sets into motion a contentious relationship between national authorities and their sister authorities from other countries. The main line of conflict we can expect to observe runs between national authorities (on a horizontal level), rather than national

authorities and EU bodies (vertically). As a result, coordination can be expected to function through a process of bargaining and persuasion in which national authorities attempt 'to get their way': National authorities can derive an 'added value' from engagement with the transnational process by influencing the proceedings in their favour, thus minimising the risk of needing to alter regulatory practices as a result of a new shared standard.[30] How coordination functions when an EU body has a standard-setting task can be expected to be dominated by the 'uploading' preferences (Börzel, 2002, p.195ff), rather than by peer pressure and learning as emphasised by the constructivist literature. Standard-setting hence sets in motion a feedback loop in which national regulators gather information about each other's behaviour in bargaining and deliberative processes of persuasion, which can act as a vehicle for behaviour modification.

One-off decision-making

The subsequent observable implications will be studied in the drug safety case study: When an EU body has a one-off decision-making task we can expect coordination to be based on epistemic competition. Whilst an agreement on a shared technical standard constrains all further regulatory behaviour to be in line with these new standard, one-off decisions usually restrain the behaviour of the risk producing industry, rather than the regulators. As a result, the decision-making process between regulators is likely to be guided by things they agree on, rather than being focused on issues they disagree on as expected in the case of standard-setting. Since the decision will not constrain all subsequent behaviour, they do not need to worry about convincing their peers of their 'way of doing things' to the same degree. Nevertheless, it requires an explicit or implicit agreement on how decision should be reached (for example, which methods or approaches decisions should be based on). Such a task hence sets up relations between national regulators in a competitive manner. At the heart of this competition which forms of data gathering and data evaluation techniques one-off

[30] This idea is expressed in the concept of 'uploading' in the Europeanisation literature, albeit in the context of legislative policy-making, rather than expert decision-making about technical regulatory standards: In this view, Member States governments have an incentive to 'upload' their policies to the EU level in order to minimise the costs of 'downloading' EU policy to the national level (for example, see Börzel, 2002, p.195ff; Radaelli, 2003).

decisions should be based on. In this respect, data-gathering and evaluation techniques of national authorities can be expected to be at the heart of the interpretative filter they apply to evaluate the transnational process taking place in an EU body: National regulators attempt to be or to become a dominant model of decision-making in order to avoid the material and immaterial costs of adjustment as they define it in the context of the social relations they are embedded in. Competition hence presents the vehicle of becoming aware of each other's practices and modifying them in the continuous cybernetic feedback loop of coordination.

Knowledge Generation

The following propositions will be studied in relation to food risk assessment: The regulatory task of knowledge generation involves the purposeful exchange of information between national regulators in the forum of an EU regulatory body and hence mainly fulfils an information-gathering and corroboration function to support the work of an EU regulatory body. At the heart of such a task is the gathering of specific information by national authorities that is collated at the transnational level in order to provide novel sources of expertise that expert decisions and advice can be based on. The task to exchange information leaves national authorities to be freer in their deliberation and sharing of ideas and practices than technical standard-setting or one-off decision-making allows for since future behaviour will not be constrained and no shared decision-making model needs to be agreed on. Mutual exchange of ideas and practices can develop in such a contexts (social organisation of national regulators permitting), and can hence be expected to be the vehicles of the feedback loop set in motion by this task. The existence of this mutual exchange can be expected to result in mutual adjustment if the involved national authorities regard such an adjustment to other regulators' practices or outputs to be beneficial to them in the framework of the social relations they are embedded in.

Table 2.3: Regulatory Tasks and Associated Coordination Patterns

Standard-Setting	One-Off Decisions	Knowledge Generation	Inspections
Bargaining and deliberation	Epistemic competition	Mutual exchange and adjustment	Hierarchy

Inspection Tasks

These propositions will be corroborated in the maritime safety and food safety (food inspections) case: When an EU agency has an inspection task we can expect the observed pattern of coordination to be largely based on hierarchical mechanisms since an EU body inspects national practices in a formal top-down procedure. Whilst EU regulatory bodies do not have the legal authority to act on their findings, their institutional link to the European Commission provides for potential hierarchical enforcement: The Commission can act on inspection findings of EU bodies, including the option of starting an infringement procedure against a Member State. Whilst this does not resemble the truly hierarchical options that are, for example, available to the Commission in competition policy,[31] the Commission's interpretation of EU law nevertheless remains a potentially potent source of coordination in these cases (see Andersen, 2012; Börzel, 2003; Mendrinou, 1996; Tallberg, 1999, 2002). This is closest to what has usually been described as 'hierarchical' or 'bureaucratic' coordination, in which the guiding principles of coordination are formal rules, ladders of authority and conscious oversight (Alexander, 1995; Hood, 2000, p.51ff; Ouchi, 1979, 835f). This task hence sets up a vertical relation between EU regulatory actors and national authorities. In order for hierarchical coordination to function national authorities need to accept the oversight of their work on part of EU bodies (Ouchi, 1979, p.836). This set-up of relations bears the

[31] The European Commission is responsible for enforcing the competition policy of the EU directly (see Art.105, Treaty on the Functioning of the European Union). This means that it intervenes in industry interactions directly, i.e. it represents a regulatory interface with industry. In other fields of EU regulation, national authorities -rather than the European Commission- directly intervene in industry activities and enforce legislation vis-à-vis the industry. (For a discussion of the European Commission's role in competition policy, see, for example, Wilks, 2005).

potential to cause conflicts if national authorities do not willingly accept inspection of their work: In order for these conflicts to be overcome or to be accepted by all involved actors, national authorities hence need to derive a benefit from hierarchical coordination for achieving their regulatory objectives. How they define such a benefit (i.e. an added value) emerges from the social organisation they are embedded in.

2.2.2 Empirical Analysis

The empirical analysis conducted for this study aimed at a deep understanding of the studied regulatory regimes and the social relations that are associated with them, rather than attempting to empirically 'test' hypothesis with a defined set of empirical data. Hence, research for each case study commenced with the development of an extensive historical understanding of regulation in each field of regulation at the international, European and national (i.e. British and German) levels through the study of secondary sources. In-depth empirical analysis of primary sources then focused on the time-period of the establishment of the given EU regulatory body and the year in which the research was carried out. Consequently, the analysis of primary data in the case of drug safety monitoring focused on the time span of 1995 to mid-2012, it covered the years 2003 to 2012 in maritime safety, in banking supervision analysis was focused on the years between 2004 and 2013, and in the case of food safety the primary material covered extended from 2003 to mid-2014 (in food risk assessment) and 1998 to mid-2014 (in food controls).

The primary material analysed varied across the four policy sectors and precise references are made to it in each substantive chapter. In broad terms, the material used to verify the above observable implications was mainly focused on the following documents:

- EU Legislation and guidelines governing the interactions between regulatory actors and the management of risk in the four regulatory regimes.
- Official documents of the studied regulatory actors (i.e. the given EU regulatory body, the British and German regulators, and the

European Commission). These included annual reports, minute meetings (especially of the administrative boards and expert bodies of EU regulatory bodies in which national officials coordinate their practices, as well as of meetings of boards and expert panels in British and German regulators), reports, position papers, and guidelines for and documentation of direct interactions between national officials in EU bodies, and between EU officials and national officials, as well as speeches of regulator executives.

- Regulatory outputs of EU, British and German regulators, such as technical standards, guidelines for industry and regulatory action, scientific opinions, risk assessments and inspection reports.
- Expert literature, such as journal publications of regulatory officials pertaining to the issues they perceive to be crucial in relation to risk management in their field.
- Semi-structured interviews with high-level officials from EU regulatory bodies, British and German regulators and ministries, and the European Commission. These were mostly officials who are directly involved in coordination activities in the forum of EU regulatory bodies. Wherever possible, interviewees covered the time periods stated above by selecting former and present officials for interviews. It was agreed for interviewees to remain anonymous, and interviews lasted between 30 minutes to 2 hours and more (see Appendix for an anonymised list of interviewees). Where interviewees are quoted in the thesis this serves as illustration of points that were supported by the corroborated empirical material, rather than being the only evidence available (see references to empirical material in the substantive chapters in this respect).

The subsequent four chapters report on the results of the empirical analysis carried out on this basis.

Chapter 3

Drug Safety Monitoring

The case study on drug safety monitoring investigates the effect of a one-off decision-making task on the coordinative behaviour of the involved pharmaceutical regulators. Almost all drugs need to be authorised before they can enter the market, which is used as a tool for ensuring sufficient standards of quality, efficacy and safety (Permanand, 2006). Pharmaceuticals regulators hence take one-off decisions about the safety of applicant drugs, as well as about the safety of medicinal products that are already on the market: Information about the safety of drugs is limited when they first enter the market since they have commonly only been tested in a very limited number of people and over short time periods (for example, Routledge, 1998). These groups usually exclude children and pregnant women, and studies presented in market authorisation applications cannot provide knowledge about the effects of long-term use of a given drug (Mann and Andrews, 2007).[32] As a result, countries have systematic monitoring schemes of adverse drug reactions in place, which are mostly based on the spontaneous reporting of adverse reactions by healthcare professionals and the industry to regulatory authorities (*ibid.*).[33]

[32] Moreover, the interactions with other medicinal products will not have been established during pre-authorisation clinical studies. Especially very rare adverse reactions to drugs can only be detected through the monitoring of drugs used by the wider population.

[33] The WHO defines adverse drug reactions (ADRs) as unintended, harmful reactions to medicinal products that occur at a normally used dosage of the medicine (2008). A widely cited review of the relevant scientific literature shows that around 5% of hospitalisations are due to adverse drug reactions (Einarson, 1993). Also, a UK study shows that 0.15% of all patients admitted to hospital die due to such an adverse reaction (Pirmohamed et al., 2004).

National officials come together in the European Medicines Agency (EMA) to take decisions on the safety of drugs on the market based on the data gathered in their respective systems. Information about adverse drug reactions is collated and evaluated at the transnational level in this respect. In evaluating the safety of a drug that is already on the market, national regulators take one-off decisions about whether they can continue to be seen as safe, or whether they should be taken off the market.

As outlined in Chapters 1 and 2, we can expect such a one-off decision-making task to result in a coordination pattern that is based on epistemic competition. The task to exchange and evaluate information provides an incentive for competition between them: In order to avoid the potential cost of adjusting to the data gathering and decision-making models of other national authorities, regulators have an incentive to become the dominant model that other authorities strive towards. At the heart of such a competition driven coordination process is the motivation to provide expertise and decision-making approaches that are seen as 'the best' by officials from other authorities.

This case study also serves as an excellent opportunity to compare the coordination pattern that has emerged between drug safety officials to that which we observe in the case of food risk assessors (see Chapter 5). Officials in both cases form part of a scientific community that arguably share relatively similar professional norms. However, at the transnational level they perform different tasks and are embedded in differing social relations beyond their professional norms. Such norms are seen as significant determinant of coordinative behaviour in the EU constructivist literature (for example, see Majone, 1997, also see Chapter 1). This thesis argues that coordinative behaviour is instead mainly driven by strategic action that is shaped by tasks and informed by social relations. In line with the argument of this thesis, then, we would expect coordination patterns to differ across drug safety and food risk assessment, rather than being similar as a result of the similar professional norms of the involved officials.

3.1 Social Relations and Tasks in Drug Safety Monitoring

The UK and German regulators are embedded in widely differing social relations in their respective drug safety monitoring regimes. The British regulator is embedded in a regime which has developed manifold data sources and data assessment tools over the years. German authorities, on the other hand, are more restricted in their access to data on adverse drug reactions (see Section 3.1.1). The lenses provided by these differing social relations can be expected to inform the assessment of the coordination task of the European Medicines Agency (EMA) on part of UK and German pharmaceuticals regulators. The coordination task of EMA is to take one-off decisions about the safety of drugs that are already on the market: Officials from national regulators come together in the expert bodies of EMA to evaluate and take decisions on safety in light of data that is collated from all Member State authorities. Such a one-off decision-making task can be expected to result in a competitive coordination pattern, in which regulators attempt to supply the best possible expertise and evaluation techniques to the transnational process in order to avoid the cost of adjustment to the models of other regulators (see Section 3.1.2).

3.1.1 Social Relations in the UK and German Drug Safety Monitoring Regimes

An awareness of potential harm arising from pharmaceutical products has been around for hundreds of years; however, market authorisation and safety monitoring procedures only came about in the 1960s as a response to the Thalidomide tragedy (Routledge, 1998). Thalidomide was first introduced in 1957 (in West Germany), followed by numerous countries in succeeding years. Supposedly a harmless cure for morning sickness and nausea, it led to severe birth defects in children of mothers who had taken Thalidomide during their pregnancy (for example, WHO, 2004).[34] Before

[34] In this respect it is vital to note that Thalidomide has undergone a 'revival' in recent years since it is now recognised that harm caused by this drug can be prevented if avoided during pregnancy (Waller, 2010, p. 3). This reflects the new tendency to conceptualise pharmacovigilance as 'risk management process' (Waller, 2010, p. 2; Mann and Andrews, 2007, p. 10). This refers to the identification of the specific risks attached to a product, followed by finding a way to manage these risks by ensuring that adverse effects cannot materialise. Thus, recognised risks are managed through targeted

Thalidomide, virtually the only way to draw attention to safety concerns was the publication of adverse reactions in the medical literature (Waller, 2010, p. 1). In this regard, the Thalidomide crisis represented a veritable turning point in the history of pharmaceutical regulation by bringing about formal market approval systems and schematic surveillance of adverse drug reactions after authorisation (which is called 'pharmacovigilance'). The UK and Germany both adopted comprehensive medicines acts as a consequence of Thalidomide, and established so-called spontaneous reporting systems for adverse drug reactions.

In the UK, the Committee on Safety of Drugs was formed in 1963 as a direct response to the Thalidomide tragedy. A successor of this committee (the Commission on Human Medicine) today forms the expert body advising the Medicines and Healthcare products Regulatory Agency (MHRA),[35] which is responsible for running the UK pharmacovigilance regime (and thus also for the British spontaneous reporting system, called 'Yellow Card Scheme').[36] In the 1980s more proactive information-gathering tools for adverse drug reactions were developed by way of tracking the records of specific patients. Disillusioned by successive drug safety disasters which had demonstrated the weaknesses of spontaneous reporting (Waller, 2010, p. 6), an expert in the field (Professor 'Bill' Inman, who had been influential in the development of the Yellow Card Scheme) developed a more proactive form of gathering data about adverse drug reactions, called prescription-event-monitoring (PEM).[37] This scheme is today run by the Drug Safety Research Unit (DSRU, which works independently from the MHRA). Under this scheme, GPs fill in a questionnaire to record all observed events in the first 10 000 patients they prescribe a newly authorised drug to. As the GPs are obliged to report all events listed in the patients' notes, they do not have to evaluate independently whether a certain event is causally linked to the

interventions (such as providing a female patient who is taking Thalidomide with effective birth control) (Mann and Andrews, 2007, p. 6f).

[35] See Part 1, Section 2 and 3 of the Medicines Act 1968. With regard to pharmacovigilance, it is the Pharmacovigilance Expert Advisory Group of the Commission on Human Medicines that advises the MHRA.

[36] The MHRA was formed in 2003 as a result of a merger between the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA).

[37] William Howard Wallace ('Bill') Inman has been a crucial figure in the development of British pharmacovigilance. For a history of British pharmacovigilance (including details about the development of the DSRU) from the personal perspective of Bill Inman, see Inman (1999).

treatment with the new prescription medicine (for an overview of the system, see Shakir, 2007). Another approach to data collection used for pharmacovigilance in the UK is the General Practice Research Database (GPRD), which also has its roots in an individual initiative (an individual family doctor who developed a database containing his patients' records). The GPRD consists of anonymous records of patients registered at around 480 GP (family doctor) practices in the UK and today forms a sub-unit of the MHRA. No comparable database exists anywhere in the world, thus making it a popular source of data for research, especially with regard to pharmacovigilance (Parkinson, Davis and Van Staa, 2007).[38] The MHRA is hence embedded in social relations that have produced a great variety of data sources on adverse drug reactions. This is likely to inform how this authority approaches and evaluates transnational coordination of pharmacovigilance activities.

Unlike the British system, Germany has not developed a multitude of information-gathering tools over the years. The German system of pharmacovigilance hence relies largely on spontaneous reporting of adverse reactions. The German authorities responsible for the spontaneous reporting system are the Paul-Ehrlich-Institut (PEI, responsible exclusively for biomedical products)[39] and the ‚Federal Institute for Drugs and Medical Devices' (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) (responsible for all other categories of medicinal products). The BfArM and PEI work with almost identical procedures and instruments when pharmacovigilance is concerned (Hagemann and Paeschke, 2007, p. 228). Spontaneous reporting in Germany also began in the first half of the 1960s

[38] The model of compiling patient data developed by a family doctor spread to other practices, firstly through personal contact with the developer, then through a Venture Capital set up for this purpose. Reuter bought this business in 1993, and then donated it to Department of Health in 1994. It was operated by the Office for National Statistics until 1999, and was henceforward operated by the MCA (now MHRA) (for a documentation of the history of the GPRD, see Lawson, Sherman and Hollowell, 1998; Wood and Coulson, 2001). At the time of writing the database has undergone another large change, as it became part of the Clinical Practice Research Datalink (CPRD) in March 2012. This is jointly funded by the MHRA and the National Health Service (NHS) National Institute for Health Service (NIHS). As the empirical data collection for this chapter was completed when this change entered into force, the chapter refers to the 'GPRD', rather than the 'CPRD'.

[39] More precisely, the Paul-Ehrlich Institut is reponsible for vaccines for humans and animals, medicinal products containing antibodies, allergens for therapy and diagnostics, blood and blood products, tissue and medicinal products for gene therapy, somatic cell therapy and xenogenic cell therapy.

as a response to Thalidomide. At that time, however, no national authority charged with the tasks existed (*ibid.*). Rather, the Drug Commission of the German Medical Association ('Arzneimittelkomission der deutschen Ärzteschaft') collected reports of adverse drug reactions in the immediate aftermath of the Thalidomide tragedy (*ibid.*, p. 229). The predecessor of the BfArM was only founded in 1975 after a lengthy period of putting together the medicines act ('Arzneimittelgesetz') as a consequence of Thalidomide. The PEI had already existed since 1896 but only took up a role as public authority of medicines control in 1972. The existence of a research insitute (which also acts as federal regulatory authority) focusing specifically on biomedicines (PEI) renders Germany an expert country in this field. However, Germany has not matched the UK in its availability of data on adverse drug reactions, and data gathering tools resembling the British case would be unlikely to develop in Germany due to data-protection concerns. Instead, recently Germany decided to establish dedicated pharmacovigilance research units in hospitals to obtain more information on adverse drug reactions occurring in specific patient groups (such as children); which was inspired by the French pharmacovigilance model (Hagemann and Paeschke, 2007, p. 229f; Vogel, 2007, pp. 38-43).[40] The relative lack of diverse data sources on adverse drug reactions in the context of social relations in the German pharmacovigilance regime can be expected to inform how German authorities assess the value of the one-off decision-making task they have at the transnational level.

3.1.2 The One-Off Decision-Making Task of EMA

At the European level, the concept of pharmacovigilance was introduced in 1993 by Council Directive 93/39/EEC.[41] The introduction of EU-level pharmacovigilance hereby formed part of the wider European

[40] As introduced in an amendment of the *Arzneimittelgesetz* in 2004 ('12.AMG-Novelle'),§ 62.

[41] Regulation concerned with the market authorisation of drugs and drug safety has since been collated in 'Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use', and 'Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency'.

pharmaceuticals policy developed at the time, which became institutionalised in 1995 through the establishment of the European Agency for the Evaluation of Medicinal Products (EMEA, now the European Medicines Agency, EMA). The main focus hereby was the set-up of EU-wide market authorisation procedures for pharmaceuticals: The centralised procedure in which EMA and the European Commission are responsible for granting market approval and the decentralised procedure and mutual recognition procedures, in which a national authority is responsible for authorising a product for the European market.[42] Pharmacovigilance stayed in the background during these developments, and it is only very recently that the regulatory framework has been strengthened vis-à-vis the regulation of market authorisation, thereby becoming more closely integrated with the latter (Bahri, Tsintis, and Waller, 2007; European Commission, 2007; Waller, 2010, p. 92f).

The requirements of the original pharmacovigilance regime of 1993 were relatively restricted in their scope, mainly demanding each Member State and manufacturer to have a pharmacovigilance system in place, enabling them to gather, collate and evaluate reports of adverse drug reactions.[43] The emphasis has been on rules extended towards the industry, which comprise of detailed reporting obligations, i.e. the type of information that companies need to pass on to the industry and the timeframes within which they need to do so. Regulations for national pharmacovigilance systems have been of a very broad scope, largely leaving the running of these systems up to the Member States. These provisions remained mostly unscathed during reforms of the EU pharmaceuticals regime in 2001 and 2004. The introduction of the data-base *EudraVigilance* in 2001, however, represented a turning point, at which all spontaneous reports started to be assimilated and shared electronically at the European level. The amount of data (i.e. spontaneous reports) to be handled by this electronic system quickly increased from a few hundred to tens-of-thousands of reports (the

[42] There is extensive literature about the European market authorisation procedures, for example, Abraham and Lewis, 2000; Gehring and Krapohl, 2007; Mossialos et. al., 2004; Hauray and Urfalino, 2009; Permanand, 2006.

[43] Art.29a-i, Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products.

facilitation of which has since become one of the major administrative pharmacovigilance responsibilities of EMA) (see EMEA/EMA Annual Reports 1997-2010).

The most dramatic departure from the status quo of the European pharmacovigilance regime occurred with a reform in 2010.[44] In contrast to previous changes to the pharmaceuticals legislation, this reform was entirely devoted to the field of pharmacovigilance (thereby also linking it more clearly to the pre-marketing and market approval stage). In general, the approach of the reform has been to 'strengthen' pharmacovigilance practices, i.e. to give them a higher profile and more wide-ranging tools instead of mainly focusing on the market-authorisation procedure to ensure the safety of drugs (European Commission, 2007).[45] The 2010 reform is crucial in that it shifts the power balance towards the regulator at the expense of the pharmaceutical industry: Regulators are now able to request specific post-authorisation studies from the manufacturer.[46] Moreover, the system has become more centralised since pharmaceutical companies now have to enter reports on adverse reactions into *EudraVigilance*, instead of reporting to their national database.[47]

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[44] Please note that this reform was due to be implemented by July 2012. The empirical analyses conducted for this chapter focused on the time period of the early 1990s to spring 2012, and hence did not include empirical study of the functioning of the reformed regime in action. Nevertheless, adequate references are given throughout the chapter to highlight any possible changes that could have affected the coordinative behaviour uncovered in this case study. However, since the central tasks of the EMA have not changed as a result of the 2010 reform, the coordination pattern described in this chapter is unlikely to have altered fundamentally.

[45] In the EU regime as it stood before the 2010 reform, regulators effectively found themselves in a power vacuum in relation to the industry in the phase between market authorisation and a situation in which there was clear evidence that a drug is unsafe (Waller, 2010, p. 92f). Regulators were thus in control before a drug entered the market as the industry had to supply additional information if requested by the regulator. The moment a drug was on the market, however, this power-balance shifted towards the manufacturer, who was (and still is) usually best informed about the drug in question after this point. The regulator only reached the lost degree of clout in the presence of compelling evidence against the safety of a given drug, in which moment the 'nuclear option' of revoking the market authorisation can be employed (*ibid.*). However, such instances are relatively rare, and often a company will voluntary withdraw a product if it thinks it will lose the battle of data analysis against the regulatory experts.

[46] Art.22a(1)(a), Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.
Art.10a(1)(a), Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

[47] Art.107(3), Directive 2010/84.

The pharmacovigilance tasks of EMA and the national officials meeting in its forum have remained stable over the years despite the mentioned reforms: EMA has the task to make decisions about the safety of drugs on the market by collating and evaluating information obtained through spontaneous reporting.[48] Within EMA, the Committee for Medicinal Products for Human Use (CHMP), comprised of officials from national drug regulators,[49] debates and decides whether a drug is safe in light of the collated data.[50] This is also the committee that authors opinions on whether to grant market authorisation for a drug in the first place (on the basis of which the Commission takes the official decision).[51] The CHMP was advised by the Pharmacovigilance Working Party (PhVWP) –also comprised of national experts– until the most recent reform was implemented in July 2012. This Working Party was subsequently superseded by the Pharmacovigilance Risk Assessment Committee (PRAC). Its membership basis goes beyond the delegates of national authorities since a representative of a patient organisation and of the health professions are also represented.[52] Both expert committees –the CHMP and the PhVWP/PRAC– meet once a month during the same time.[53] The PhVWP/PRAC usually discusses and formulates scientific advice about post-marketing safety of a drug on the request of the CHMP or a Member State authority.[54] In this regard, then, this EMA committee holds the advice the CHMP about the evaluation of the safety of marketed drugs on the basis of collating the spontaneous reporting data from all Member States and

Please note that this is not a comprehensive list of the 2010 reform.

[48] Art.21-29, Regulation 726/2004. The EMA has this task only in relation to products that were authorised by EMA and the European Commission. If products are concerned which were authorised in the decentralised procedure, the national authority in question remains the responsible body for pharmacovigilance (Art. 101-108, Directive 2001/83). Please also note that the EMA and the Commission have issued various guidelines and standard operating procedures for national pharmacovigilance systems in order to facilitate the correct implementation with the European legislation. The most crucial guidelines in this respect are the *Volume 9A Guidelines.* Also see EMA's website for an up-to-date overview of pharmacovigilance Standard Operating Procedures (SOPs); relating to, for example, vocabulary to be used in reporting and communicating about adverse drug reactions.

[49] Art.61(1), Regulation 726/2004.

[50] Art.22, Regulation 726/200; Section 2A of *Volume 9A ('The Rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Human Use,* 2008).

[51] Art.5(2), Art.10, Regulation 726/2004.

[52] Art. 61a(1)(c) and (d), Regulation 1235/2010.

[53] The meeting of the two committees were streamlined in 2003 in order to faciltate exchange between the two bodies (EMA Annual Report, 2003).

[54] Section 2A Section 3.3.3. and Appendix 1.A of *Volume 9A.*

forming coordinated opinions on how this information should be evaluated. Such a task can be expected to provide an incentive to the involved regulators to supply the best possible expertise to the transnational process: This provides them with an opportunity to avoid the cost of adjustment to the data gathering and evaluation tools of other regulators that might be seen to supply 'better' knowledge. Strategic coordinative behaviour of national regulators in such a case can hence be expected to equate to a competitive coordination pattern, in which national authorities attempt to be seen to supply the best data and assessment tools to the transnational process.

3.2 Identifying the Coordination Pattern among Drug Safety Monitoring Authorities

Officials from national authorities come together in the expert bodies of EMA to take decisions on the safety of pharmaceutical products that are already on the market. This requires coordinated standards of how data on adverse drug reactions should be collected and evaluated. The EU regime and EMA, however, do not prescribe how national regulators should collect and assess data (see Section 3.2.1). Potential agreement between national regulators on which forms of data gathering and assessment should be striven towards must hence be reached on informal level, rather than being orchestrated by an EU body. In line with the argument of this thesis, we can expect that UK and German authorities only engage proactively with transnational coordination processes if they perceive this to add value to their own work. In this regard, they assess the value of the coordination pattern that is shaped by EMA's one-off decision-making task (see Section 3.2.2).

3.2.1 Potential Impediments to Coordination

The requirements of the EU regime concerning how data collection and evaluation systems of national regulators should look like are very limited. If coordinative behaviour was only driven by such authoritative rules, then, we would expect national regulators to engage in the coordination of their data collection and assessment models to a very limited degree. Largely, the EU-level regime merely requires national regulators' to run a functioning spontaneous reporting system.[55] It is not specified how these systems should operate. Reporting by healthcare professionals is not mandatory under the EU-level regime and is largely left to national authorities, as is the running of the system in general.[56] Moreover, the EU regime extends rules towards the industry concerning how companies should handle information about adverse drug reaction that come to their attention. In this respect, each company needs to operate an internal pharmacovigilance system, which is a company-internal data collection and evaluation unit for adverse drug reactions.[57] A specifically trained person (the 'Qualified Person') needs to be in charge of this system.[58] This 'Qualified Person' is also responsible for ensuring that any serious adverse drug reaction that comes to the attention of the manufacturer is notified to the authorities within 15 days.[59] Also, the industry is required to submit safety documents about each of their drugs on a regular basis.[60] It is the task of national regulators to enforce these standards in their territory.[61]

Such procedural requirements do not specify safety targets or standards of scientific quality to be met. Rather, they lay down which kind of system needs to be present, when certain issues need to be notified etc. As such, then, the emergence of coordinated standards relating to the substance of pharmacovigilance –such as how data should be collected and which scientific approach to use to evaluate this data– remains entirely in the hands of national regulators. These, in turn, arguably must have a good

[55] Art.102, Directive 2001/83.
[56] *Ibid.*, Art.101, Art.102.
[57] Art.23(a), Regulation 729/2004.
[58] Art.103, Directive 2001/83.
[59] *Ibid.*, Art.103(b), Art.104(1),(2),(3),(4).
[60] *Ibid.*, Art.104(6).
[61] *Ibid.*, Art.105(1),(2); Art.25, Regulation 729/2004.

reason to engage in such coordination despite the absence of an authoritative imperative to do so. This is especially so since national authorities such as the UK and German regulators are largely sceptical about the contribution of EU rules to the enhancement of drug safety. For example, a German regulator noted that it would be preferable to receive a report on an adverse drug reaction which is of high informational quality on the 16th day after it came to the attention of the manufacturer, rather than receiving it 15 days after the company was informed (as required by the EU regime) with lower informational content and quality.

> I mean, to receive a report after exactly 15 days, yes, of course, that needs to happen. But on the other hand, if we receive a very detailed report about an adverse drug reaction, including a very good assessment, on day 16; then I find that downright positive and acceptable.[62]

In this regard, it was expressed that the presence of the EU regime limits the scope for flexibility in this matter, hence potentially affecting substance for the sake of procedure. Thereby, an interplay between the proceduralising nature of EU rules and the approach taken by industry reinforces this logic: Industry compliance with regulatory standards is most easily shown by adhering to specific requirements (such as reporting an adverse effect after 15 days), rather than bending the rules in order to deliver a qualitatively better report.

> It's not ideal that industry is so focused on process requirements. The fact that a report is submitted from A to B in a certain timescale, according to the letter of the law or the guidelines, doesn't actually stop a patient getting a serious adverse drug reaction. So 90% of what industry does tend to focus on having a compliant pharmacovigilance system. That does not mean you have safe drugs.[63]

EMA, on the other hand, is insistent on compliance with reporting timelines and has expressed concern about instances of non-compliance (European Commission, 2010, p. 145).[64] This might negatively impact national

[62] Interviewee D2.
[63] Interviewee D1.
[64] Also see *Volume 9A,* Chapter I.4, Section 2, and Chapter III.8.

regulators' assessment of the value EMA can add to their work, and thus their commitment to engage proactively with its activities. This is especially so since UK and German authorities associate the EU regime and EMA with procedural requirements to a considerable extent. Pharmacovigilance inspections, for example, are carried out at the site of pharmaceutical companies in order to verify whether they comply with the regime's rule (i.e. whether they have an internal pharmacovigilance system and 'Qualified Person' in place). These inspections are carried out by national regulators (sometimes at request of EMA). The inspection regime is procedural in that it is mainly concerned with checking whether a system to collate and analyse information is present,[65] rather than scrutinising the quality of the results this system can provide in terms information on adverse drug reactions and patient safety. This essentially renders inspections into a 'box-ticking' exercise, rather than providing for contemplation whether a specific company internal system is able to collate information of high quality in terms of providing detailed and accurate knowledge about an adverse drug reaction. National regulators are under the impression that there is a potential trade-off between compliance with procedural EU regulations and the enhancement of safety, which a German regulator commented upon as follows:

> That is one of my worries, that due to the EU, since there are so many guidelines etc. it will go more into this direction, where things get formalised. […] You might see a signal-detection in a company that has an amazing data-base, and then you realise that it has very grave shortcomings substantively. I think these things also need to be captured, not only that signal-detection exists. I think that we really had this in Germany, that we focused on substantive aspects. And now we need to be careful – despite the importance of QM – that this is preserved.[66]

Whereas each company's internal pharmacovigilance system is regularly inspected by regulators in line with procedures established under EU

[65] See Art.111, Directive 2001/83; Art.19(1), Regulation 726/2004; *Volume 9A,* Chapter I.2.4. For example, *Volume 9A* states that "the focus of these inspections is to determine that the Market Authorisation Holder has personnel, systems and facilities in place to meet their regulatory obligations" (p.31). Also, see the EMA standard operating procedures (SOP) for pharmacovigilance inspections, and the MHRA guide for industry (MHRA, 2008).
[66] Interviewee D2.

requirements, the national pharmacovigilance systems are not regularly monitored by EMA or the European Commission. The European Commission once contracted an independent party to assess the pharmacovigilance systems of the Member States (see Fraunhofer Institute, 2006). This assessment, however, focused mostly on the problem of weak pharmacovigilance structures in the new Member States, and does not attempt an analysis of substantive aspects, such as variation in scientific approaches to pharmacovigilance or data collection tools. National authorities are hence under no formal pressure to coordinate their practices in relation to such aspects.

This part of the chapter has demonstrated that national pharmaceuticals regulators are under no formal pressure from the EU regime and EMA to coordinate their data collection tools and their approaches to data evaluation. Moreover, UK and German authorities associate their participation in the EU regime with the proceduralising nature of EU requirements, which has the potential to undermine safety in their view. If UK and German authorities are to proactively engage with EMA's one-off decision-making task despite this negative perception and the absence of formal pressure, they must arguably perceive it to be 'worth it' for their regulatory work.

3.2.2 Transnational Coordination: Adding Value through Epistemic Competition

If national authorities are to coordinate their substantive pharmacovigilance practices in the absence of formal requirements to do so, they must perceive themselves to be 'getting something out of it'. Indeed, this case study finds that both UK and German authorities engage proactively with the transnational process and actively participate in the coordination of their practices –albeit on an informal basis– since they both perceive it to add value to their pharmacovigilance work at home. What they perceive to be getting out of the transnational process differs, however, since it is informed by the different social relations they are embedded in domestically:

Proactive engagement with transnational decision-making about the safety of drugs has enabled the UK to become the informal 'gold standard' of how data should best be collected and evaluated. Engagement with the transnational process hence provides the British MHRA with the advantage of not having to adjust its own practices to a different model, which in its perception would be inferior to its own model. German authorities, on the other hand, gain an insight into the exceptional data sources of the UK through its engagement with transnational processes in EMA, which they cannot obtain in the context of the social relations they are embedded in. At the same time, the German regime has followed the incentive to improve its own data sources in order to remain competitive vis-à-vis the 'gold standard' of the UK model.

When discussions about the 'substantive standard' of drug safety are concerned, the UK MHRA has been able to establish its own practices as 'informal gold standard'. The 'substantive standard' of drug safety is the so-called benefit-risk balance, i.e. an evaluation whether the potential risks of a medicinal product are outweighed by its potential benefits. Spontaneous reports about adverse drug reactions and other available data are evaluated in this light to analyse whether the benefit-risk balance of a given product has shifted or not. In the transnational coordination process, the CHMP of EMA (comprised of national experts) undertakes this analysis when centrally authorised products are concerned, whilst being advised by the PhVWP/PRAC.[67] There are no EU requirements, however, as to how the benefit-risk balance should be evaluated. In carrying out such form of analyses in EMA, it hence depends on national regulators to coordinate their approaches in order to make the transnational process feasible. In this regard, the British model has established itself as 'gold standard' in a competitive coordinative process.

> I think we have seen ourselves, rightly or wrongly, as having one of the strongest –if not *the* strongest- system of pharmacovigilance. But we have basically seen ourselves as this big team player.[68]

[67] Art.21-29, Regulation 729/2004; Art.101-108, Directive 2001/83.
[68] Interviewee D1. In this respect, the interviewee also stressed that the MHRA as a clear financial interest to do so, as national authorities will obtain more resources from EMA the more

One manifestation of this clout of the UK is its possession of the chair of the Pharmacovigilance Working Party. Out of sixteen years of operation (1995-2010), its chair was held by British experts for twelve years.[69] Largely, it has been able to establish itself as 'gold standard' as it has a greater wealth and quality of pharmacovigilance data available than other countries, and it has a scientific research tradition that claims to be superior to the scientific traditions present in other countries. Arguably, it is the combination of these aspects that has mattered as other national authorities possess some of these qualities but not all. Hereby, the existence of the General Practice Research Database (GPRD) and Prescription-Event-Monitoring (PEM) in the UK have been decisive. Especially the GPRD allows for a unique possibility to study 'signals' (i.e. hypotheses) that emanate from spontaneous reporting data further (Parkinson, Davis and Van Staa, 2007), which the data available to German –and other authorities– simply does not permit. Overall, both data-bases represent a distinctive opportunity for linking given medicinal products with specific symptoms as both data sources hold a comprehensive record of a patient's history, rather than individual, out-of-context entries about a symptom in a given patient (*ibid.*; Shakir, 2007).

It is questionable, however, whether the UK would have been able to establish and maintain itself as the informal standard without its claim to a superior scientific research tradition in this field as some national authorities have not been lacking far behind in the commitment of resources and the availability of data (the Nordic countries, for example, also have sophisticated databases in this respect).[70] Rather, its influence in essentially setting the coordinated standard of substantive pharmacovigilance practices also emanates from the perceived superiority of its research tradition in this field: The research approaches of evidence-based medicine (and thus epidemiology and pharmacoepidemiology) are rooted in Anglo-

rapporteurships (i.e. main responsibility for the authorisation of a new drug in the centralised procedure) it takes.

[69] See EMA Annual reports 1995-2010. 1995-1998, chaired by Dr.Susan Wood; 1999-2000, chaired by Dr.Patrick Waller; 2005-2010, chaired by Dr.June Raine. (The three years in-between were chaired by a French expert, and one year was chaired by a Spanish representative.)

[70] Please note in this respect that the populations of these countries are too small to carry equal weight as the UK in terms of data quantity.

Saxon tradition, and as one German regulator said "epidemiology is en-vogue". In other words, its research methods are currently widely seen as resulting in research of higher quality than, for example, the German tradition of 'Grundlagenforschung' (pure research or basic research) and casuistics. Whereas the former methods rely on controlled experiments and the observation of the distribution of health-events in a population, the latter focuses on the discussion of the underlying principles of medical research and the generalisation of findings from single cases.

As the UK MHRA owes its ability to represent the coordinated standard that other authorities need to strive towards to its availability of data sources, other national authorities have an incentive to develop more elaborate forms of information-gathering as well. In the case of Germany, the need to dispose of better data to assess adverse reactions (specifically with regard to testing 'signals' that emerge from spontaneous reports) has resulted in the establishment of 'national pharmacovigilance centres' as part of an amendment to the Medicines Act in 2004.[71] These are dedicated research institutes in hospitals, which focus on research of adverse drug reactions in specific patient groups, such as pregnant women or children, or in relation to specific diseases. Currently, six of these centres exist (with the aim of widening this network to more centres), each possessing a distinct research focus.[72] All of them, however, specifically study whether non-elective admissions to hospitals are due to an adverse drug reaction in the population of patients admitted to the hospital they form part of. This approach was inspired by the French pharmacovigilance system (Vogel, 2007, p. 38f), which is composed of 31 'Centres régionaux de pharmacovigilance'. These collect reports about adverse reactions from healthcare professionals and conduct independent pharmacovigilance research.[73]

[71] See change to §62 of the *Arzneimittelgesetz* in 2004 ('12.AMG-Novelle').
[72] Hospitals in the cities of Wuppertal, Jena, Rostock, Greifswald, Weimar and Munich currently operate such pharmacovigilance centres. Please note that these centres were not necessarily established after 2004; rather, they existed beforehand as independent research institutes. The change in the 2004 legislation, however, envisages using these systematically as part of the German pharmacovigilance system. As a consequence of the 2004 legislation, the further development of such a network of national pharmacovigilance is still ongoing. For an up-to-date overview of the work of the centres, see http://www.pharmacoepi.de.
[73] Art. 5144-14 and Art. 5144-15, *Code de la Santé Publique.*

Germany, then, attempts to compete with the British model by learning from the French system, rather, than the 'gold standard' of the British GPRD and Prescription-Event-Monitoring. Such systems would be difficult to implement in Germany due to the nature of data protection laws and its decentralised health care system, as opposed to the UK's National Health Service, which has greatly facilitated the emergence and existence of the GPRD and PEM (see Parkinson, Davis and Van Staa, 2007; and Shakir, 2007). The UK, on the other hand, having established itself as 'informal standard' in the transnational coordination process is not necessarily of the view that there is a lot to learn from other national authorities or that it needs to compete with these:

> Clearly we have gone there [to meet at the transnational level] in a collaborative spirit, but I don't think we got an awful lot out of Europe in a sense, specifically in the area of pharmacovigilance. I can't think of an example where we thought, hey, that's a good idea, let's bring this to the UK.[74]

The informal standard set by the UK affects how scientific arguments need to be brought forward by national officials when they come together at the transnational level in the forum of EMA. Scientific argumentation based on evidence-based medicine and (pharmaco-)epidemiology is dominant in the coordination process, in which the UK experts are practically 'at home'. This is not necessarily the case for other national officials, as other research traditions might play a more crucial role in their country, such as basic research and casuistics in Germany.

> 'We have problems with data protection here in Germany, and I think it is necessary to be careful in this regard, but that does limit the possibilities for conducting epidemiological studies, and thus the assessment of risk [...]. In that respect the Nordic countries and the Brits have an advantage and they are better in this field than we are. Well, currently in pharmacovigilance we go from the assessment of an individual case of a spontaneous report to 'which evidence do we have?', and hence to epidemiology. Epidemiology is thus what is meant to provide us with information about the critical value of the risk stemming from a medicinal product. Evidence-based medicine [from which epidemiology derives] has Anglo-

[74] Interviewee D1.

> Saxon roots. [...] So the British just have more practice in thinking in these terms.'[75]

Since this dynamic is even observable when German authorities are concerned –which are also 'big players' in this field with a qualitatively high research base– this competitive coordination pattern can arguably be expected to be present in other national authorities as well.[76]

Since the MHRA sees itself as having access to the best data and the best approach to assessing this data, its officials can at times perceive the coordination process in EMA to 'lower standards':

> People do bring different perspectives to the table. Obviously you are working together with these people and there is a very friendly collaboration. Pharmacovigilance in Europe has done a good service in terms of getting people together. But of course if we are talking about making a specific decision... You know that idea that the best decision will be the one that is reached through compromise, rather than by the best arguments winning the day is - I think- potentially a problem.'[77]

A German expert, on the other hand, said that the deliberation among European experts provided the opportunity to discuss differing viewpoints, whereby the strongest arguments tended to come out on top (rather than compromise).

> Then we have to discuss with our colleagues from across the EU, and that is of course sometimes overly bureaucratic. However, it does bear the advantage that one gets to hear the opinion of others and has to justify, so you have to be very precise in expressing your view and you might really have to justify it, which might be quite a good form of control.'[78]

The discrepancy between these two perceptions is not surprising if one considers that the UK has established itself as informal gold standard in the field of pharmacovigilance in Europe: As UK regulators perceive their expertise in assessing the benefit-risk balance to be superior to other

[75] Interviewee D2.
[76] Especially in Member States which lack expertise in this field, this form of knowledge sharing of course bears great potential to be beneficiary. At the same time, however, it is likely to affect national experts from countries that are active players in the regime more than national experts from Member States that stay relatively passive in expert deliberation (European Commission, 2010, for example, p. 120).
[77] Interviewee D1.
[78] Interviewee D2.

national regulators' expertise, they are likely to have the impression that deliberation in the forum of the Pharmacovigilance Working Party and the CHMP result in 'compromise'. At the same time, in this context it is not surprising that a German official is of the view that there is something to be learned from deliberation among colleagues in the forum of the EMA's expert committees. In this regard, then, the social relations the MHRA is embedded in at home frame these perceptions: It can add value to its own regulatory work at home by ensuring that coordinated decisions are based on its own way of doing things to the greatest degree possible. This, in turn, requires active engagement with the transnational process. German authorities, on the other hand, perceive the added value of engagement with EMA's one-off decision-making task to be the access to such potentially 'superior' forms of data and data analysis that they lack as a result of the social relations they are embedded in at home. This form of access has hence the potential to improve the work they carry out 'at home'.

In this regard the engagement with EMA provides German authorities –and others– access to data collected from across all national authorities. All data on adverse drug reactions collected by the national authorities needs to be passed on to EMA. In order facilitate this information-gathering exercise, EMA set up the online database *EudraVigilance* in 2001 in which all reports on adverse reactions are compiled (EMEA, 2001, especially p.11, 13 and 35). This enables all national regulators to access reports gathered on an EU-wide basis (*ibid.*). The 2010 reform centralised the system further in that industry will have to pass all reports on adverse reactions directly to *EudraVigilance*.[79] Data-mining techniques are used by the experts (in their capacity as national and EMA regulator) in order to extract 'signals' from this data (Waller, 2010, p. 44ff). These serve the purpose of verifying any potential shifts in the benefit-risk balance, i.e. determining whether the risk of a given drug is still acceptable in the light of newly emerged information on adverse reactions related to this drug. The detected signals hereby serve as hypotheses, which then have to be further tested (for example, by making use of existing databases, such

[79] Art.107(3), Directive 2010/84.

as the GPRD, or the conduct of novel studies) (*ibid.*). Engagement with the transnational process hence also bears the advantage that it provides direct access to the expertise of British officials, for example in relation to the testing of 'signals' with GPRD data.

Engagement with the transnational coordination process also provides access to spontaneous reporting data that might have been created in starkly different ways. In this respect, the route a report has taken before it reaches *EudraVigilance* can differ significantly: Whereas around half of the reports received by the British MHRA originate from doctors, the German BfArM receives the vast majority of these reports from the industry (Davis, King and Raine, 2007, p. 202; Hagemann and Paeschke, 2007, p. 231; Hasford, Göttler, Munter, Müller-Oerlinghausen, 2002**;** Waller, 2010, p. 36).[80] While this gives the impression that German doctors are less involved in spontaneous reporting, research has shown that both countries have roughly similar rates of reporting by doctors (Belton, 1997; Hasford, Göttler, Munter, Müller-Oerlinghausen, 2002). What the figures thus show is that German doctors hardly ever report to authorities directly. Rather, a few of them report to their professional association and most of them report to the relevant pharmaceutical company, which then passes the information on to the authorities.[81] In this regard, it is likely that German doctors pass on the information about adverse drug reactions to the industry in informal personal exchanges (Hasford, Göttler, Munter, Müller-Oerlinghausen, 2002, p. 948).[82] In the UK, the opposite is the case where doctors (and other actors) report directly to the authorities, using the so-called Yellow Card form.[83] German regulators regret that doctors will not report to them

[80] This pattern was also confirmed by all interviewees. Moreover, in the German case confirmation of this can be found in the Annual Reports of BfArM and PEI. The MHRA does not publish reporting numbers in detailed breakdown; however, a Freedom of Information Request for reporting data for the years 2004-2007 confirmed the above reporting route.
Please note that it is professional duty under the respective professional codes of conduct for doctors to report adverse drug reactions in both countries.

[81] Germany is an outlier in comparison to other European countries in this respect, in most European countries doctors tend to report directly to public authorities as is the case in the UK (Belton, 1997). In the US, however, reporting is very similar to the German pattern.

[82] German regulators that were interviewed shared the view that this is the case.

[83] This is arguably the case since it is the most time-efficient way for doctors to report adverse drug reactions to the sales representative of the relevant pharmaceutical company when he or she is visiting the practice. The sales representative then passes on the information to the company's pharmacovigilance unit, which in turn has to report to the authorities. This is, however, theoretically the case for German and British doctors since they receive similarly frequent visits from sales

directly as this would enable German experts to get in touch with the reporting doctor directly, thereby giving them the opportunity to ask more detailed information.[84] Reports which are entered into *EudraVigilance* might hence have passed through very different channels and might be of different informational content, depending on the practices of the country they originate in. The engagement with EMA hence provides national authorities with an opportunity to access data with these different qualities.

The dynamic coordination process that entails the gathering of information about each other's practices, the setting of an informal behavioural standard (i.e. the UK model), and the modification of behaviour hence takes place through a competitive coordination pattern. UK and German authorities assess the value of this process as a whole through the specific lens provided by the social relations they are embedded in. This competitive coordination pattern is characterised by direct horizontal exchanges between the involved national authorities without the direct intervention of staff of EMA, which national authorities also take into account in their implicit 'cost-benefit-analyses'. In this regard, the permanent body of pharmacovigilance staff at EMA does not express an 'appetite' to extend its own role in terms of 'adding value' to the practices of

representatives in both countries (Lieb and Brandtönies, 2010; Prosser and Walley, 2003). Hence, the reason for this is most likely to be rooted historically, where British authorities were very actively engaged in encouraging doctors to use the Yellow Card soon after the Thalidomide crisis (Inman, 1999). This process was not present in Germany to a similar extent where an authority to collect ADR reports was only established in 1978 (Hagemann and Paeschke, 2007, p. 228). Given the stability of these reporting patterns over the past decades, it is also likely that doctors in both countries today consider their behaviour as appropriate as it 'has always been done this way'. Theoretically speaking, the industry in Germany could filter the information before only passing on selected data to the authorities. Consequently, if one assumes that German doctors value the health of their patients and would like to prevent future adverse drug reactions, German doctors must instil a certain degree of trust in the pharmaceutical industry by only reporting to companies, rather than authorities. At the same time, it is vital to point out that doctors (and other healthcare professionals) do not necessarily consider themselves as part of a 'pharmacovigilance regime' (as pointed out by a British regulator during an interview). As their priorities are naturally more focused at the immediate task of diagnosing and curing patients, they might choose the well-established route in their country without lengthy contemplation.

[84] In general, however, regulators are glad about each report that is filed, even if it is communicated to the industry, rather than the regulator. 'Under-reporting' on part of healthcare professionals is a widely discussed issue among experts in the field (for example, Bateman et. al., 1992; Hasford et. al., 2002; Martin et. al., 1998), and studies show that time-constraints are a major source of this problem. Reporting is a legal obligation for healthcare professionals in some countries, such as Sweden; however, observers usually note that this is not significant for the practice of reporting since such an obligation is not enforceable (*ibid.*). Medicines regulators do not regulate the healthcare professions and hence have to rely on the methods of persuasion, such as providing information about the importance of reporting.

national authorities in an explicit manner, by, for example, engaging in research of how to further patient safety:

> How important is it [the national differences]? I think it probably does have an impact on, for example, the quality of the data that is collected. [...] If you then take that to the European level, considering that we have 30 Member countries (EU plus European Economic Area countries) it probably does not make a big difference to the end result, which is detecting new safety issues and taking action to protect public health.[85]

Whereas EMA arguably does not possess the resources to engage in such activities at the moment, it is also arguable that the agency is in a unique position to 'add value' to questions of conceptual innovation in the management of adverse drug reactions in Europe in a more overt manner. The agency, however, has been keen to assert itself as 'mere' hub of a network, which values national diversity in expertise and practices (see discourse of EMA in its Annual Reports, for example, EMEA, 1995, p. 6; EMEA, 1996, p. 7; EMA, 2004, p. 6). The 2010 reform, however, adds an element of monitoring of national regimes. This happens through 'self-audit' of national regimes by national authorities, the results of have to be communicated to the Commission.[86] As of yet, the impact this has had on the assessment of the value of EMA's tasks by national authorities remains to be uncovered. The usage of the term 'audit' in this respect, however, gives reason to suspect that this furthers the proceduralisation of national regimes, rather than contribute to studying what each of these national regimes can achieve in a substantive sense (i.e. enhancement of patient safety). Such a process of self-audit and peer review has already developed outside the official framework of the EU regime over the years (BEMA, 2006, 2012).[87] It is likely that the new legal provision mainly formalises this existing practice and hence does not alter the assessment of the transnational coordination process on part of the UK and German authorities that was observed here.

[85] Interviewee D5.
[86] Art.101(2), Directive 2010/84.
[87] The 'Benchmarking of European Medicines Agencies' ('BEMA') is a process that the Member States authorities began autonomously in 2003 in the framework of the Heads of European Medicines Agencies forum. It is a benchmarking exercise in which the regulators assess themselves and each other (peer review).

This part of the chapter shows that the one-off decision-making task of EMA in relation to drug safety monitoring shapes a coordination pattern of epistemic competition. In this process the UK authority has established itself as 'gold standard' of data gathering and evaluation techniques as a result of the particular social relations it is embedded in at home. The German authorities perceive the access to this ostensibly 'superior' expertise to add value to their own work, whilst also attempting to compete with the British model by improving the quality of their own data sources.

3.3 Conclusions

This chapter has demonstrated that the one-off decision-making task of EMA shapes a coordination pattern that is based on epistemic competition. UK and German pharmaceutical regulators perceive this task to add value to their own work in the context of the social relations they are embedded in. Although EU rules and EMA do not require national authorities to coordinate their substantive pharmacovigilance practices and despite their negative view of the proceduralising tendencies of EMA's insistence on EU rules, UK and German authorities proactively engage with the coordination of their drug safety monitoring practices in the forum of EMA. They do so because they perceive themselves to be getting something out of it in the specific frame of the social relations they are embedded in: The competitive coordination pattern unleashed by EMA's one-off decision-making task has provided the UK authority with an opportunity to establish its own data gathering and evaluation model as 'gold standard' of the regime. As a result of the specific social relations the UK MHRA is embedded in, it possesses access to an extraordinary wealth and quality of data on adverse drug reactions, as well as a highly regarded scientific approach to evaluate this data. The proactive engagement with coordination, then, adds value to the work of the UK regulator by ensuring that it does not have to conform to a

model of a different national authority, which it would perceive to be inferior. The German authorities, in turn, gain an added value through active engagement with transnational coordination since it provides them with access to the data and expertise of the perceived 'gold standard' (i.e. the UK model), which German authorities would not be able to attain within the context of the social relations they are embedded in (such as a different approach to data protection found in Germany in comparison to the UK). At the same time, this competitive coordination process provides them with an incentive to improve their own expertise in order to avoid the perpetual costs of adjustment to the 'gold standard' supplied by the model of a different regulator. As a result, the quality of data available in the German drug safety monitoring regime has improved through reforms that have established new pharmacovigilance research centres in hospitals.

The positive assessment of EMA's one-off decision-making task is hence largely a result of the evaluation of the informal coordination processes of gathering information about each other's practices, which provide a perceived motor for positive change, rather than the role played by EMA staff in the coordination process. Indeed, EMA staff has not attempted to intervene in these informal coordination processes as such, for example, by surveying the practices of national authorities or promulgating a 'best practice' model. Arguably, this lack of interference has contributed to the positive assessment of the added value of the engagement with EMA's tasks since it has allowed national authorities to render transnational coordination feasible –and beneficial– for the very specific sets of social relations in which they carry out their regulatory work at home.

Overall, then, this chapter shows that EMA's one-off decision-making task leads to a competitive coordination pattern, which is sustained by the positive assessment of its value by national authorities. This finding will serve as a vital point of comparison with the coordination pattern observed in the case of food risk assessors in Chapter 5: The regulatory officials in both cases form part of scientific communities that can be argued to possess relatively similar professional norms. The constructivist EU literature has argued that coordinative behaviour is mainly determined by such

professional norms, resulting in a coordination pattern based on mutual exchange and learning across very different policy areas. This chapter, however, indicates that coordination patterns are more complex: The pattern observed here goes beyond mutual exchange and learning in its competitive nature. According to the argument advanced in this thesis, then, we would expect coordination among food risk assessors to function differently than what was observed in this case study since they carry out a different task in the body of the European Food Safety Authority and since they are embedded in different social relations.

Chapter 4

Maritime Safety

The maritime safety case allows us to study the effect of an inspection task on the coordinative behaviour of the involved regulatory actors. The European Maritime Safety Agency (EMSA) has been entrusted with monitoring and the facilitation the implementation of the European maritime safety regime by national authorities. It has two main tools at its disposal to do so, namely the active monitoring of member state practices through inspections of national authorities, and through training provided for national officials at its premises in Lisbon. This case study hence also provides us with a chance to study how coordinative behaviour is affected by two different tasks, which structure the relations between the involved actors in different ways.

Moreover, the case presents an excellent opportunity to compare the coordinative behaviour of regulatory actors in cases where the EU body has an inspection task, but the social relations that national authorities are embedded in differ (see food control authorities in Chapter 5). In the case of food control authorities, the social relations that UK and German officials are embedded in are characterised by the extraordinary decentralisation of the industry and the administrative structure that they need to oversee. In maritime safety, in contrast, national authorities are embedded in an international regulatory framework as a result of the highly international character of the shipping industry.

To exemplify the international character of the issues surrounding maritime safety, a look at the history of the *Prestige* is enlightening:[88] The *Prestige* was built by a Japanese shipyard and was completed in 1976. When it shipwrecked in 2002, it was flying the flag of the Bahamas. It was owned by a Greek, who himself was registered in Liberia. For its fateful journey it was chartered by a Russian company, which had its offices in Switzerland. On this trip, the *Prestige* was transporting oil from Latvia to Singapore. Its classification society –the expert body certifying the safety of a ship– was the American Bureau of Shipping. Before shipwrecking, port state control inspections of the tanker had been carried out in Saint Petersburg, Dubai and Guangzhou (Traisbach, 2005, p.169). A vessel such as the *Prestige* hence operates in a sector in which virtually no barriers to entry exist: Ship-owners can re-flag their vessels within a day and can register in different jurisdiction to evade liability. Due to this highly global context, the International Maritime Organization (IMO) has played a crucial role in the regulation of this industry.[89]

The UK and German maritime safety authorities have been dominant players in the IMO and continue to regard it as the most crucial regulatory body in the field. The European Union, in turn, only became active in maritime safety in the mid-1990s. In doing so, the EU added another level of regulatory activity to a field that had since been governed through the interaction of national, regional and international actors. In the maritime case, then, UK and German authorities are embedded in social relations that are focused on the extensive transnational regulatory structures built to govern a highly global industry that precede the coordination efforts of the EU.

[88] The *Prestige* was an oil tanker which sank off the Galician Coast of Spain in November 2002, thereby polluting thousands of kilometres of the coasts of Spain, Portugal and France.
[89] It does so largely by way of setting the overall framework of standards to be applied in the field as expressed in the 1973 International Convention for the Prevention of Pollution from Ships (MARPOL 73/78).

4.1 Social Relations and Tasks in Maritime Safety

The EU maritime safety regime only came into being in the 1990s and started operating in a web of international and regional arrangements. In light of the argument of this thesis, it can be expected that the embedding of UK and German authorities in social relations that are characterised by transnational ties beyond the EU are vital for how they evaluate their engagement with EMSA (see Section 4.1.1). In this regard, we can expect these social relations to act as interpretative filters for national authorities' of EMSA's inspection and training tasks (see Section 4.1.2 for an overview of EMSA's tasks). The existence of two tasks –which set the involved regulatory actors into different relations with each other– provides an opportunity to study how coordinative behaviour is affected by such differing tasks.

4.1.1 Social Relations in the Maritime Safety Regimes of UK and the Germany

The social relations that UK and German maritime safety authorities are embedded in are characterised by the importance of transnational links that precede coordination efforts in the EU: The International Maritime Organization (headquartered in London) was established in 1948, and became operational in 1959.[90] International regulation of the shipping industry had already existed in 19th century and the foundation of the IMO was an attempt to make such international arrangements more effective by way of establishing a permanent international body. In the field of oil pollution, the *Torrey Canyon* disaster was the decisive trigger to bring about an international agreement aimed at preventing environmental damage from this source, which came into being in the form of MARPOL 73/78. This

[90] Please note that it was called Inter-Governmental Maritime Consultative Organisation, IMCO at the time. It is a specialised agency of the United Nations, which has 170 members at the time of writing. The European Commission has an agreement of cooperation with the IMO. (For an overview of the history of IMO, see, for example, Mankabady, 1984; and Srivastava, 1990.)
To this day, negotiations and policy at the IMO are mostly influenced by the dominant developed countries, including the UK and Germany (Tan, 2006, p.98ff). Some emerging countries, such as Brazil and India, have also started to wield power in the IMO setting. Overall, it is largely the developed countries pushing for stringent environmental protection, whereby developing countries are more likely to defend the interest of the maritime industry, which has gradually became located in these countries over the past decades (*ibid*.).

framework was henceforth complemented by regional agreements aimed at vessel-source oil pollution prevention (for example, see Boehmer-Christiansen, 1984). One of the earliest in this respect was the 1969 Bonn Agreement for Co-operating in Dealing with Pollution of the North Sea by Oil, which was a reaction of the North Sea states to the *Torrey Canyon* disaster. The first agreement to tackle the problem of marine pollution generally (rather than focusing on oil) was the Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (HELCOM). Hereby, ship safety measures have traditionally been aimed at protecting human life at sea, which have become complemented by international standards for seafarer training to further this objective.[91] In order to enforce such measures more effectively, port state control (which renders it possible to verify the safety of foreign flagged vessels in one's own ports) became a transnational effort in the 1980s. The Paris Memorandum of Understanding on Port State Control (Paris MoU) has traditionally fulfilled this task in Europe.[92] When the EU entered the scene in the 1990s, cooperation was hence already firmly transnational in character. Information on oil spills and ships calling at European ports had been shared through regional bodies for several decades, such as HELCOM, the Bonn Agreement and the Paris MoU. Especially in the field of oil pollution these efforts (specifically port state control) have shown great success in modifying the behaviour of the industry, whereby oil pollution and accidents have been declining.[93] The UK and German authorities have been fundamentally involved in these transnational regulatory efforts from the beginning. As a result, we can expect that their assessment of the value of engagement with EMSA processes is informed by this history of coordination efforts beyond the EU.

Historically, the UK has been very influential in the globalisation of the maritime safety regime, dating back to the crucial developments in the

[91] Convention on Standards of Training, Certification and Watchkeeping for Seafarers of 1978 (STCW), implemented in Directive 2008/106/EC of the European Parliament and of the Council of 3 December 2008 on the minimum level of training of seafarers.
[92] The Paris MoU is an administrative agreement which maritime authorities of participating states forged in 1982 (as set out in MARPOL 73/78 and other relevant international treaties) (for a discussion of the Paris MoU, see König, 2002).
[93] For an overview of studies of pollution from oil and other sources, see GESAMP, 2009.

19th century when its fleet accounted for half the world's tonnage (Braithwaite and Drahos, 2000, p. 425). To this day, it strongly favours regulation at the IMO level over EU rules if the latter 'gold-plate' international standards. The UK has remained highly influential in IMO negotiations, not least due to its large number of staff and representatives there as a result of being the host nation (Tan, 2006, p.98ff).[94] Germany's role has been somewhat less prominent but nevertheless the country holds a relatively large degree of influence due to its expertise (*ibid*.), whereby it also emphasises that the IMO, rather than the EU, is its favoured level of regulating the maritime industry.[95] The UK and Germany used to belong to the 'traditional' maritime states, which in the past defended the freedoms of the maritime industry. Today (and for the past decades), however, both countries can be categorised as defending the interests of 'coastal states', such as environmental issues. This has developed due to increasing internal political pressure but also the changed nature of the global regime, whereby a small but persistent number of sub-standard ships register in 'flags of convenience', which is of great concern to them in relation to the environment and the levelling of the playing field (i.e. their competitiveness as flag states). Both countries continue to host a shipping industry to this day and remain important flag states. Whilst the number of ships registered under the German flag has generally fallen, the registered tonnage has actually increased due to the increasing size of ships.[96] The UK, in turn, has recently witnessed an increase in number of ships and registered tonnage (MCA, 2009, p. 21).[97] This reflects deliberate efforts of the UK to attract

[94] Interviewees also regularly referred to the UK's influence as experienced host nation.
[95] The industry and national officials usually argue in favour of IMO rules -as opposed to European rules going further than the international ones- arguing that a global industry needs global regulation. For a counter view to this, see Ringbom, 2008, pp.7-14.
[96] In 2008, for example, 618 merchant vessels were registered in Germany, equalling a tonnage of 13 250 181 (representing an increase in registered tonnage from the year before) (Dienststelle Schiffssicherheit, 2008, p.61). The number of registered merchant vessels was at 530 in 2011, having fallen by 7.2% from 2010, whereby the tonnage increased by 0.2% to 15 550 829 (Dienststelle Schiffssicherheit, 2011, p. 39).
[97] 1550 ships were registered in 2008, representing a tonnage of 15 888, 843 (MCA, 2009, p. 21.). In 2011 this had increased to 17 490 000, distributed over and 1 489 vessels (MCA, 2011, p. 15). All ship numbers presented refer to ships of over 100 Gross Tonnage (GT). All tonnage numbers are provided in GT.

ships to its flag,[98] but Germany has also devised investment and cooperation schemes with industry to retain ships on its register.[99]

Although the UK and Germany are embedded in similar social relations with regard to their engagement with the IMO in which they both defend coastal and maritime state interests, each country also has a specific national context of social relations they are embedded in: As island state the UK requires large capacities to monitor its coasts and the ships calling at its ports. Germany, on the other hand, has a much shorter coastline but an accident has the potential to have grave consequences due to the delicate and specific nature of the Wadden Sea and a lack of connection between German coastal waters and the oceans (Pallas Report, 2000, p. 44; Tomuschat, 2005, p. 16ff; also see Lagoni, 2001). Neither British nor German waters were directly affected by grave accidents in recent years (such as the *Erika* and *Prestige*) but incidents in the 1990s shaped the regimes of both countries. In the UK the *Braer* accident in 1993 caused pollution of the coasts of the Shetland Islands and subsequently heavily influenced the UK regime (Anderson, 2001, p. 349; Tan, 2006, p. 96f).[100] As a result of 'Donaldson Report' on this accident, the UK took the lead at the EU level: For example, it pushed vehemently for the Classification Societies and Port State Control Directives (Plant, 1995, p. 466). Indeed, the UK pioneered crucial aspects of the European port state control regime, most notably operational inspections and the principle of discriminating against ships with poor safety record (Bell, 1993, p. 368). Germany, on the other hand, experienced an accident of the *MS Pallas* in 1998, which resulted in an oil spill near the island of Amrum, causing considerable discussion about possible reform of

[98] The UK has devised a 'Quality Shipping initiative' in this regard, which aims to attract high quality ships to its flag, which is reflected in the above numbers. As part of this a 'tonnage tax' was introduced in 2000. This is a method of calculating corporation tax using the net tonnage of the ship. It is linked to an obligation on shipping companies to provide training or to make payments instead.

[99] This initiative is called 'Maritimes Bündnis', whereby the German shipping is supported by public money for training activities in exchange for a pledge to register ships under the German flag (see, for example, Dienststelle Schiffssicherheit, 2008, p. 60). However, in a re-formulation of this initiative, this pledge has not been renewed (Dienststelle Schiffssicherheit, 2011, p. 38). The German approach has hence been more passive, especially with regard to the attraction of foreign vessels. It has mostly focused on stopping ships from leaving the German flag, whereas the UK has aimed to get especially new ships to register under UK flag, whilst not necessarily aiming to stop other ships from leaving its flag.

[100] The recommendations of the Commission of Inquiry chaired by Lord Donaldson that was subsequently set up (see 'Safer Ships, Cleaner Seas' Report, 1994) were all adopted by the government (Plant, 1995).

the German regime (Lagoni, 2001, p.267). The immediate consequence was the setting-up of an accident response authority shared by the federal and the *Länder* level. However, the official inquiry that followed also urged Germany to get more involved in EU and IMO discussions (Pallas Report, 2000, p. 89).

Although Germany remains less involved than the UK, it is reported to belong to the group of most interested states, thereby carrying considerable weight, also in EMSA's Administrative Board.[101] In this forum, ministry officials from the UK and Germany have not only stressed the importance of IMO in their view,[102] but have also continuously emphasised the need to keep resources devoted to EMSA in check: Hereby, the decisive issue in the view of these countries has been whether tasks given to EMSA have the potential to 'add value' to national practices in the field in order to ensure that resources are not devoted twice for the same purpose.[103]

The regulatory authorities that are in charge of negotiating IMO rules and implementing international and European rules in the UK and Germany differ with regard to the degree of their centralisation: Whereas tasks are centralised within the Maritime and Coastguard Agency (MCA) in the UK, various governmental agencies are involved in Germany, whereby some are found at the federal level and some on the *Länder* level. The German authority concerned with the assurance of ship safety is the *Dienststelle Schiffssicherheit* (Ship Safety Division).[104] Overall, the UK has a larger administrative capacity, for example, since it has around 130 ship inspectors, where Germany has around 35 (MCA, 2011, p.11, and Dienststelle Schiffssichherheit, 2011, p. 52f). Considering the length of the British coast and the number of its ports, however, this is not surprising.[105] Generally speaking, variation in practices and compliance with international

[101] As pointed out by interviewees.
[102] EMSA, 2011c, p. 7; EMSA, 2012, p.6.
[103] This is generally visible in the discourse of 'Northern' countries in the notes of Administrative Board meetings, for example, see EMSA, 2006b, p.5. This was also confirmed by interviewees.
[104] Overall, one of the major issues in Germany is coordination between authorities in its federal structure, not only between federal authorities but also between federal and Länder authorities (and between Länder and Länder authorities) (e.g. Douvier, 2005, p. 124).
[105] The UK has around three times as many ports as Germany. However, it is difficult to provide numbers which are accurate for the purpose of comparison because of the inclusion of different types of ports (i.e. seaports, inland ports, various sizes of ports etc.) across statistics in this area.

and EU legislation is often related to capacity and expertise in the field,[106] and both countries are seen to fare well in this regard. Nevertheless, maritime safety is a field in which the Commission has often initiated infringement proceedings, and the UK and Germany are not exception in this regard.[107]

General distinctions between national practices of regulatory philosophies are difficult to draw in maritime safety. This is not to say that these do not exist, but due to the international history of the regime, laws and practices were becoming streamlined before the EU started operating in the field. Practices tend to differ from port to port, and even from ship inspector to ship inspector: For example, the way ports are run is crucial for how ship waste reception facilities are organised and how port authorities communicate with governmental authorities in terms of how long a certain ship will remain in this port (this is crucial to know for port state control officers since these inspections are unannounced). This, on the other hand, can be different from port to port depending on whether they are privately or publicly owned and –in the latter case– under the jurisdiction of which *Länder* or local authority they fall.[108] It is hence difficult to unambiguously identify differences in national practices or philosophies that could contribute to coordination problems, and which might act as interpretative filter for evaluating the activities of EMSA. However, it is often stated that there are different 'cultures' across the different countries that lead to

[106] This was explicitly pointed out by interviewees: For example, without sufficiently experienced port state control officers it is difficult to comply with the port state control regime. However, the number of experienced staff is related to whether a country has an active maritime sector (and hence experienced seafarers) or not. Also, often compliance with EU legislation in this field equates the need to provide sophisticated information-technology (such as the national implementation of vessel-traffic-monitoring via *SafeSeaNet*), which is not a straightforward task for national administrations in general.

[107] European Commission, 2002; 2003; 2003b; 2003c; 2004; 2006; 2008b; 2008c; 2008d; 2008e; 2008f; 2009; 2009b; 2009c; 2010b; 2010c; 2011; 2011b; 2011c.

[108] In Germany, *Länder* have jurisdiction over ports, whereby organisation of port authorities and oversight varies not only across *Länder*, but also within them (some ports are being serviced by private or public organisations, or a mix of the two). In the UK, authority over ports is devolved in Scotland and Northern Ireland. In Wales and England we see municipal, company and trust ports (thus private and public ones), which are all organised along commercial principles (for an overview, see Department of Transport, 2012). Over the past years, the busiest UK port in terms of tonnage has been Grimsby and Immingham with 57 200 000 tonnes, followed by 48 800 000 tonnes in London and 48 700 000 in Milford Haven in 2011 (Department of Transport, 2012b). According to Eurostat, in 2010 in total all German ports handled 276 000 000 tonnage of freight, whereas all UK ports processed 511 900 000 tonnes of freight (including inwards and outwards freight). Germany's largest port Hamburg handled 104 520 000 tonnes in 2010, followed by Bremen and Bremerhaven with 59 107 000 tonnes, and Wilhelmshaven with 24 728 000 tonnes (Statistisches Bundesamt, 2011).

different practices. One interviewee, for example, stated that "Finnish, Italian and British practices in port state control differ and will always differ".[109] Yet, interviewees generally were unable to produce concrete examples in this regard, which might also be due to a certain reluctance to do so as a result of possible worries about reports of non-compliant practices reaching the Commission. In general, it is seen as crucial which type of training, experience and expertise ship inspectors have, which, in turn, can differ across Member States. British and German inspectors usually were at sea as technical (e.g. ship engineer) or nautical crew members (e.g. captains), and then undergo an apprenticeship before becoming ship inspectors. Since ever fewer young people from each country go to sea, however, this picture could change dramatically in the future, and in Germany staff which has no experience at sea is already being trained to become port state control officials.[110] Especially in port state control the principle of 'professional judgement' (as opposed to procedural checklists) on the basis of the professional experience their staff possess is defended by the MCA and the *Dienststelle Schiffssicherheit*. As a result of the principle of 'professional judgement', differences in practices and philosophies are likely to exist from inspector to inspector, rather than merely from one country to another. Overall, then, it is likely that social relations marked by differences in national practices and regulatory philosophies are less crucial in the framing of coordinative behaviour than the perception of the overriding importance of the IMO on part of British and German officials.

4.1.2 The Inspection and Training Tasks of EMSA

The first wave of EU legislation in the field of maritime safety was an attempt to harmonise the implementation of international standards across

[109] Interviewee M8.

[110] Both countries are investing in training of seafarers, Germany via the 'Maritime Bündnis', established 2001, which invested around €90 million in 2011 (close to €60 million hereby being provided by the government and €30 million being funded by the industry) (Dienststelle Schiffssicherheit, 2011, p.38). The UK runs the Support for Maritime Training (SMarT) Scheme, established in 1998. According to the MCA, "in 2011-12 SMarT provided funding for a total of 1,903 officer trainees, including: 903 new officer trainees who started their training; and 629 officer trainees who completed their training" (MCA, 2012, p. 17). The UK's scheme hereby far surpasses the German efforts.

Member States, while also being aimed at the creation of a level-playing field for the shipping industry in the framework of the Single European Market (European Commission, 1993, also see, Blonk, 1994). Part of this early involvement was the establishment of a port state control regime in 1995, thereby directly building on the Paris MoU, and creating close cooperation between the two regimes (König, 2002, p. 44).[111] The maritime policy of the EU was then fundamentally reformed as a direct response to the *Erika* disaster (for a detailed elaboration on the historical evolvement of EU engagement in the international context, see Jenisch, 2004; Pallis, 2006, 2007; Ringbom, 2008, p. 31ff). As a consequence of the tragedy, the EU passed various measures which further strengthened existing legislation and established a European Maritime Safety Agency.[112] EMSA was entrusted with the task of monitoring the application of the relevant legislation in the Member States with the aim of coordinating the practices of national authorities across Member States.[113] The agency is governed by an Administrative Board that is comprised of one representative of each Member State, four representatives of the Commission, and four professionals from the concerned sector (who do not have the right to vote).[114] The Member State representatives are often officials from the country's Ministry of Transport, as is the case with the representatives of the UK and Germany. The board appoints an executive director who is in charge of managing the agency.[115]

EMSA –which has around 200 members of staff- has the overarching objective to "help them [Member State authorities] to apply Community legislation properly".[116] Hereby, the agency also has the responsibility to

111 Originally established under Council Directive 95/21/EC of 19 June 1995 concerning the enforcement, in respect of shipping using Community ports and sailing in the waters under the jurisdiction of the Member States, of international standards for ship safety, pollution prevention and shipboard living and working conditions (port State control). This has been amended several times since. The current port state control regime is regulated under Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control.
It has to be noted that the Paris MoU still exists as separate entity in order to involve Russia and Canada in a shared port state control regime (Gulbrandsen, 2011, p. 1048).

112 See Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency.

113 Recital (1), Art.1(1), Regulation 1406/2002.

114 *Ibid*., Art.11(1).

115 *Ibid*., Art.15, Art.16(1).

116 *Ibid*., Art.1(2).

evaluate the "effectiveness of the measures in place".[117] Moreover, EMSA provides Member State authorities with very specific services: It delivers training programmes for national authority staff,[118] and operates various data-bases for the exchange of information between Member State authorities.[119] It also operates an emergency response vessel fleet and a satellite system to monitor oil spills.[120] As part of its monitoring activities, EMSA officials carry out inspections of national inspectorates (i.e. 'inspecting the inspectors').[121] In this regard, EMSA plays a somewhat double-edged role: On the one hand, its task of delivering training sessions sets an institutional framework in place in which all involved regulatory actors are envisaged to meet at a horizontal level in order to facilitate the exchange of knowledge between national authorities. This requires EMSA to play the role of a partner authority of its national counterparts. At the same time, EMSA has to actively monitor the practices of national authorities and then inform the Commission about cases of non-compliance, which could bring an infringement proceeding against the country in question on the basis of this information. Its inspection task provides a institutional framework which provides for a vertical relationship between the EU regulatory body and its national authorities and can be expected to structure the coordination process in a hierarchical fashion (see Chapter 2). EMSA's inspection task, then, also gives it the role of a supervisor of national authorities that has to be prepared to 'tell on' national colleagues (COWI, 2008, p. 35, p.64). Whereas its training task ostensibly provides an arena for agreement between all involved actors, the latter is more prone to causing contention between EMSA and national authorities. It is this tension between EMSA's tasks –and the relations and roles associated with them– that renders this case into a particularly intriguing case of the study of the effect of tasks on coordinative behaviour.

[117] *Ibid*., Art.1(2), Art.2(b).
[118] *Ibid*., Art.2(c)(i).
[119] *Ibid*., Art.2(d)(ii).
[120] *Ibid*., Art.2(c)(i). Currently the most vital data-bases in this regard are *SafeSeaNet* which is a vessel-traffic tracking system (hence allowing national authorities to locate ships in EU waters) and *Thetis,* which is the port state control data-base. It allows national authorities to record and view all port state control inspection reports on a common data-base.
[121] Art.2(b)(i), Art.3, Regulation 1406/2002.

4.2 Examining the Coordinative Behaviour of Maritime Safety Authorities

EMSA's role in the European maritime safety regime is primarily one of monitoring and facilitating the implementation of EU maritime safety law. This, in turn, is aimed to be achieved through EMSA's 'visits' to Member States (i.e. inspections) and its varied training programme for national officials. It is within these two forms of tasks related to the coordination of national practices that we find an inherent tension: EMSA has the task to observe whether Member States practices are compliant on behalf of the Commission, whilst also being required to take the role of a partner authority to national authorities by providing a forum for mutual exchange in its training sessions. The dialectic in EMSA's tasks is also mirrored in differing visions as to how transnational coordination should function: A focus on compliance and harmonised practices in need of hierarchical enforcement co-exists uncomfortably with the idea of coordinating practices through mutual exchange (see Section 4.2.1). Since these two tasks provide different institutional frameworks and frames for action, it remains intriguing how these two differing frameworks affect the coordinative behaviour of the involved regulatory actors (for findings in this regard, see Section 4.2.2 and Section 4.2.3).

4.2.1 Balancing Inspection and Training Tasks

EMSA's inspection tasks set up a vertical relation between its staff and national authorities, whilst its training task requires EMSA to set up a horizontal relation with national officials in order to act as a 'partner' authority. As a result, the two tasks of EMSA represent an inherent dialectic, in which this EU regulatory body is –in theory– required to play two fundamentally different roles. EMSA inspections of national authorities usually take the following form: The inspected national authority presents an overview of their inspection system and the related procedures. EMSA officials then collect written evidence, carry out interviews with officials at the headquarters of the relevant national authority and conduct analyses of

national statistics of inspections. They then observe actual inspection practices for several days.[122] A team of EMSA inspection officials tends to be comprised of three assessors, who spend a few days at the headquarters of the national authorities and with the inspection teams in ports, whereby inspections on board of ships are witnessed. EMSA officials report back an overview of the findings while still on site. It then takes several weeks for the formal EMSA report to be written, and even longer for the final report (including the Commission's assessment) to be drafted (EMSA, 2007c, p.5). These reports remain confidential (between EMSA, the Commission and the Member State in question).[123] In case EMSA detects deficiencies when inspection national authorities' work, the Commission tends to request that EMSA revisits such authorities in order to verify whether they are meeting their obligations (EMSA, 2010, p. 70).

The EU maritime safety regime has several cornerstones with implications for EMSA's inspections: Firstly, the organisations which set technical standards for ships, and survey whether ships registered in a particular country are of adequate standard are inspected by EMSA (these so-called classification societies are responsible for 'flag-state control').[124] Moreover, the inspection of foreign-flagged vessels in European ports ('port state control') is organised under the IMO, Paris MoU and the equivalent EU Directive.[125] EMSA's role in this regard is to inspect the practices of national inspectors: Hence, EMSA staff inspects whether MCA and Ship Safety Division officials carry out port state control inspections as envisaged in the relevant EU requirements. Also, the reception facilities for ship waste provided by ports are regulated, thereby aiming at ships to leave their waste in ports, rather than in coastal waters or the open sea (such as ballast water which is polluted by oil).[126] The provision of these is inspected by EMSA as

[122] The visits policy is laid down in Decision 25/06/2004 of EMSA's Administrative Board (EMSA, 2004b). Also see Administrative Board meeting notes from the 17th meeting on 20.03.2007 concerning the involvement of Commission officials in accompanying inspections (EMSA, 2007b). The described inspection procedure was also explained as such by the interviewees from the MCA, Ship Safety Division, EMSA and the European Commission.
[123] Art.3(3), Regulation (EC), No 1406/2002.
[124] See Regulation (EC) No 391/2009 on common rules and standards for ship inspection and survey organisations; and Directive 2009/15/EC on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations.
[125] See Directive 2009/16/EC on port state control.
[126] See Directive 2000/59/EC on port reception facilities for ship-generated waste and cargo residues.

well.[127] Of these measures, especially port state control is seen as an effective means to deal with the most feared source of pollution: Sub-standard ships, which are registered in states that do not enforce international safety standards for ships, so-called 'flags of convenience'.[128]

The rules for the above mentioned cornerstones are laid out in the international IMO instruments, which are mirrored in regional agreements and EU law. Hereby, the key principle is the inspection of ships by flag and port states. Next to EMSA's operational capacities, its main task is to ensure that already existing standards and procedures are followed across all Member States. Thus, EMSA's task is to ensure that practices across Member States are coordinated. This is regarded to have the potential to ensure that all ships passing through EU waters adhere to the same standards in practice; thereby closing loopholes which had previously enabled sub-standard ships to go undetected due to (for example) inadequate implementation of internationally agreed inspection procedures in some countries.[129] It is in this realm that the EU detected a gap to be filled by its involvement in a highly international regime, namely through the tough enforcement of international/EU standards that could be a more potent motor for the coordination of practices than the role of the IMO, Paris MoU etc. could allow for (Knudsen and Hassler, 2011; Koivurova, 2012). In this area, then, we find one of the major tasks of EMSA, which –in line with the argument of this thesis– sets up a vertical relationships between EMSA and national authorities.

At the same time, EMSA also has the task to run an extensive training programme in order to facilitate the coordination of practices.[130] Topics of training workshops are spread over the whole range of EU activities in the field. For example, there are workshops which teach the content and implications of EU maritime legislation and trainings focusing on 'best

[127] See EMSA Annual Reports.
[128] For example, Recital (6), Directive 2009/16/EC.
'Flags of convenience' are seen as one of the major issues, if not *the* major problem, with regard to the continuing existence of sub-standard ships. The marine insurers and Protection and Indemnity (P and I) Clubs, however, also contribute to this problem: Due to fierce competition between insurers even unsafe ships can get insured against oil pollution claims (Tan, 2006, p.40ff).
[129] For example, Recital (3), Regulation 1406/2002.
[130] For example, the agency provided 27 training activities involving 543 officials in 2010. These are organised following consultations with representatives of the Member States in the forum of the Consultative Forum on Technical Assistance (CNTA).

practices' in port state control. Equally, workshops on the implementation for specific legal instruments of the EU regime are available. The underlying idea hereby is that coordination between national officials can be facilitated if national officials come together to discuss how they are doing things within their home administration, hereby possible being able to learn from each other to reduce incompliant and ineffective practices.[131] A coordination pattern shaped by this task of EMSA could hence be expected to be based on horizontal exchanges between the involved actors that provide an arena for finding agreement on shared practices. EMSA's training programme represents a combination of distance learning courses and workshops. The agency attaches high hopes to the potential of these sessions:

> As much as the networks that EMSA has established through workshops, seminars, assessment visits and training sessions feed knowledge into the Agency, knowledge is also diffused across the European Union, promoting a *common culture of maritime safety* through the exchange of knowledge and know-how by the relevant experts [emphasis added].[132]

EMSA not only sees these trainings as service provision to national authorities but also reports to be using them to learn about national practices, formulate 'best practices' on the basis of this knowledge and as a means to disseminate these (see, for example, EMSA Annual Report, 2008, p. 33). In this regard, the agency describes itself as active motor for the increased coordination of practices since it establishes and disseminates informal standards in form of 'best practices' amongst national authorities from assessments of all reports on the inspections of national administrations (the so-called 'horizontal assessments') (EMSA 2010b, p. 33).

EMSA's tasks hence have the potential to shape coordinative patterns based on hierarchy *and* mutual exchange. As a result, maritime safety represents an interesting case to explore how coordination functions when it is shaped

[131] For example, Recital 5, Regulation 1406/2002. Also, see, sections on training activities in EMSA Annual Reports.
[132] EMSA, 2005, p.7.

by such differing tasks. Since the role of EMSA in carrying out these two tasks –and the institutional framework for interaction provided by them– represent an inherent tension, it is particularly intriguing to examine their effect on coordinative behaviour.

4.2.2 A Hierarchical Coordination Pattern

Indeed, in practice the above described tension between inspection and training tasks of EMSA creates an environment in which the former diminishes the potential of the latter: Due to the 'shadow of hierarchy' present in EMSA's inspection tasks, Member State officials are less inclined to openly share experience and practices in the forum of the European agency. This is largely so since the Commission has been a zealous enforcer of EU norms on the basis of EMSA inspection reports.[133] This dominance of EMSA's inspection task over its task to further mutual exchange needs to be understood in the context of the social relations that regulatory actors are embedded in: The highly international character of maritime safety regulation renders the perceived 'added value' of the involvement of EU bodies in this field questionable, and many national authorities –including the British and German ones– question the role of the EU in this field altogether. The added value that EU bodies *can* provide in comparison to the IMO is the tough enforcement of supranational norms.[134] This zealous approach, in turn, antagonises national authorities further, which has the potential to strengthen the contentious nature of their relationship with EMSA and the European Commission. UK and German authorities hence assess EMSA's tasks from the context in which they are embedded, namely the highly international regulatory process which they perceive to the most crucial arena for transnational coordination in this field.

In this light, national authorities have often voiced their unease with the zealous approach to infringement proceedings of the Commission on the

[133] See, for example, European Commission, 2009; 2009b; 2009c; 2010; 2010b.
[134] Overall, experts in the field are of the view that the main safety issue remaining is not the quality or quantity of existing regulatory standards, but rather their effective enforcement in a highly complex, global arena (Ringbom, 1997, p. 3; Tan, 2006, p. 4; also see Donaldson Report (Department of Transport, 1994, para. 4.26); and Pallas Report, 2000, p.44ff).

basis of EMSA's inspection reports. For example, national officials have complained that they had usually already changed their system on the basis of EMSA preliminary findings that were reported to them immediately after the EMSA inspection.[135] There have also been complaints by national officials that they do not get sufficient time to remedy negative inspection findings before an infringement procedure is started against them, and German officials have repeatedly questioned whether the level of intensity of inspections is necessary (EMSA, 2007c, p. 5; EMSA, 2011c, p. 6; EMSA 2011d, p.10). The first time the Commission initiated an infringement procedure on the basis of a report, it failed to inform EMSA about this, which reportedly irritated the agency and the given authorities.[136] After the first letters announcing the impending infringement procedures based on EMSA's finding had gone out, Member State officials remarked that this potentially tainted the image of EMSA's inspections and might result in a less open atmosphere between the involved actors (EMSA, 2006c, p. 8). National authorities are hence today acutely aware of the flow of information between EMSA and the Commission, and mainly worry about having to take corrective steps, even in cases where they think they are applying EU law correctly. This inhibits them to speak openly about their practices in the forum of EMSA's trainings. Coordination in this case is hence dominated by EMSA's inspection task, resulting predominantly in a hierarchical coordination pattern that overshadows EMSA's training responsibility to further mutual exchange between national officials in its training sessions.

This is amplified by the confidential nature of EMSA's inspection reports, as a result of which possibilities of mutual learning through one another's EMSA inspection reports is limited. In the forum of EMSA's Administrative Board, officials from some Member States have voiced that it would be useful to be able to learn from inspection reports, which would

[135] This was found interviews by Groenleer et al (2010). Administrative Board meetings show the constant worry of national officials about the Commission handling of EMSA inspection findings. Member States have asked the Commission to discuss inspection findings with them in the forum of the Administrative Board. The Commission, however, insists that these are discussed in more detail in the relevant Comitology Committee (COSS, the Committee on Safe Seas and the Prevention of pollution from ships) (see EMSA 2007b, p. 10; EMSA, 2010c, p. 6).

[136] Groenleer et al (2010) report this (p.1220), and the irritation of the given Member States clearly emerges from Administrative Board minutes (EMSA, 2006c, p. 7f).

require them to be of a transparent nature (EMSA, 2010d, p. 3 and 6). In this regard, the equivalent IMO inspections have more potential, whereby inspectors of national authorities form small teams and inspect another country's practices.[137] Officials are able to observe how things are done in other authorities first hand but the procedure lacks the enforcement possibilities of the Commission. Indeed, a Polish official brought forward the idea to establish a similar system in the EU regime to allow for mutual learning; however, the Commission is of the view that not all Member States would feel comfortable with this (EMSA, 2009b, p.9). Currently, the EMSA 'visit to Member States' structure a hierarchical relationship between EMSA and inspected national authorities. Whereby relationships between EMSA and national authorities are reportedly of a very cooperative and friendly exchange, the hierarchical element remains present due to EMSA's link to the Commission's enforcement powers.[138] MCA and Ship Safety Division staff reported that these inspections clearly matter to them in terms of avoiding an infringement procedure, thus resulting in a hierarchical coordination pattern.

> Well, in the end those [EMSA inspection teams] are the same people one meets in relation to various topics in different national and international organisations. We know each other, of course. So the whole thing does have a rather cooperative character. Of course they have a close look, and of course one does not want to be noticed in a negative way, and what you really, really don't want is an infringement procedure.[139]

> To give you an example, we came very close to being infracted for our late transposition of the Vessel-Traffic Monitoring Directive and the Port State Control Directive, and so that was quite obviously one of the things, and we weren't alone as a Member State.[140]

[137] See IMO 2005 and 2005b for the resolutions establishing the voluntary audit scheme. Also see IMO website for an explanation and further documents related to the audit regime.
[138] It needs to be pointed out that the notion of hierarchy when EMSA visits to Member States are concerned is related to the possible consequences of such in form of enforcement action by the Commission, rather than the conduct of the inspections as such: It might be a nuisance for UK and German officials to accommodate these in terms of the extra work their create but the atmosphere is usually described as a friendly one. This also owes to the fact that EMSA officials are often former national officials and that the highly multi-national environment of regime provides for an environment where officials from different countries have frequently known each other for a considerable time.
[139] Interviewee M1, Germany.
[140] Interviewee M10, UK.

Both officials mentioned infringement procedures immediately when asked which significance EMSA inspections bear to them. EMSA officials directly involved in carrying out 'visits to Member States' also emphasise the checking of compliance, as opposed to an enhancement of practices as the focus of these inspections, and the Commission is intent on 'putting EMSA inspection reports to use'.

> EMSA's input doesn't create effects by itself. They come to us [the European Commission] to be able to follow up with the remit that is given to us by the treaties, whether it is to clarify subjects with Member States, whether it is to take them to the Court, so an infringement procedure, or even to impose fines, that is now the case under the new Class Regulation. So all these things have to be assessed here, by the Commission.[141]

The inspection task of EMSA hence creates a hierarchical coordination pattern that is focused on the use infringement procedures. EMSA's role in this regard is hence to be seen rather as an enforcement agency of the Commission (which supplies the necessary information for enforcement), than a hub of national authorities in which mutual exchange happens. British and German officials also expressed a worry about the role that the flow of information between EMSA and the Commission poses to them in terms of revision of existing legislation and proposals of new legislative initiatives, which is generally shared by many other Member States (EMSA, 2011e, p.11.).

> The Commission has difficulty accepting that [standards are set by the IMO]. They know it is the realpolitik of it to a certain extent. But the problem is that they are always pushing at competence, they are always trying to nibble away at competence... And I will be perfectly honest with you, we always need to be on our guard. Us and other EU Member States, we always need to be on our guard what is coming out of the Commission. Asking what's there in the sub-text, what's there in the fine print.[142]

We hence observe an underlying impression of some national officials that even practices which are compliant with EU maritime safety law could result in an uncomfortable situation whereby currently 'valid' legislation

[141] Interviewee, M6, European Commission.
[142] Interviewee M10, UK.

and practices at the national level are turned into incompliant ones. The Commission is also very explicit that it uses information from EMSA to revise and propose legislation (EMSA, 2011d, p. 9). For Member States which defend the IMO's place as international rule-maker –like the UK and Germany– an added worry in this regard is to keep purely European rules in check since these undermine, rather than promote, maritime safety in their perception. The assessment of transnational coordination in EMSA on part of UK and German authorities is thus fundamentally characterised by the social relations they are embedded in, namely their perception of the importance of the international regulatory arena. The ensuing struggles for competence –and hence contention– between the international, the EU and the national level have a direct impact on how EU bodies carry out their tasks and how these are then evaluated by UK and German officials that are worried about a loss of importance of their coordinative work in the IMO.

Currently, EU Member States often coordinate positions before IMO meetings and hence wield their influence in such crucial arenas like the Maritime Safety Committee (MSC) and Marine Environment Protection Committee (MEPC) en bloc. The Commission acts as an observer at IMO, but has been aiming to become a fully voting member. This is controversial amongst UK and German officials, as is the potential role played by EMSA in coordinating positions, and the coordination of an EU-wide position in general.

> Sometimes it is good when EU interests are bundled somewhere, through the Commission or whomever. But not in this field. After all, international cooperation at the IMO is very well-rehearsed indeed. And if the EU wants to have a common position you can get together on a case-by-case basis. We always do this before IMO sessions, there is always a meeting, a coordination in the EU. That exists anyhow, we do not need to have EMSA for that.[143]

> I would say the biggest issue in that area [maritime safety] is the competence ambitions in trying to create and EU standard for maritime safety, an EU platform for maritime safety within an industry that is international. Now why do I say that is a problem? Well, it's because the shipping industry is more than international, it's global, and it appears to be, we have seen evidence of an EU-centric approach going further than is necessary for approximated risk associated to safety and hence putting European flags at a

[143] Interviewee M1, Germany.

> comparative disadvantage. […] And to some extent there is within that the risk to undermine and to undo a lot of the good work that has come out of the Paris Memorandum, for example.[144]

The role of the Commission and EMSA in transnational coordination is hence contentious in the perception of British and German officials (also see EMSA, 2011c, p.7 and EMSA, 2012, p.6). Whereas a coordination of a position to be defended internationally between some Member States is seen as desirable by them (the UK, Germany, the Netherlands and the Nordic countries often coordinate their position, and often the Commission pushes for an EU-wide coordinated position), British and German officials think that a long-standing convention of doing so is sufficient, and are weary of the Commission's ambitions to formalise these. Moreover, in their view there is a safety trade-off in appearing as a bloc in the IMO: Reportedly non-European countries become less cooperative when faced with an already agreed European position: With the aim of having a global regime, rather than a European one, this has potential implications for safety as non-European countries become less willing to agree to more stringent safety standards mainly supported by EU countries.

Informal coordination (in parts orchestrated by the Commission) of positions of European administrations nonetheless remains a key feature when IMO standard-setting is concerned. In this regard, EMSA's Administrative Board (attended by ministry officials in the case of Germany and the UK) provides an additional forum for coordinating on a transnational level, which British and German officials see as highly valuable. The Commission was only slow to accept the use of the Administrative Board as a platform for discussion of national positions, while at the same time profiting from being able to hear what happens on the national level.[145] In the forum of EMSA national officials are hence involved in standard-setting in a highly informal manner. Whereas national officials represented on its Administrative Board formally only oversee the work of the agency and decide on its overall direction,[146] national officials

[144] Interviewee M10, UK.
[145] Interviews M5, M6 and M7. Also see, EMSA, 2012b, p. 6.
[146] Art.10, Regulation 1406/2002.

have become accustomed to use this as a forum to exchange positions and practices with colleagues from other administrations. Hereby, national officials do indeed exchange (views on) national practices and invite each other to observe work being done in their home administration: For example, a British official explained that officials from other administrations had attended a contingency exercise for the case of a vessel running into an off-shore wind farm. Equally, he reported that his team had observed Danish attempts to build an infrastructure for liquefied natural gas fuelled ships.[147] Sweden invited other Member States to view its scheme to measure ship emissions from planes (EMSA, 2011c, p.7), and Poland has suggested exchanges of port state control officers in the forum of the Administrative Board (EMSA, 2006b, p.8). The struggle over competences and the hierarchical nature of coordination do not necessarily exclude mutual exchange as form of coordination per se.

Whilst, EMSA training sessions, however, are potentially the most likely place to find exchange of practices and mutual learning, the picture in practice is rather different. The majority of training sessions are lecture-type trainings on the content of EU legislation, whereby EMSA staff explain these legal provisions to national officials from ministries or maritime safety authorities. Port state control training sessions are meant to provide more of a forum for exchange of practices but according to a German port state control officer time for these can usually only be found after the end of the training sessions in the evenings and whether they take place hence depends largely on the levels of motivation of the individual inspectors.[148] Whereas all interviewees agreed that the trainings are popular amongst officials (not least because attendance is fully paid for by EMSA), national officials are permanently aware of the potential flow of information between EMSA and the Commission, hence hampering their willingness to exchange worries candidly. An EMSA official, on the other hand, also noted that the difference in the level of expertise between national officials can make an effective exchange of practices difficult.

[147] Interviewee M5.
[148] Interviewee M9.

> But I think another issue here is since EMSA is an EU body, Member States that are not performing superbly are a bit reluctant to come to EMSA and very openly share their problems because they sometimes feel that that might be used against them. The EU Commission is then ultimately the body that may sue them for non-compliance, so there is a little bit of that as well. But I think generally we create a relatively good atmosphere in the sense that we are of course not trying to cheat Member State representatives in the sense that they come here and discuss their problems and then we go and use the information obtained in that way by knocking on the Commission's door. But it's still on the back of the minds of the Member State officials that they cannot be too open about things that they are doing.[149]

> The training office of EMSA basically puts people together in the same room, and they listen, and there is not really an exchange of good practices. It is more a process of EMSA preaching the good word, on what a good practice should be. [...] Nobody will -in public like that when everybody is present- admit certain weaknesses in their system.[150]

The hierarchical coordination pattern that emerges from EMSA's inspection task hence dos not easily coincide with less defined tasks to promote mutual learning and a 'common culture' of managing risk.

Although EMSA has an inspection task *and* the task to provide a forum for mutual exchange –for example through its training programme– coordination between regulatory actors in maritime safety is largely hierarchical: In the perception of national authorities EMSA's inspection task is directly linked to the enforcement action on part of the European Commission. This close link between EMSA and the Commission results in a willingness to openly exchange practices in the forum of EMSA. That EMSA's inspection task is more prominent in shaping coordination between officials can only be understood in the specific context of the social relations that regulatory actors are embedded in: The presence of the IMO -which authorities in countries like the UK and Germany continue to view as pinnacle of maritime safety regulatory efforts– affects how coordination functions in the EU setting. Due to the presence of international norms, the European Commission can 'only' add value in this regime if it enforces EU

[149] Interviewee M4, EMSA.
[150] Interviewee M3, EMSA.

requirements zealously on the basis of EMSA inspection reports. This results in the strictly hierarchical nature of coordination that adversely affects coordination between national officials that is based in mutual exchange.

4.2.3 The Perpetuation of Hierarchical Coordination despite Contestation

A central question arising from the above analysis is why hierarchical coordination is perpetuated: UK and German officials continue to proactively engage with EMSA processes –not least in its Administrative Forum and in its training programme– despite the contentious relationship they have with EMSA and the European Commission. In this regard, EMSA's inspection tasks need to be considered in the wider context of the services it provides to national authorities, which UK and German officials take into account when assessing which 'added value' EMSA's tasks bring to them. Overall, authorities with small administrative capacities report to derive distinct advantages from EMSA services, whereby especially the provision of the vessel-traffic monitoring system, the port inspection data-base, and the satellite oil-spill monitoring scheme are seen to decrease cost at the national level whilst enhancing overall safety. Administrations with large capacities and expertise like the UK and Germany, however, remain to be convinced of the benefits of some of EMSA services. They are keen to avoid a duplication of effort in EMSA and 'at home'. Nevertheless, in their perception they derive a crucial benefit from EMSA's tasks that contributes to the effectiveness of their work: Under conditions of interdependence, they regard EMSA's inspections as a vehicle to ensure that their colleagues in other countries are also carrying out effective port state controls, which is a prerequisite to the effectiveness of their work on the whole.

In order to understand which added value national authorities can derive from the engagement with EMSA processes, it is vital to recognise that EMSA's inspection task is not evaluated in isolation by national officials. Rather, the inspection of the practices of national authorities by EMSA only

represents a part of the work national officials connect with EMSA. National officials also associate EMSA with its operational tasks, whereby especially the provision of the vessel-traffic-monitoring system *SafeSeaNet,* the port inspection data-base *Thetis* and the oil-spill satellite-monitoring scheme *CleanSeaNet* are seen as effective service delivery on part of the agency.[151] In this respect, national authorities see these tools as 'adding value' to their operations by reducing costs whilst creating a greater capacity to reduce risk. *CleanSeaNet*, for example, is able to provide satellite pictures of all European seas to Member State authorities (EMSA, 2011b). These pictures monitor potential oil spills and can detect the polluting vessel.[152] If a potential oil spill is detected in national waters the relevant national authorities are informed within 30 minutes of the satellite passing over the oil spill (EMSA, 2011, p. 4).[153] The national authorities can then decide to check upon the possibility of a spill on site.[154] This system is economically advantageous for all Member States as it is cheaper than aerial surveillance by plane (COWI, 2008). EMSA's well-developed rhetoric of 'adding value' to the work of national administrations particularly emphasises the role of *CleanSeaNet.*

> In certain cases economies of scale can be achieved by transferring activities to the Community level. The establishment of EMSA will clearly benefit the Member States by providing services that would otherwise have meant additional expenditure at national level.[155]

This 'added value' of *CleanSeaNet* is even recognised by Member States with large administrative capacities, such as the UK and Germany (for example, COWI, 2008, p. 54; EMSA, 2011c, p.5, p.12, p.14). Nevertheless, with regard

[151] Art.10(2)(a), Directive 2005/35/EC of the European Parliament and of the Council of 7 September 2005 on ship-source pollution and on the introduction of penalties for infringements.
[152] See EMSA, 2011. A satellite of the European Space Agency and two satellites of the Canadian Space Agency are used for this purpose.
[153] *CleanSeaNet* supplements monitoring systems at the national and regional level, which were in place before its inception. For example, members of HELCOM operate aerial surveillance in cooperation, thereby flying over heavy traffic routes at least twice per week and once per week in areas of sporadic traffic (see, for example, HELCOM, 2010, for an overview, including flight hours of individual countries). The Bonn Agreement operates a similar arrangement (for example, see Bonn Agreement, 2008). This service now cooperates with EMSA's *CleanSeaNet* facility.
[154] In its first phase of operation (from April 2007 to January 2011) 8000 satellite pictures were taken, of which 2828 were checked on site. 745 of these were confirmed to be pollution in the form of oil or other substances.
[155] EMSA, 2004, p.8.

to the further development of EMSA's operational tasks fault lines remain between Member States with large administrative capacity at home (like the UK and Germany), which would like to avoid duplication of efforts on the national and supranational level, and administrations with less capacities aiming to balance their potential shortcomings through EMSA.[156]

This attitude is also reflected when the provision of training by EMSA is concerned. The exchange of practices in EMSA trainings might be hampered through their hierarchical nature and the fear of admitting to possibly non-compliant practices; nevertheless, national officials stress that EMSA trainings can be very helpful for them in certain regards, such as the possibility to get assistance from EMSA in securing correct implementation (see COWI, 2008, p.34f).[157] German and UK authorities, however, do not perceive this as helpful assistance (*ibid*.), whilst recognising that it is helpful for authorities with smaller administrative capacities.[158] Most Member States also state that they profit from EMSA's inspection of the STCW Convention (i.e. training certification of seafarers) in third countries since this renders it unnecessary for each individual Member State to carry out such check-ups in order to verify whether seafarers from third-countries are qualified to be employed on vessels flying their flag (COWI, 2008, p.36).[159] The UK, however, does not participate in this mechanism and continues to run its own inspection regime in this regard.

Overall, then, the presence of EMSA's operational services can far better explain which perceived 'added value' small capacity authorities derive from EMSA than what UK and German authorities get out of this transnational process. Authorities in the UK and Germany only perceive *SafeSeaNet, Thetis* and *CleanSeaNet* to 'add value' to their work, whilst remaining keen to avoid a duplication of effort in other areas. This is especially the case in the realm of port state control inspections, where the UK and German officials stress the importance of relying on the experience

[156] This issue came up frequently in interviews and is also exhibited in the Administrative Board meetings of EMSA (see, for example, EMSA, 2006b, p. 5; EMSA, 2011c, p.5).
[157] EMSA officials stated that they generally receive this feedback from many Member States (however, they did not differentiate across national authorities in this respect).
[158] Interviews with German and British officials.
[159] Member States officials are especially content with the system since STCW inspection results are shared across all national authorities by a secure website (EMSA, 2009b, p.12).

and expertise of their port state control officers instead of introducing a proceduralised EU regime. The continued importance of 'professional judgement' of national inspectors contributes to the acceptance of the strictly hierarchical form of coordination on part of the MCA and the Ship Safety Division. The setting of social relations in which the necessary expertise for ship safety inspectors continues to exist in their national regimes thus informs their evaluation of EMSA's work. In this regard, in the Paris MoU it was decided from the outset that the use of checklist and highly proceduralised forms of port state inspections would be avoided (Kasoulides and Ringbom, 1997, especially p.132).[160] The reliance on the expertise of highly experienced ship inspectors has been the cornerstone of this regime since, whereby the Paris MoU and the EU regime have set rather broad standards for the procedures to be used,[161] whilst also specifying the level qualifications needed by national inspectors.[162] As a result, the conduct of inspections remains largely based on 'professional judgement': It is set out which documents need to be checked on board for the most basic form of inspection ('initial inspection') but whether the inspector goes further and what he/she chooses to scrutinise more closely is not strictly regulated. Hereby, the principle of 'professional judgement' is vehemently defended by MCA and Ship Safety Division officials: "I have well qualified inspectors, it is not for nothing they are trained for 15 months", a German official said. A German port state control officer remarked that it was his experience of having been at sea for 40 years that mattered for assessing risk, rather than checklists.[163] At the same time, he contemplated whether the new generation of staff –which often lacks this form of experience at sea– might perhaps be better able to assess risks if they used checklists.

The reliance on 'professional judgement', rather than proceduralised inspection norms, renders the hierarchical coordination acceptable to MCA and Ship Safety Division officials: Whilst EMSA inspections verify whether national officials are trained sufficiently, whether the port state control data-base *Thetis* is run correctly by national authorities etc., national

[160] Also see Paris MoU, Code of Good Practice for Port State Control Officers, Annex I, Rule 1.
[161] See Paris MoU text, especially Section 3 and Annex I.
[162] Art.22(1) and Annex XI of Directive 2009/16.
[163] Interviewee M9.

officials retain autonomy in the realm of 'professional judgement'.[164] British and German officials might have to endure the inspections of their port state control systems, but the regime also provides them with a solution to its coordination problem by assuring them that other Member States administrations are carrying out their work 'properly', which is essential for the closing of loopholes used by unsafe ships (i.e. more lenient authorities). Continued maintenance of the acceptance of hierarchical coordination is hence likely to be contingent on the maintenance of professional judgement as core logic of control in the port state control regime.

The continued existence of the hierarchical coordination is also likely to depend on the perception of the feasibility of compliance with the EU regime in future, whereby especially the meeting of inspection targets represents an increasing challenge. The main underlying principle of the port state control regime is that ships with good safety records will have to undergo fewer inspections, thus providing an increased incentive to maintain safe vessels. As a result, fewer ships which have a risk profile that permits them to be inspected are entering European ports. The risk profile of a given ship is created according to certain criteria, such as flag, age, number of past deficiencies etc.. Moreover, explicit sanctions are attached to non-favourable inspection findings, namely possible detention of the ship or refusal to let a ship enter a port in the first place, which are very costly consequences for ship-owners. Any ship that flies the flag of state which is on the black or grey list of the Paris MoU is refused access to ports.[165] At the same time, the public display of results of inspections on public databases - *Thetis* allows for a historical record to be kept and reviewed at a glance, whereby a record of deficiency is likely to render the inspector more careful and strict in his/her assessment of the ship- and the existence of the Paris MoU lists provide for behaviour-modification through a mechanism of naming-and-shaming.[166]

[164] Also see Paris MoU Annual Reports in this regard, (Paris MoU 2006-2010).
[165] Art.16 and Annex VIII, Directive 2009/16/EC.
[166] *Ibid*., also see Recital (30).
This is not to say that the findings of deficiencies are low in the Paris MoU area: Even diligently kept ships are not necessarily able to avoid deficiencies since the absence of the newest update on, for example, specific training manuals can be deemed as deficiency by an inspector (as observed by the author when accompanying a port state control officer in the port of Bremen in December 2012).

The effectiveness of these mechanisms coupled with the risk-based regime results in ever fewer numbers of ships with the necessary risk profile being available to be inspected by British and German officials. This is stretching MCA and Ship Safety Division capabilities to the limits: Whereas the former stated that it is a challenge to comply with the Port State Control Directive in terms of ensuring that each port state control officer carries out the required number of inspections per year due to the UK's exceptionally large number of officers,[167] the latter stressed that it was now necessary to employ a constant on-call policy for port state control officers to inspect ships day and night even in the absence of imminent danger to reach the required number of inspections per year.[168] The new regime has also resulted in an increased 'race' between national authorities, whereby authorities attempt by all means to inspect ships that have the necessary risk profile before a different authority within the regime gets a chance to do so. Continued acceptance of national officials of EMSA's inspection task will hence also depend on the feasibility of compliance with the EU regime in future, especially with regard to the meeting of inspection targets.

This section of the chapter has shown that UK and maritime safety authorities continue to engage with transnational processes in EMSA despite the contention its inspection task causes because they perceive EMSA to add value to their work in certain respects: Some of EMSA's operational capacities are evaluated as beneficial by UK and German authorities. Also, through the context of social relations in which they are embedded in at home, they appreciate the reliance of the EU regime on the 'professional judgement' of ship inspectors, whilst valuing that EMSA's inspections provide them with reassurance that other national authorities are carrying out their work adequately.

[167] Interviewee M10. The UK has around 130-150 officers, for example, see MCA, 2011, p.11.
[168] Interviewees M1, M8 and M9.

4.3 Conclusions

This chapter demonstrates that the inspection task of EMSA indeed results in a hierarchical coordination pattern: The activities of EMSA and the European Commission are at the heart of the coordination process with regard to proclaiming what the practices of national maritime safety authorities should look like, as well as the gathering of information about the work of national authorities on the ground, and the modification of their behaviour through infringement proceedings. The UK and German maritime safety authorities contest the zealous interventionist approach of the European Commission as they perceive it to be potentially detrimental for furthering safety in this highly global regulatory regime, in which the IMO plays a crucial role. EMSA and the European Commission, in turn, arguably perceive a necessity to justify their added value in a field in which the role of yet another transnational bureaucracy is potentially questionable.

In this regard, the case study also shows that EMSA's inspection task has a direct impact on its training task: The mutual exchange between national officials in the forum of EMSA is inhibited by the awareness of national officials that information is passed from EMSA to the European Commission and subsequently used in infringement proceedings. The contention that EMSA's inspection task provokes among British and German authorities –as well as the effect of EMSA's inspection task on its task to provide training to national officials– can only be understood in the context of the social relations in which regulatory actors operate in this field, namely a highly global regime in which British and German authorities question the value of an additional transnational coordination body (i.e. EMSA) and EMSA's and the Commission's perceived need to justify their *raison d'être* in relation to the IMO. As a result of this dynamic, coordination remains primarily hierarchical in nature despite EMSA's task to further mutual exchange between national officials.

The maritime safety authorities of the UK and Germany are willing to engage with the EMSA process (for example in its training programme and in its Administrative Board) despite their contention of the hierarchical

coordination pattern since they also perceive EMSA's work to add value to their own regulatory activities: Firstly, EMSA carries out operational activities, which even UK and German authorities assess to add value to their work. Secondly, officials from the British and German authorities find that EMSA's inspections at least give them the reassurance that other national authorities are carrying out their work adequately, which ensures that their work is effective under conditions of interdependence. In this regard, the maritime safety authorities of the UK and Germany thus indeed not only contest, but also value EMSA's and the European Commission's efforts to enforce regulatory standards, which the IMO is unable to do.

The findings of this case study also serve as crucial comparison to the case of food controls (see Chapter 5): The EU regulatory body in this field (the Food and Veterinary Office) also has an inspection task. However, regulatory actors in the fields of maritime safety and food controls are embedded in very different sets of social relations. A comparison in this regard thus provides us with further insights into how the social organisation that regulatory actors are embedded in informs their perception of the value of transnational coordination.

Chapter 5

Food Safety

The case of food safety offers an opportunity to study the effects of a knowledge generation task, as well as an inspection task, on coordinative behaviour. The European Food Safety Authority (EFSA) has to provide scientific advice on food safety issues, in which it is supported by national food risk assessors. Together, they have the task of generating knowledge about questions of risk and safety. For example, this entails the scientific assessment of the safety of foods deriving from new technologies under conditions of uncertainty about their long-term consequence, such as nanotechnology and genetically-modified organisms. The Food and Veterinary Office (FVO), in turn, has been tasked with the inspection of the practices of food control authorities in the Member States: Food controls are usually carried out by local authorities due to the heterogeneous nature of the food industry and the complexity of the food chain. Each stage of the production, processing and distribution of foods potentially bears hazards, which are hence verified for their safety by local authorities. Food control oversight authorities –which are the point of contact for FVO inspections– have the responsibility of ensuring that these decentralised activities add up to an effective control system in each Member State.

As argued in Chapter 2, a knowledge generation task provides a framework conducive to a coordination pattern that is based on mutual exchange and adjustment. An inspection task, in turn, is expected to set the

involved regulatory actors into a hierarchical framework that has the EU regulatory body at its apex. In line with the argument of this thesis, we can expect that national authorities accept and engage with these transnational coordination processes if they perceive themselves to be 'getting something out of' them.

This case study also offers two excellent points of comparison in relation to the drug safety and the maritime safety case studies (see Chapter 3 and 4 respectively): The scientific experts involved in food risk assessment can be deemed to have relatively similar professional norms to the scientific experts involved in drug safety monitoring. If professional norms were indeed the main determinant of coordinative behaviour we could expect coordination to function very similarly in these two cases. If, however, tasks and social relations drive coordinative behaviour, we can expect coordination patterns to vary across these cases. Moreover, we can compare the coordinative behaviour of food control and maritime safety authorities. In both cases the practices of national authorities are coordinated through an inspection task of an EU regulatory body, but regulatory actors operate in a context of very different social relations in the two cases. This allows us to study whether regulatory actors indeed evaluate the same task differently under these conditions.

5.1 Social Relations and Tasks in Food Safety

National risk assessors have the task to support EFSA in its scientific work (i.e. the formulation of scientific opinions) by generating knowledge at the transnational level. The effect of this task on coordinative behaviour is of particular interest since national risk assessors do not comprise EFSA's scientific bodies, which instead consist of 'independent' experts. As a result, the extent of their engagement with the transnational process is highly conditional on their perception of the added value that supporting EFSA's work has for them. This, in turn, is depended on the social relations they are embedded in. The FVO, in turn, has an inspection task. The expected

hierarchical nature of the coordination process has the potential to cause contention between food control authorities in the Member States and the FVO: After all, they are the operative arm of this transnational bureaucracy, which faces the day-to-day challenges of applying European norms. In order for authorities in the Member States to accept the FVO inspections despite contestation –or in order for contestation to not arise in the first place– they must perceive their engagement with the FVO audit process to add value to their work of overseeing highly complex control systems (see Section 5.1.1 for an analysis of the social relations food safety actors are embedded in, and Section 5.2.1 for an overview of the tasks of EU regulatory bodies in this field).

5.1.1 Social Relations in the UK and German Food Safety Regimes

Authorities in both countries face similar social relations in which they need to carry out their tasks of risk assessment and the oversight of food controls, despite having different organisational structures in place in this regard. In food risk assessment, authorities in the UK and in Germany are embedded in social relations that are characterised by mistrust towards their scientific advice. In food controls, in turn, food control oversight authorities in both countries face the extraordinary challenge to oversee a heterogonous, decentralised administrative control apparatus.

The UK and Germany fundamentally reformed the organisation of scientific advice in their risk assessment regimes in the aftermath of the BSE crisis. In this regard, this crisis can be seen as a veritable turning point in the approach to food safety in Europe: Public confidence in producers and public authorities was (in-)famously low as a result of the BSE crisis, in which it was often unclear whether public authorities were claiming beef to be safe or risky on scientific or political grounds (for example, Vincent, 2004, also see the Medina Ortega Report, European Parliament, 1997). Whereas Germany institutionally separated 'risk assessment' (i.e. scientific expert advice) from 'risk management' (i.e. policy-making and food control activities) as a result of the crisis, the UK integrated these tasks in one

authority. In Germany, the Federal Institute for Risk Assessment (BfR)[169] – which was founded in 2002 under the auspices of the Federal Ministry of Consumer Protection, Food and Agriculture (BMELV) – is responsible for the risk assessment of food stuffs.[170] The BfR supplies risk assessments to the 'risk managers', namely the BMELV and the Federal Office for Consumer Protection and Food Safety (BVL).[171] The latter was also founded in 2002 in conjunction with the BfR and henceforward started acting as coordinating authority in relation to food safety controls, which fall under the responsibility of the *Bundesländer*[172]*.* In the UK, the Food Standards Agency (FSA) – an independent non-ministerial government department– was established in 2000 in order to re-establish the confidence of consumers in the capacity of state to manage risk responsibly in the aftermath of the BSE crisis (James Report, 1997).[173] The FSA combines risk assessment and risk management tasks. It is hence responsible for delivering scientific opinions, as well as for formulating (some) policy and being responsible for food controls.[174] The FSA hence oversees the food controls carried out by local authorities.

Next to differing in the separation of risk assessment and risk management, the FSA and BfR also differ in relation to the nature of the scientific basis for their decision-making. Whilst many FSA staff members have a background in relevant scientific research, no primary research is carried out in-house (in other words, no laboratories can be found on the FSA premises). Rather, the FSA relies on eight scientific committees composed of independent experts in the respective field and at least one lay member. Moreover, it can commission research from third parties. In

[169] BfR stands for Bundesinstitut für Risikobewertung.
[170] BMELV stands for Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz.
[171] BVL stands for Bundesamt für Verbraucherschutz und Lebensmittelsicherheit.
[172] For a critique of the pre-BSE system and a reform proposal, see Von Wedel, 2010.
[173] The legal foundations of the British food safety regime are the Food Safety Act 1990 and the General Food Regulations 2004.
[174] In this regard, it needs to be pointed out that nutrition and nutrition labelling was removed from the FSA's responsibilities and transferred to the Department of Health in a reform in 2010 initiated by the coalition government which came to power that year (in Wales this remit was also moved to its health department, while it remained within the FSA in Scotland). In this regard, a large part of the FSA's work (such as driving forward reductions in salt in food, and tackling the question of sugars and non-saturated fats in food) was removed from its remit. Moreover, non-safety related labelling was moved to the Department for Environment, Food and Rural Affairs (Defra) (for example, see FSA, 2010, p.7). However, its regulatory responsibilities pertaining to food safety per se were not curtailed in this reform.

contrast to EFSA and the FSA, the BfR carries out research in-house. In other words, a visitor will be able to find laboratories on its premises.[175] The key rationale in this regard is that only active researchers are fully integrated in the scientific community.[176]

Despite these differences in the formal organisation, authorities in both countries are embedded in similar social relations. In the case of risk assessment, this means that authorities in both countries perceive the need to foster trust in their capabilities in a context of (perceived) public mistrust towards the ability of science to answer food safety questions. For example, the task to work in the 'interest of the consumer' has been the key rationale in how the FSA underpins and justifies its actions:

> But I am always thinking ahead to what's around the corner for consumers. What they are worried about. The Daily Mail has a lot to answer for! [...] In our latest survey, 65% [of the public were] confident in FSA to protect health with regard to food safety. That trust is not a given. It has to be earned every day. It can be lost far more easily than won.[177]

The central theme that "we must ensure that we maintain trust"[178] or that in case of ineffective control systems "we risk damaging our most valuable commodity: that of consumer trust"[179] thus runs through FSA thinking like a red line: "Putting the consumer first" is at the forefront of its strategic objectives (for example, see FSA, 2013, p.6).[180] The UK regime was particularly affected by the BSE scandal of the 1990s due to the central role played by British beef in the outbreak of the crisis. At the time, the Ministry of Agriculture, Fisheries and Food (MAFF) was responsible for food safety. It was widely regarded as having failed to handle the crisis adequately (for an overview, see Rothstein, 2006). Due to the widespread perception that

[175] Additionally, in its scientific work the BfR is being advised by 15 expert panels (called 'BfR-Committees'), of which each comprises of at least ten external experts who contribute to the BfR's work on a voluntary basis.
[176] Interviewee F3.
[177] Speech by Tim Smith, then Chief Executive of the FSA, entitled 'What the Food Standards Agency does to ensure healthy food', 19 November 2008.
[178] Speech by Tim Smith, then Chief Executive of the FSA, to the Association of Independent Meat Suppliers conference Saturday 18 October 2008.
[179] Speech by Tim Smith, then Chief Executive of the FSA, for a meat trades journal event, 13 February 2009.
[180] For a review of the FSA's degree of success in 'putting the consumer first', see the 'Dean Review' (Dean Review, 2005).

government had lied to and deceived the public, a central tenet in the reform of the regime was to regain public trust.[181]

Similarly to the FSA, the BfR's approach to science is also shaped by considerations of the confidence of consumers placed in these processes:

> In its daily work the Federal Institute for Risk Assessment is confronted with a wide range of expectations all aimed at the same goal – *reliable, sound knowledge for decisions* [emphasis added by author].[182]

> Today, scientific statements are interpreted in the cross-fire of divergent interests. Science itself no longer speaks with one voice. Scientific statements are frequently challenged, and this is a popular pastime. […] Scientific progress and the fine-tuning of measurement methods and analytics have led *to a feeling of growing uncertainty particularly in the food sector*. One objective of our Institute and its staff is, therefore, *to win back the confidence of the general public* [emphasis added by the author].[183]

The BfR hence does not only perceive its responsibility to be the provision of high quality expertise, but also the maintenance of public confidence in its work. Food risk assessors are hence embedded in a context of the historical legacy of the BSE crisis and contested forms of expertise. Extensive engagement with the transnational coordination process despite a lack of formal rules requiring proactive participation is hence potentially explainable if the BfR and the FSA both see this to be of value to them in the context of these social relations they are embedded in.

In food controls, in turn, we also observe differing formal organisational set-ups in the two countries: In Germany food safety controls are mostly carried out by local authorities, which, however, come under the responsibility of the relevant ministries of the *Bundesländer*, rather than the BVL (for a detailed overview of the German control system, see FVO, 2008, 2011; BVL, 2011).[184] The BVL, in turn, is the national contact point of the FVO in relation to the organisation of FVO audits, without, however, possessing the authority to oversee the work of the *Bundesländer.* During an audit in Germany, the FVO usually visits two *Bundesländer* that were

[181] BSE Inquiry Report (2000), p.1, paragraph 2-3.
[182] BfR, 2005, p.4.
[183] BfR, 2007, p.4.
[184] Also see the so-called Multi-Annual National Control Plans (MANCPs) that each *Bundesland* prepares for the European Commission.

selected by the BVL. The audit report produced by the FVO, on the other hand, is about Germany, rather than the specific states that were visited. In contrast, in the UK the FSA is responsible for the delivery of food safety controls: The FSA monitors, audits and liaises with local authorities in their delivery of food safety controls. In this regard, it is also the contact point of the FVO, for which it organises audits in the UK.[185]

The work of the FVO in Germany is thus situated in a setting of many potential fields of tension, such as among the *Länder,* and between the *Länder* and the BVL, which might be feared to be intervening into the responsibilities of the *Länder*. On the contrary to the BVL, the FSA has legal authority to be well-informed about what happens at the local level and to attempt to effect changes when practices are not satisfactory. The coordinating function of the FVO in the UK is thus potentially less likely to cause tensions between control authorities if one considers the formal organisational set-up of food controls in the two countries. At the same time, however, authorities in both countries operate in the context of the complexity of overseeing a system that is faced with a highly decentralised industry and administrative control structures. If they are to accept the FVO's role in orchestrating the coordination of their practices, they need to perceive this to add value in the context of these social relations they are embedded in.

5.1.2 Tasks of EU Regulatory Bodies in Food Safety

In the EU –just as in the UK and in Germany– a large part of the legislation, institutions and processes in place we currently find in regard of food safety were established as a response to the BSE crisis of the 1990s. In an attempt to avoid conflicts between political and scientific arguments in future and to restore consumer confidence (European Commission, 2000), the EU embarked on a reform process which culminated in the establishment of the European Food Safety Authority (EFSA) in 2002[186] This authority has the

[185] For a detailed overview, see FVO, 2012.
[186] For an overview of its creation, see Buonanno, 2006; Vogel, 2010. For the initial reform proposal for a 'European Food and Public Health Authority', see James, Kemper and Pascal, 1999.

task to provide scientific advice to the European Commission, thereby also being tasked to liaise with risk assessors in the Member States.[187] In this respect, national risk assessors and EFSA have the task to generate knowledge about questions of risk and safety in food related issues.

EFSA's overarching task is the provision of scientific advice and support for food safety policy-making in the EU,[188] especially in regard to supplying scientific opinions which form the basis of relevant legislation.[189] In this regard, it has the responsibility to act in close cooperation with national authorities,[190] and Member States have the duty to cooperate with EFSA to pool expertise and hence generate knowledge in conjunction with each other.[191] However, the precise role of national risk assessors in the European system is peculiar since national experts neither play a formally institutionalised role in EFSA's expert panels, nor in its Management Board. EFSA has around 450 members of staff that mainly organise the scientific panels and working groups; it also has some scientific experts that help to prepare the scientific work of the panels. The core of its scientific work, however, is carried out by 'independent experts', rather than expert representatives from national risk assessors.[192] The peculiar nature of national authorities in the EFSA context is amplified since –contrary to many other EU agencies– the board presiding over EFSA's actions is not composed of national representatives either. Rather, it consists of 14 members chosen for their competence and relevant expertise, whereby the aim is to achieve a broad "geographic distribution".[193] Four of these members should either represent consumers or "other interest" in the sector and an additional member is representing the Commission.[194] The

[187] EFSA is responsible for 'risk assessment', which is institutionally separated from 'risk management' in the EU. This distinction originated at the US National Research Council (see NRC, 1983). This principle was then incorporated in to Codex Alimentarius principles (for example, see FAO, 2010).
[188] Art.22(2), also see Art.29, and Art.31, Art.33 and Art.34, Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[189] *Ibid.,* Art.22(6), Art.23(a).
[190] *Ibid.*
[191] *Ibid.,* Art.22(8).
[192] *Ibid.,* Art.28(4).
[193] *Ibid.,* Art.25(1), Recital 41.
[194] *Ibid*., Art.25(1).

Management Board is responsible for the overall steering of the organisation in conjunction with the agency's Executive Director.[195]

Rather than being directly involved in the steering of the agency or its scientific work, representatives from national authorities come together in the so-called 'Advisory Forum', where they have the task to generate knowledge that can support EFSA in its scientific work.[196] Other than advising the Executive Director of the agency, its main purpose is to support EFSA in its formulation of scientific advice by establishing a forum of exchange between national risk assessors that pools expertise.[197] In this regard, then, EFSA is peculiar in its set-up in comparison to other EU regulatory bodies: National representatives do not directly comprise its scientific panels, as a result of which they could keep their engagement with the transnational process to a minimum. This renders this case an excellent opportunity to study why national authorities engage with coordination since their formal responsibility to do so is limited. If, however, they are found to engage extensively in order to support EFSA in its scientific work, we can expect that they perceive the coordination process ensuing from a knowledge generation task to add value to their own work. As put forward in Chapters 1 and 2, the institutional framework provided by a knowledge generation task sets up horizontal relationships between national authorities –as well as between EFSA and national authorities– that are focused on finding agreement, rather than causing contention: None of the involved regulatory actors have to worry about locking in their practices by engaging in the transnational generation of knowledge. In this regard, we can expect that information about each other's practices and the modifying of behaviour functions through mutual exchange and adjustment in the case of a knowledge generation task.

In turn, the EU body responsible for the inspections and control of food safety legislation (i.e. 'risk management') –the Food and Veterinary Office (FVO) – did not become 'agencified' as a result of the BSE crisis. Instead, its mandate was extended considerably. The Commission's *White*

[195] *Ibid.,* Art.25 and 26.
[196] *Ibid.,* Art.27(1).
[197] *Ibid.,* Art.27(3) and (4), Recital 44.

Paper stressed the view that there was a "lack of [a] harmonised Community approach to the design and development of national control systems" (European Commission, 2000, p.29f). Hence, the FVO's mandate became more far-reaching, thus being entrusted with carrying out detailed audits of Member State authorities' control practices. The office remained part of the Commission but was moved to Grange (County Meath, Ireland) in 2002 in order to emphasise its special status within the Commission. Overall, then, the FVO's task is to inspect whether EU food safety law is adhered to on the ground in EU countries and in Third Countries exporting food to the EU.[198] Whereas this was initially carried out by inspecting food businesses, there has been a gradual shift towards inspecting and auditing control practices of national control authorities instead. The emphasis shifted to verifying whether national control authorities carry out their tasks in line with EU requirements in the late 1990s (FVO, 1999, p.3f), when the FVO was restructured in the aftermath of the BSE crisis (FVO, 1999b). With the adoption of Regulation 882/2004, in turn, this trend has been reinforced towards audits of national control systems (also see FVO, 2004).[199] FVO audits in Member States now assess whether their control system adheres to EU norms, whereby food businesses are only visited in order to observe control officials during their work, rather than inspecting the businesses as such. In this vein, it is seen to be the responsibility of Member States to ascertain themselves through internal audits that their control system meets EU requirements, which they need to present to the Commission is so-called Multi-Annual National Control Plans (MANCP).[200] The FVO's

[198] Art.45 and Art.46, Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
[199] Please note that at the time of writing (February 2014), a reform proposal of Regulation 882/2004 is being discussed (see Commission Proposal for a Regulation of the European Parliament and the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [....], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC)). By tying various sectoral Regulations and Directives and Regulation 882/2004 into one piece of legislation, it is primarily concerned with a change to the manner in which official controls are financed, which has so far been under discretion of Member States. The proposal foresees that Member States should fully recover these costs. It also foresees the harmonisation of import controls across the plant, animal, feed and food areas.
[200] Art.46, Regulation 882/2004.

inspection task provides an institutional framework that structures a vertical relationship between the FVO and national authorities. The role of the FVO in the coordination process is to act as overseer, whilst authorities in the Member States play a role of potential wrong-doers who bear the burden of proof of presenting their compliance to the FVO. This bears the potential for contention to arise between the FVO and national authorities, for example, in cases of disagreement whether particular practices are compliant or not. In such a hierarchical form of coordination, the FVO is the main vehicle of information-gathering and behaviour-modification in the coordination process. In order to accept this hierarchical coordination process despite the potentially contentious nature of the relationship established between the FVO and national authorities, the latter must perceive the FVO audit process to add value to their own work in the context of the social relations they are embedded in.

5.2 Uncovering the Coordinative Behaviour of Food Risk Assessors

Formally, EFSA does not have wide-ranging structures to coordinate the work of national risk assessors. We might thus expect that in practice risk assessors do not engage in extensive coordination of their scientific work. If they are to engage proactively in EFSA's work, we can expect that they perceive the knowledge generation task they hold in EFSA to add value to their own work in the specific context of social relations they are embedded in (Section 5.2.1). In turn, if national risk assessors indeed engage heavily in the coordination of their work in EFSA although they are not formally required to do so, this holds potential for contention on part of national risk assessors if they feel that their contribution to EFSA's work is not formally recognised (see Section 5.2.2).

Based on its experience of practices 'on the ground' in Member States, the FVO was charged with the development of the guidelines for the MANCP (FVO, 2006, p.24), whilst, however, the Commission is now in charge of evaluating these reports.

5.2.1 Coordination based on Mutual Exchange as a Mechanism for Maintaining Reputation

EFSA has a legal mandate to develop network and cooperation structures with national authorities and scientific organisations that work within its remit:

> The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.[201]

In this regard, coordination between EFSA and national authorities was institutionalised through the Advisory Forum.[202] Whilst national authorities do not have an official role in carrying out EFSA's work through expert representatives as found in other EU agencies (such as in drug safety monitoring, see Chapter 3), EFSA and its Advisory Forum were envisaged as coordinative bodies that bring national authorities together to generate knowledge.[203] However, the Advisory Forum consists of high level officials (usually the directors of national risk assessors and EFSA) and merely meets four to six times a year, which does not allow for the generation of knowledge in fields of highly specialised expertise. The organisational structures of developing a network of risk assessors at the operational level that would indeed be able to generate knowledge were left largely undefined in the formal set-up of the regime. To what extent such structures were to be developed was thus highly dependent on EFSA's and national risk assessors' initiative and willingness to engage in the transnational generation of knowledge.

Indeed, in practice extensive structures through which national risk assessors and EFSA coordinate their scientific output and pool their

[201] Recital (44), Regulation 178/2002. Also see Recitals (40) and (51). For legal mandate see Art.22(7), Art.27(4) (on the Advisory Forum's role), Art.32(1), Art.36, and Art.40(4).
[202] *Ibid.,* Art.27.
[203] Other than merely being expressed in EFSA's founding regulation, the Commission also clearly had this expectation of EFSA. This is, for example, very clearly expressed in a speech by then European Commissioner for Health and Consumer Protection David Byrne in 2006 (see speech entitled 'EFSA: Excellence, integrity and openness', Brussels, 18.September 2002).

expertise have developed. This process was formally initiated by EFSA and national risk assessors through the *Strategy for Cooperation and Networking*, which was formulated by the Advisory Forum and then adopted by EFSA's Management Board in 2006. It is based on the premise that EFSA and national authorities have the task to develop scientific opinions "which are recognized as truly authoritative both within the EU and in the wider international arena" under resource constraints which can be counteracted through transnational cooperation (EFSA, 2006d, p.2).

Intricate tools for networking and cooperation have thus developed: National authorities have started to establish new links and institutional relations in order to share resources and expertise. Whilst they continue to do so on an *ad hoc* basis in the Advisory Forum, the more formalised ESCO projects ('scientific cooperation projects') are carried out by national experts as chosen by the Advisory Board, members of EFSA's scientific panels and EFSA's scientific staff in order to generate new knowledge. Moreover, 'scientific networks' –which are chaired by EFSA– enable EFSA and national risk assessors to make use of expertise available in relevant specialist bodies in other Member States (and beyond since networks can invite experts from outside the EU to participate). They act to collect and exchange scientific data and information, share risk assessment practices, and to contribute to the coordination of risk assessment practices.[204] Another tool to exchange information on a wider range of issues is the Information Exchange Platform, which started operating in 2008: EFSA and national risk assessors can upload notifications that they have started working on a particular risk assessment, final risk assessments, national work plans and country profiles onto this platform in order to make sure that they all have easy access to each other's work (see EFSA, 2012b). Overall, then, EFSA and national risk assessors have developed extensive structures to coordinate their work and to generate knowledge on a transnational basis on the basis of a relatively loose formal framework envisaging them to do so (also see Ernst and Young, 2012).

[204] See EFSA's Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission.

In order to manage these manifold coordination activities 'Focal Points' were introduced in 2008: These are individuals or units in national authorities which ensure the practical implementation of the above described activities. The Focal Point network is also used for disseminating requests for assistance, which can, for example, be requests for data on a specific issue, such as animal cloning (155 such request were made by EFSA and national risk assessors in 2012,), and the dissemination information (for example, about scientific conferences) (EFSA, 2012c, p.6).[205] Whilst these mechanisms are particularly useful for counter acting resource restraints (such as information deficits) and for avoiding duplication of work, the Focal Point network was also created in order to prevent public disagreement over scientific output.

> Experience shows that scientific advice can vary occasionally. In order to address divergences, actions need to be taken at an early stage. To support the efforts made by the Advisory Forum in the past, the identification of divergences were included in the Focal Point Agreements. […] Being vigilant is a precondition for identifying diverging views between and among Member States and EFSA. Parties involved will discuss any divergences, looking for a possible solution in good time (EFSA, 2008f, p. 10).

In this regard, circulation of information via the Focal Point Network –and the other identified coordination mechanisms– can be used for the identification of potential scientific divergences whereby all authorities can screen each other's scientific outputs for potential divergences.

An additional strategy to mitigating the occurrence of divergent opinions is avoiding these altogether as much as possible by harmonising risk assessment methods "to establish a common approach of risk assessments throughout Europe in order *to reinforce both the credibility and coherence of scientific opinions* […]. This strategy *will help build greater confidence* in the advice available to the European Commission, Member States and food businesses […]" (EFSA, 2006d, p.4, emphasis added). Credibility and the absence of diverging scientific opinions thus seem to be intimately linked in the view of risk assessors. This, in turn, is linked to the

[205] Details on all requests for information and assistance (etc.) can be found in the annual Focal Point Activities Reports.

(perceived) need to build confidence in the output produced by risk assessors. Since risk assessors would like to avoid countering individual scientific opinions, there might be a perceived need to raise standards to an all-around high level in order to avoid disagreements (ESCO, 2008, p.32).

Knowledge generation is thus used as tool to prevent diverging scientific opinions, which might be detrimental to the maintenance of public trust in the science provided by risk assessors. Risk assessors, in turn, perceive their support of EFSA in its responsibility provides scientific advice to add value to their work by helping them to maintain trust in the authoritative nature of their scientific outputs. This can explain the puzzle why high capacity authorities like the FSA and the BfR engage so actively in 'volunteering' their expertise to another research body, thus potentially loosing credit for their work: The standing of their organisations in the social relations they are embedded in depends on the recognition that they are able to produce 'sound science'. In the context of the social relations they are embedded in, risk assessors perceive it to be mutually beneficial to act as united 'scientific front' since frequent disagreements between them could be interpreted as the inability of science (and hence risk assessors) to provide risk managers with the authoritative answers to questions of risk and safety.

The underlying idea to prevent scientific disagreement is present in EFSA's founding regulation, which states that the agency "shall exercise vigilance" in order to identify diverging scientific opinions at an early stage.[206] It then needs to seek direct contact and deliberation with the body that is in disagreement.[207] The product of this process should be a joint statement to be delivered to the Commission –and made public– that clarifies the scientific uncertainties underlying the disagreement.[208] This formal procedure, however, is rarely used (for an example of its usage, see EFSA, 2012c). Usually, EFSA and national authorities prefer to make use of the manifold coordination structures developed in the aftermath of the adoption of the *Strategy for Cooperation and Networking* to solve

[206] Art.30(1), Regulation 178/2002.
[207] *Ibid.,* Art.30(2).
[208] *Ibid.,* Art.30(4).

divergences –if possible– at an early stage and at a more informal level than the formal procedure allows for in order to then communicate a clear scientific message to risk managers.

At least on an informal level, then, a key aim of engaging proactively in the coordination of their scientific work is not only to counteract resource constraints, but also to resolve scientific divergences across national authorities and/or EFSA before scientific opinions (or other advice) are adopted in order to maintain the scientific credibility of risk assessors (EFSA, 2012d, p.6f): Although diverging interpretations of scientific data are to be expected under conditions of uncertainty, risk assessors aim to resolve these –if possible– before publication of scientific opinions in order to maintain the confidence in risk assessors' ability to assess risk accurately. National authorities are hence keen to share their projects and results with each other not only to make efficient use of resources and to exchange information per se, but also to ensure that everyone is 'on-board' with their opinion in order to prevent public disagreement about their scientific output. The aim to prevent divergences could, for example, clearly be seen in the BfR's opinion of isoflavones,[209] which it send to EFSA in order to achieve Europe-wide agreement on the issue as quickly as possible (EFSA, 2008d, p.11).

In this regard, risk assessors are aware that divergences might be picked up and miscommunicated by the media: Divergences were present in cases of Bisphenol A and ethyl lauroyl arginate (ELA) as pointed out by the Norwegian risk assessor in the Advisory Forum.[210] The BfR commented on this by way of confirming that these are common results of scientific uncertainty but that risk assessors needed to be aware that they can

[209] Isoflavones are a class of plant substances, which often occur naturally in foodstuffs. For example, they occur in high concentrations in soybeans. Some scientific studies point out beneficial effects of these substances (such as a reduction in breast cancer). At the same time, there is evidence that they can have detrimental effects for people with particular conditions, such as a thyroid dysfunction.

[210] ELA is used as a food preservative. Bisphenol A –a chemical used in food packaging- continues to be one of the most contentious issue surrounding food safety, thus frequently being picked up in media reports: After decades of use of Bisphenol A in baby bottles (etc.) concerns were raised about its neural and behavioural effects, as a result of which it is now banned for use in infant feeding bottles due to the remaining uncertainties of the effects of Bisphenol A on human health and the fact that young infants had the greatest exposure to this chemical present in their feeding bottles (see Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles).

provoke criticism in the media (EFSA, 2009b, p.8). EFSA thus attempts to communicate with national risk assessors during the process of writing scientific opinions in order to avoid divergences after publication (*ibid.*), especially in cases where such a divergence could have been avoided with ease: Cooperation provides the opportunity to "make effective use of synergies, benefit from the European pool of expertise and avoid duplication of work and unnecessary divergence of opinion".[211] Moreover, bilateral meetings between EFSA and a given national risk assessor take place before publication in areas were opinions might be diverging (EFSA, 2008e, p.20). In this regard, then, risk assessors are acutely aware of the perception of their work in the public sphere: Criticism by the media or other public and political actors has the potential of undermining the credibility of risk assessors by questioning the extent to which they are indeed able to produce 'sound science'. In this vein, the maintenance of the scientific reputation is also seen as question of how to communicate uncertainties to risk managers and the public by risk assessors (EFSA, 2009b, p.8).[212]

In order to understand this coordination pattern of mutual exchange and adjustment, it is crucial to consider that EFSA and national risk assessors are embedded in social relations in which they have been under enormous pressure –from NGOs, the media and the European Parliament– in relation to the value of their scientific output: It is often criticised of being influenced by industry interests. In this context, diverging scientific opinions can potentially fuel controversies as to whether they differ as a result of influence by particular interests.

> No matter if it is about the chemical Bisphenol A (BPA), meat from cloned animals or the authorisation of GMOs, the Parma-based EFSA rarely has concerns. So far it has regularly decided in favour of the industry, for example when it increased the safety limit for BPA whilst other countries prohibited it.[213]

[211] Speech by Catherine Geslain-Lanéelle, then Executive Director of EFSA, entitled 'Food Safety in Europe: Progress through Cooperation', Oslo, 12.June 2008.
[212] Also pointed out by interviewee F1.
[213] Rögener, W. (2010, 2 December 2010). EU-Lebensmittelsicherheit: Der lange Arm des Geldes. S*üddeutsche Zeitung*. Retrieved on 23 March 2014, from http://sz.de/1.1030889.

'Inconsistencies' or frequent changes of scientific opinions are thus picked up in the media, such as in this example from the German press: "Safety limit up, safety limit down: The manner in which regulatory authorities are handling the controversial chemical Bisphenol A is unlikely to increase consumer confidence".[214] EFSA and national risk assessors view it as crucial to prevent such undermining of their scientific authority through their coordinative efforts.

> To build a bridge between science and consumers it is important to know the consumer and to be aware of and to understand the public perception of risk […]. We know how important it is to speak with one voice, as a result of which we go to great lengths to ensure that statements about risk assessment are commonly agreed upon and harmonised.[215]
>
> Unless the scientific basis for EU food law is trusted, from an untainted and reliable source, free from undue sectoral or political interests, it cannot help risk managers build confidence.[216]

NGOs and the European Parliament have been particularly forceful in their sustained critique of EFSA in relation to its independence from the industry (for example, see CEO, 2013; Friends of the Earth, 2004; also see Chalmers, 2005).[217] As national experts play a crucial role in EFSA's scientific work, this critique in essence touches upon the practices of risk assessors at large, whilst also amplifying EFSA's attempts to ensure confidence in its scientific authority through scientific coordination. Moreover, the relationship between the Commission has been fraught with tensions as a result of EFSA's wish to establish its scientific authority as clear dividing line to the Commission's sphere of authority, whilst also acting as partner of the Commission (Groenleer, 2009, p.183ff). The maintenance of scientific

[214] Rögener, W. (2014, 21 February). Grenzwerte von Bisphenol A: Schwenk mit Symbolwert. *Süddeutsche Zeitung*. Retrieved on 23 March 2014, from http://sz.de/1.1894674.

[215] Statement by Catherine Geslain-Lanéelle, then Executive Director of EFSA (BfR, 2012, p.7). Translated by the author, original in German: "Um eine Brücke zwischen Wissenschaft und Verbraucher zu schlagen, ist es wichtig, den Verbraucher und die öffentliche Risikowahrnehmung zu kennen und zu verstehen […]. Wir wissen, wie wichtig es ist, mit einer Stimme zu sprechen; deshalb werden alle Anstrengungen unternommen, Aussagen zur Risikobewertung abzustimmen und zu vereinheitlichen."

[216] Speech by Catherine Geslain-Lanéelle, then Executive Director of EFSA, entitled 'Joining forces for safer food in Europe: the food safety system in the EU', Lisbon, 19.September 2007.

[217] As a result of this concern, the European Parliament delayed its approval of EFSA's past expenditure for the year 2010. The European Medicines Agency and the European Environment Agency was also subjected to this process by the Parliament. Similarly, the Court of Auditors has criticised the presence of conflicts-of-interest of experts in four EU agencies, including EFSA (see European Court of Auditors, 2012).

authority which EFSA and national risk assessors wish to achieve thus needs to be understood in the context of their existence in social relations that represent an antagonistic environment. In order to fulfil the (perceived) need to maintain public trust –and their scientific reputation– mutual exchange and adjustment of scientific output is strategically important for EFSA and national authorities as this can mitigate the occurrence of public disagreement over scientific outputs.[218]

This part of the chapter shows that the knowledge generation task of national authorities and EFSA shapes a coordination pattern of mutual exchange and adjustment: National authorities and EFSA exchange information about their scientific work and adjust their output in order to avoid the public voicing of diverging scientific opinions wherever possible. The British and German authorities engage heavily with this transnational task, despite a fairly limited formal responsibility to do so. They do so because they perceive the transnational knowledge generation task to add value to their own work in the context of the social relations they are embedded in: They carry out their work in an antagonistic environment, in which the authority of their scientific outputs is frequently questioned. In this context they perceive their engagement with the transnational coordination process to help them to maintain confidence in their work through the avoidance of diverging scientific opinions.

5.2.2 Contestation despite Mutual Exchange and Adjustment

In order to maintain public trust in their work –and thus their scientific reputation– national risk assessors engage in transnational knowledge generation in EFSA. By their very nature, however, group processes tend to undermine the recognition of individual contributions. This might be perceived as particularly grave by members of the group that contribute most. Indeed, the BfR and its French counterpart –which both carry out in-house research– contest the formal organisational set-up of scientific

[218] See, for example, EFSA, 2003, p.2, 2006c.

coordination in EFSA since the contributions of national risk assessors are not formally recognised. The mismatch between EFSA's formal 'light-weight' incorporation of national risk assessors in its work and the realities of the active engagement of national risk assessors in these processes has an impact on the acceptance of the EFSA system among national risk assessors that contribute most in terms of primary research. Whilst coordination is necessary for maintaining their reputation, they would prefer a system which provides formal recognition for the immense input of their authorities to the transnational system. Coordination in EFSA thus results in a paradox for high-capacity research intensive authorities since in their perception they need to coordinate to maintain public trust, whilst also needing to maintain the reputation of their own scientific output.

The BfR has questioned which benefits national authorities derive from sharing their expertise with EFSA (EFSA, 2008b, p.7; 2008c, p.8 and 10). This has gone hand-in-hand with the complaint that national experts are taken away from their daily work to do EFSA's work instead, whilst also reporting a lack of resources provided to Focal Points by EFSA (EFSA 2008b; 2008d, p.9). The German risk assessor has also noted that EFSA is too busy with fulfilling Commission requests to take into account the priorities of national authorities in its work (EFSA, 2008d, p.4f). Similarly, the French authority has argued that EFSA should not just "take advantage of national competencies" (EFSA, 2008d, p.4) and thus wants networked cooperation to be more formalised in order to provide for adequate recognition of the work of national officials.

In this regard, the BfR has suggested reforming EFSA into a rapporteur system akin to the institutional set-up of the European Medicines Agency, especially since in practice more than half of EFSA's panel scientists are staff of national authorities (EFSA, 2009a; 2009b, p.9; also see EFSA, 2004a, p.4). In the eyes of the French and German authorities this would avoid duplication of work, whilst also providing for a recognised contribution of national officials. Other authorities –such as Ireland, Belgium and Sweden– on the other hand have disagreed vehemently with this view as a rapporteur system would be too resource intensive for small

authorities (*ibid*.). Arguably, smaller authorities fear the dominance of larger countries in a rapporteur system.

The mismatch between the formally limited contribution of national risk assessors and their large-scale involvement in practice is hence not easily accepted by authorities with the highest scientific capacities: EFSA's scientific work is not formally carried out by national representatives, but by 'independent experts'. In practice, however, the majority of 'independent experts' are officials from national risk assessors. Moreover, EFSA's work would not be possible without the extensive input national risk assessors provide through their knowledge generation in the forum of EFSA.

Yet, the contestation on part of the French and German authorities is merely an articulation of dissent: The organisational set-up of EFSA cannot be changed by national risk assessors and even if risk assessors views were equivalent to national governments views on the matter, it is doubtful that France and Germany could rally enough support for such a radical reform of the system, which was designed to avoid the 'biases' of national officials. Their dissent demonstrates, however, that formal organisational solutions for coordination (i.e. the lack of national representatives in EFSA's expert bodies) can be at odds with the form of coordination that has been shaped by a particular task (i.e. knowledge generation), and social relations (i.e. the antagonistic environment risk assessors are embedded in).

This part of the chapter points out that coordinative behaviour of regulatory actors that is primarily characterised by the seeking of agreement can still bear contestation if national authorities feel that their input into the work of an EU body (that is shaped by their task and informed by their social relations) is not recognised in formal coordination structures.

5.3 The Coordinative Behaviour of Food Control Authorities

The FVO audit process was established to coordinate food control practices across Member States. The formal organisational set-up of this audit process

–which has the Commission's enforcement actions attached to it– leads us to expect a hierarchical form of coordination in practice.[219] If national authorities are to accept such a hierarchical form of coordination, they arguably need to perceive to be 'getting something out of it' (for findings in this regard, see Section 5.3.1). At the same time, the FVO inspection process is increasingly being complemented by horizontal coordination processes that provide national authorities with access to the expertise of their colleagues across all Member States. We can hence expect that that national authorities also take these processes into account when assessing the 'added value' of the work of the FVO for their own work (see Section 5.3.2).

5.3.1 A Hierarchical Coordination Pattern

The FVO has the task to inspect national authorities and the Commission can make use of FVO reports when significant deficiencies are noted to enforce EU legislation in the Court of Justice. Moreover, the Commission evaluates national control systems in relation to EU law.[220] In this regard, it makes use of a wide array of sources to portray the functioning of national control activities, including the so-called Multi-Annual National Control Plans (MANCP reports) that national authorities have to submit to the Commission, FVO inspection reports and discussions in the Standing Committee on the Food Chain and Animal Health (SCFCAH) (European Commission, 2012). In comparison to many other EU policy areas, then, the Commission possesses an extraordinarily detailed picture of application of EU law on the ground. It can use this knowledge not only to initiate infringement proceedings, but also to impose trade restrictions when the FVO finds grave shortcomings in the application of EU standards in third countries.[221] In light of the task of the FVO, then, we could expect to find a form of coordination that is heavily dominated by the FVO's and the Commission's conception of 'how things should be done'.

[219] 'Hierarchy' is here not used in the sense of strict command-and-control. Rather, it refers to a process in which the Commission can make use of detailed knowledge of national practices to enforce EU legislation in court. Please refer to Chapter1 1 for further discussion of this issue.
[220] Art.44, Regulation 882/2004.
[221] *Ibid*., Art.56. Also see Art.53 of Regulation 178/2002.

We could expect inspections which are tightly linked to enforcement action by the Commission to provoke resistance amongst national officials. Instead, however, national authorities use FVO audits to increase control over their own territory. Despite the differing formal set-up of control systems in Germany and the UK, authorities use FVO audits in a similar manner in the context of the social relations of a decentralised administrative system which they have the responsibility to oversee. Whereas FVO inspections were reportedly dreaded by control authorities in the Member States in the past, this has become much less pronounced in recent years: Largely, authorities in the UK and Germany find FVO recommendations helpful as a means to improve the functioning of their control systems since it provides them with an expertise they do not have, thereby enabling them to increase control over their own territory. The emphasis placed on control systems –rather than the inspection of food businesses– has rendered this change possible.[222] National authorities hence continuously re-evaluate the engagement with transnational processes while being involved in them.

In comparison to the other EU regulatory bodies studied in this thesis, the FVO does not formally act as a hub of a transgovernmental network of national officials. Whilst it interacts directly with control authorities in all Member States, it is not designed to provide a forum for direct interaction between these national authorities. In this regard, then, the FVO's and the Commission's interpretation (and enforcement) of EU legislation –rather than group processes involving national officials– can be expected to be used as main motor for the coordination of regulatory practices: FVO missions are clearly targeted at the assessment of compliance, rather than the provision of advice to national officials (Lodge and Wegrich, 2011, p.96).[223] A FVO official expressed this by saying that "after all, we are not a consulting body".[224]

The rather hierarchically structured audit process is organized as follows. Member States are informed about the upcoming inspections of the

[222] As introduced in Regualtion 882/2004.
[223] Also see wording of Art.45(1), Regulation 882/2004.
[224] Interviewee F10.

next year in November of each year. Two to three months before the audit, the FVO then sends the FVO contact point (the FSA in the UK and the BVL in Germany) in the given Member State a pre-audit questionnaire on the implementation of certain pieces of legislation and also provides them with contact details of the lead auditor and their audit plan. Based on the information received in this questionnaire, the FVO informs the contact point which type of competent authorities they would like to visit (usually two; for example, in relation to the UK, the FVO might want to visit on authority in Wales and one in England). The FSA or the BVL then decide which local authorities or *Länder* to visit (unless the audit is due to an alert having been raised about a particular premise or authority). The local authorities or the *Länder* usually devise a list of premises that could be visited and on the day it is decided which businesses are going to be visited (for example, often inspections in a small and a large business will be accompanied by the FVO).

The audit begins by an introductory meeting at the FSA or the BMEL, which the other authorities to be visited also attend. Then the audit continues in a specific local authority or *Land* with another introductory meeting in which this authority presents its control system to the FVO team. After this, several businesses are visited, whereby the FVO team observe the officials of the competent authorities carrying out a control. After having visited the foreseen local authorities or *Länder* a closing meeting is held at the premises of the FSA or the BMEL respectively. These final meetings have a formal character in which the FVO presents its findings, rather than engaging in deliberative exchange of views with the visited control authorities. In large countries like the UK or Germany, this FVO audit process in general takes 10 days to two weeks. The FVO then submits a draft report of the visit on which the competent authorities can comment, whilst also needing to submit an action plan on how to remedy the identified shortcomings. The draft report has been put together after potential consultation with the Commission's legal service if necessary and is hence not as such 'up for discussion'. Overall, then, FVO missions serve to assess

and to achieve compliance with EU legislations, thus formally being of a hierarchical nature.

Despite the formally hierarchical nature of coordination in this field, UK and German authorities do not contest FVO audits. Rather, they perceive them to be helpful to their own work by enabling them to increase the control over their own territory. In Germany, the role of FVO audits has helped to create a role for the BVL which the *Länder* perceive to be helpful in comparison to having been 'left alone' to cope with FVO audits in the past. Moreover, in recent years *Länder* authorities have also started to coordinate their actions extensively as a response to the work of the FVO, which the federal level and the *Länder* see as beneficial in identifying and remedying shortcomings in official controls. After the BVL's inception, German *Länder* authorities were at first "suspicious"[225] about the role played by this new body in coordinating FVO audits. Since the implementation of food controls rests firmly in the hands of the *Länder* it remained to be seen whether this federal institution would be able to carve out a role for itself in this realm without causing struggles over competence between the federal and the *Länder* level. By now, the *Länder* find the BVL's assistance in the organisation of FVO audits very helpful, not least since they arrange the administration of these visits (such as providing a car for the FVO team and booking their hotels).

> The BVL is like a bundling body. [...] It reduces our workload, I would say. [...] We perceive this to be a supporting hand. They gather all the relevant information from the *Länder* and compare them against each other, that is especially important when the action plan for the implementation of the recommendations is concerned.[226]

FVO audits have thus 'interfered' in the relationships between federal and *Länder* level actors in a positive manner, which can partly account for the change from 'dreading' FVO audits to appreciating these as helpful on part

[225] As expressed by interviewees.
[226] Interviewee F8. Original in German: "Das BVL is wie ein Bündler. [...] Das BVL nimmt uns Arbeit ab, sag ich mich mal. [...] Wir empfinden das BVL als Hilfestellung. Sie führen für uns die Informationen von den Bundesländern zusammen und gleichen sie untereinander ab; das ist ganz besonders bedeutsam wenn es nachher um den Maßnahmeplan zur Umstezung der Empfehlungen geht."

of the *Länder*. In this sense Germany's federal system is now seen to be working extremely well in relation to FVO audits, which was not the case before the BVL was established and built a working coordinating role for itself.[227] In this sense, coordination between *Länder* has also intensified as a means to follow-up on FVO recommendations. These are addressed to Germany as a country, although they are based on observations in (usually) two *Länder*. In the relevant working groups of the consortium of the *Länder* for consumer protection ('Länderarbeitsgemeinschaft Verbraucherschutz', LAV), *Länder* now discuss how to change practices across the whole country to bring them into line with FVO recommendations.

> That has really improved, the coordinating working groups of the *Länder* are very good, they really disperse the results of an audit in the whole country, so that everyone knows what's going well or what isn't going so well.[228]

In this regard, the FVO process has also started to pull the *Länder* together in areas in which no agreement on practices could be found amongst them before, for example, in the case of mechanically separated meat: Clearly set out recommendations of the FVO audit report prompted agreement on shared guidelines on practices.[229]

In case of the UK, FVO audits do not interfere in similarly complex federal structures. However, they also provide an opportunity for the FSA to increase control over its territory since they have an impact on the relationship between the FSA and local authorities: FVO audits give the FSA an additional tool to coax local authorities into compliance. For example, the FSA communicates to local authorities that any severe shortcomings found in a given Council during an FVO audit could adversely affect the entire UK as they could undermine consumer confidence in UK products.[230] The FSA has also used negative FVO audit reports to justify the need for action to the industry. For example, as the then Chief Executive of the FSA Tim Smith put it to the UK dairy industry:

[227] Interviewee F10.
[228] *Ibid.*.
[229] Interviewees F8 and F10. This happened in the working group on meat and poultry hygiene ('Fleisch- und Geflügelfleischhygiene und fachspezifische Fragen von Lebensmitteln tierischer Herkunft, AFFL').
[230] Interviewee F13.

> Although the last FVO mission in September 2007 found no serious shortcomings, they will be coming back in 2009. Our house needs to be in order. We need to impress them and secure a clean bill of health. I think it's fair to say that having been caught out once none of us wants a repeat. So let's continue to work together to ensure we get it right.[231]

Moreover, the FSA sees the FVO's work as critical to maintain the reputation of food safety authorities in the context of interdependence: It has emphasised that it welcomes the 'tough' approach taken by the FVO, especially in order to safeguard the effectiveness of food controls in the new EU Member States (FSA, 2003, p.8).

Overall, authorities in the UK and Germany have come to value FVO audits in a similar manner since they have induced better coordination within their country and can be used as a justification for action vis-à-vis the industry: Since the FVO provides them with additional expertise on how to run their control systems, the FVO audit processes provides overseeing control authorities to be in more effective command over their own territory. More crucially, UK and German authorities explicitly value the input provided by the FVO as a means to improve their practices. In other words, they do not perceive the FVO as a body that is mainly contributing to the enforcement of EU law. Rather, they view its recommendations to further safety by enhancing their practices. As one interviewee put it "it is as if you were getting management consultants in for free".[232] Another interviewee stated in this regard that "it is a bitter pill to swallow, but it needs to happen".[233] This, however, was not always the case: When the FVO was inspecting businesses –instead of national control systems– its recommendations were easily dismissed as being an unfair evaluation (i.e. what was found in individual businesses was not seen to evaluate the overall practices in place by other businesses and control authorities). After the shift to auditing control systems as a result of Regulation 882/2004 – and several rounds of audits in each topic area– authorities in the Member States have come to see FVO recommendations as highlighting problems in

[231] Speech by Tim Smith, then Chief Executive of the FSA, entitled 'Is dairy fit for the 21st century diet?' Delivered at the Dairy UK Conference, 16. September 2008.
[232] Interviewee F12.
[233] Interviewee F13.

their overall control system.[234] They thus continuously re-assess the added value of these coordination processes whilst being engaged in them. As noted by a FVO official, "we often get the feedback that our comments are helpful. Because we see things with different eyes".[235] National officials share this view.

> In my experience, if something was criticised [by the FVO] it was usually justified. Even if one then normally tries to defend the system and to find excuses because usually it will have something to do with the complexity of the task and staffing issues... But one does know that they have struck a nerve.[236]

Improving practices and demonstrating satisfactory results in FVO audits hereby also bears an external dimension: Third countries might ban imports of EU products on basis of FVO reports. As a result, all Member States have an interest in 'looking good on paper'.

In order to understand why national authorities are able to view the FVO's recommendations in this manner, we need to consider that the European Commission is not a zealous enforcer in the field: This means that although the FVO provides 'tough' criticisms of national control systems it is the exception –rather than the rule– that the Commission makes use of this information to initiate infringement proceedings. Usually, the Commission only makes use of this option in case of severe and lasting incompliance (i.e. which are not found to have been remedied by the FVO after successive rounds of audits in a particular field).[237] In this regard, the FVO sees infringement proceedings initiated by the Commission as failure of its work.[238] Moreover, national officials are also aware that the FVO's work not only assesses their compliance but also highlights to the Commission where legislation needs to be clarified or is unfeasible for national authorities to

[234] Interviewee F8.
[235] Interviewee F10.
[236] Interviewee F8. Original in German: "Wenn dann etwas kritisiert wurde, dann war das schon berechtigt. Auch wenn man dann nicht gleich in Sack und Asche geht und immer noch versucht sein System zu verteidigen und Ausreden zu finden, ist ja logisch…Weil meistens hängt es einfach mit der Komplexität der Aufgabe zusammen und personellen Dingen und Ähnlichem. Aber es ist dann schon so, dass man merkt, sie legen den Finger in die Wunde." This view was also expressed by interviewees F5, F6, F10, F11 and F12.
[237] See the Commission's annual reports on national implementation of EU law in this regard. Largely, they show that only long-lasting cases of incompliance (often found in Greece in this policy area) result in infringement proceedings.
[238] Interviewee F6.

implement. Overall, the Commission is willing to consider simplifications in legislation if Member States display great difficulties to comply, for example, with reporting requirements (i.e. the MANCP) (European Commission, 2009d, p.9). The character of the FVO's work in being helpful for national authorities and the Commission alike is also demonstrated in its use of so-called fact finding missions: These serve to, for example, observe and analyse problems that Member States are facing in their work without being linked to an audit and FVO recommendations, whereby the results are not published publicly.

This section of the chapter has demonstrated that the inspection task of the FVO leads to a hierarchical form of coordination. British and German officials are willing to accept –and to engage with– the FVO audit process since they perceive it to add value to their work: FVO audits provide them with a tool to increase the oversight over the decentralised control systems in their countries.

5.3.2 Horizontal Forms of Coordination in a Hierarchical System

The formal set-up of FVO audits leads us to expect that the coordination process in food controls is only based on vertical exchanges between the FVO and national officials. However, in practice the control arm of the regime has developed a more transgovernmental nature which tries to promote mutual exchange and learning as a form of coordination in recent years. In this respect, the FVO has increasingly put an emphasis on mediating the horizontal exchange of practices between national authorities through the increased use of tools such as 'Overview Reports' and fact finding missions. Moreover, this is especially visible in the manner in which the Commission (and subsequently the Executive Agency for Health and Consumers) has structured the 'Better Training for Safer Food' programme, which results from the Commission's responsibility to establish a training programme for national control officers under Regulation 882/2004. Whilst the Commission hereby essentially continues to mediate the establishment

of transgovernmental ties and the identification and dissemination of best practices, it is not focused on hierarchical enforcement as only mechanism to coordinate practices across Member States. As a result, the system has started to foster a hitherto non-existent professional community of food control officials. This, in turn, is seen as an added value for the improvement of their own practices by British and German. This adds to their positive perception of the value of coordination activities that are orchestrated by EU bodies (i.e. the FVO and the European Commission).

Hierarchical coordination in the control arm of the regime is becoming gradually more interwoven with horizontal forms of coordination as resource pressure renders intensive FVO audits in all sectors and countries more difficult. The FVO summarises its observations in the so-called 'Overview' or 'General' reports. The main aim of these reports is to pull together the main findings of several audits in a relevant issue area as observed across different Member States. They thus highlight where problems with compliances are widespread and where implementation works well across countries (for an example, see FVO, 2010, p.2.). At the same time, they also point out 'good practices' observed during their audit (for example, see FVO, 2013c, p.13).

This aims at making practices across countries more accessible to competent authorities. Also, the overview reports try to establish whether legislation is working as intended and whether implementation is feasible for control authorities in the Member States. In this regard, these reports also provide recommendations to the Commission, for example, about the need for clarification of a particular legal provision. After EU legislation is passed, Member States are usually "left to their own devices"[239] and the overview reports attempt to counteract this by bringing together officials from the Member States at the FVO premises to discuss the overall state of control systems in a given issue area. The FVO is hereby establishing transgovernmental ties at these events, whereby national officials can hear the points of view of their counterparts in other countries. These reports have existed since 2001, but FVO officials state that they have grown in

[239] Interviewee M10.

importance, especially in relation to bringing together national officials to discuss them and explicitly pointing out 'good practices' (which became an explicit feature of the reports in 2013).

The underlying idea is hereby that competent authorities can more easily identify practices of authorities in other Member States as a source of learning, which is indeed used by national authorities (albeit in relatively rare cases).[240] We thus observe elements of mutual exchange in this part of the regime, which, however, is mediated by the FVO as it remains the body that identifies 'good practices'. Such horizontal forms of coordination can also be found in the FVO's training and use of 'national experts' which acts as FVO team members during audits (see, for example, FVO, 1999, p. 3; 1999b, p.4; FVO, 2007, p.30): These officials get to know other countries' practices and can use this knowledge in relation within their home administrations. They receive FVO training since in their role as FVO national experts they are expected to act as EU official, thus transcending their national perspective, whilst also giving national officials the opportunity to develop transgovernmental links and additional expertise.[241]

Similarly to the FVO's approach to 'Overview Reports', the Commission also singles out 'good reporting practice' in relation to reporting practices in the Multi-Annual National Control Plans (MANCPs): For example, the Commission has pointed out that substantive indicators of performance and tracking of costs of control activities –which are found in France, Finland, Sweden and Slovenia– should be seen as 'best practice' (European Commission, 2012, p.4). Similarly, it has put forward that the process of risk categorisation of food businesses in the Netherlands, Finland and Slovenia should be used as examples by other authorities (*ibid*., p.5). It also finds the publication of business inspection results (as found in Denmark, the UK, Belgium and the Czech Republic) noteworthy (*ibid*. p.10). Another 'good practice' in the view of the Commission are quality management systems which are measured against external standards (i.e. ISO 9001), which we find in the Czech Republic, Lithuania, Slovenia, and

[240] Interviewee F5, F6, F10.

[241] Interviewees emphasised the importance of this. Hereby, FVO officials value the specific expertise of national experts and an interviewee who has acted as national expert explained the value of acquainting oneself with other administrative systems and control practices.

Germany. As in the case of the FVO's identification of 'good practices', this is a novel development. In this vein, the Commission has also started to run a forum of exchange about how to run national audit systems (European Commission, 2013, p.6). Although the Commission hereby remains at the centre of proclaiming what works well, this provides a platform for competent authorities to learn from reporting practices and control systems of other countries.

The increasing prevalence of transgovernmental ties and horizontal coordination is particularly visible in the 'Better Training for Safer Food' programme which was established under the auspices of the Commission in 2006.[242] The training programme was devised to ensure that control staff is kept "up to date with relevant EU standards. This should ensure that controls become more harmonised and effective" (European Commission, 2006b, p.5). A key idea hereby is that the training should be cascaded by participants, i.e. they should present what their learned during the training in their home authorities (this indeed happens in the UK and Germany, see FSA, 2011, p.11, and the MANCPs of the *Länder*). The programme was introduced in the wake of a shift from rather prescriptive Directives to Regulations which allow for more freedom of interpretation of legal norms,[243] (such as from provision prescribing that tiles in food businesses need to have a specific size to the legal norms that walls should be easy to clean). In the programme, national control officials attend training programmes on a specific topic which is run by national authorities or independent organisations. Although Commission staff is present in these trainings, tutors are not Commission staff. Rather, they are national officials or experts in the field (for a detailed overview of the programme see its Annual Reports which have been published since 2006). The Commission (and the Executive Agency for Health and Consumers that it has delegated the organisation of the programme to) are hereby only responsible for the organisation of the programme, whilst the content is delivered by experts in

[242] The legal mandate for the programme derives from Art.51, Regulation 882/2004.
[243] As stated by Interviewee F9. An example is the so-called 'hygiene package' (Regulation No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs; and No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

a given field selected particularly for this purpose across different Member States.[244] This, for example, may be officials from a national authority which excels in its control systems in a particular field, which is seen to disseminate 'best practices'.[245]

Hence, whilst the programme is hierarchically devised, it establishes mutual exchange and transgovernmental ties between national officials.

> But in addition what we saw with this training since 2006 was also that –and initially that was not foreseen- by bringing together people from different Member States, they start to get this network. One of the things that we see now is that the people which come in contact with each other during the training, afterwards they continue to be in contact because they think 'now I know someone, for example, in Germany or someone from Poland etc., I will just call that colleague'. That's gives them another point of contact if they have a problem, they call and ask 'what do I have to do?'[246]

Hereby, the programme is seen as success by all involved actors (see European Commission, 2009e, p.15),[247] although language barriers remain a problem (*ibid*.). For example, especially older control officials might not speak English well enough to dare to attend such training.[248] Nevertheless, the trainings are consistently over-subscribed, whereby the high quality of the substance delivered by tutors is seen as key to this success.[249] It has hereby been noted that officials often would like to improve their know-how in a given area –rather than just being focused on compliance with EU standards– which is rendered possible through the high quality substance of the courses (which also include 'hands-on' training, such as practicing inspections by visiting food businesses). The programme is linked to the FVO audits since it is consulted in the selection of topics to be covered by the courses: The FVO can thus single out areas in which widespread shortcomings exist in control systems across countries. The BTSF team of the Commission then also asks the FVO to monitor whether the training courses are taking effect on the ground. The hierarchical audit mechanism

[244] Although in some cases Commission officials act as tutors.
[245] Interviewee F12.
[246] Interviewee F9.
[247] This view was also unequivocally expressed by all interviewees.
[248] Also pointed out by interviewees.
[249] F6, F8, F11, F12. Also see European Commission, 2009e, p.15.

has thus become intertwined with a training programme through which expertise of national officials and experts is spread horizontally to other national officials to improve practices.

Overall, then, coordination among food control authorities has developed elements of mutual exchange between national officials, although these exchanges to some extent remain mediated by the FVO and the Commission. Especially, the BTSF programme, however, is firmly built on the expertise of experts outside these EU bodies. These developments need to be seen not only in the light of increased use of Regulations, but also the effect of resource constraints on the FVO and Commission auditing process in an enlarging EU, combined with increasing amounts of EU food safety standards: The FVO, for example, is trying to move away from auditing all Member States for all issue areas as this has become increasingly difficult in an EU of 28 Member States. Rather, in future it will aim to audit a representative cross-sections of countries in each issue area; "Our aim is to help them improve their systems. If we can do this without going to see all of them [the Member States], we will do so."[250] Mutual exchange mechanisms contained in overview reports, Commission reports on Member States' MANCPs and the Better Training for Safer Food programme –which are building a transgovernmental network of sorts between national control staff– are thus a pragmatic response to achieving similar practices and conformity with EU law in changed circumstances. In regard of the more horizontal forms of coordination, control officials in the Member States are being bound into a professional community, which does largely not engage in interactions outside this EU system. This is perceived as an added value by the involved regulatory actors. The rather novel mechanism complements the hierarchical FVO audits in relation to the gathering of information about practices across Member States as well as the modification of behaviour. British and German authorities take this form of coordination into account in their assessment of the value of the engagement with transnational processes in this field.

[250] Interviewee F5.

This part of the chapter demonstrated that national authorities regard the engagement with transnational processes to be beneficial since the newly emerging forms of horizontal coordination between food control authorities provide them with additional access to expertise that helps them to oversee the extraordinarily complex food control systems in their country, for example, through the creation of a hitherto non-existent professional community of food control officials. Authorities in the Member States take these novel processes into account when evaluating the added value of the inspection task of the FVO.

5.4 Conclusions

This chapter demonstrates that the knowledge generation task of national authorities in the forum of EFSA results in a coordination pattern of mutual exchange, which the UK and German authorities proactively engage with despite the lack of formal provisions requiring them to do so. Indeed, national risk assessors and EFSA have developed extensive structures for the coordination of their scientific output that surpass what is formally demanded of them. The case study demonstrates that they do so because the involved authorities perceive transnational coordination to add value to their work: They operate in a context in which the authoritative nature of the science they provide is persistently questioned by NGOS, political actors, and the media. The public voicing of diverging scientific opinions by national authorities and EFSA is seen to undermine confidence in their work, as a result of which they value the coordination of their scientific output in the forum of EFSA: In their view, this helps them to maintain the authority of the scientific advice they provide. This drives their proactive engagement with the coordination of scientific outputs, which, in turn, supports the scientific work of EFSA.

This finding serves as a vital comparison to the case study on drug safety monitoring presented in Chapter 3: The coordination pattern

observed between food risk assessors differs from that found in the case of drug safety monitoring. Whilst the coordination pattern in the former is characterised by mutual exchange and adjustment, the latter is of a more competitive nature. In this regard, it seems that professional norms –which can be deemed to be similar in these two cases– are not the most pervasive determinant of coordinative behaviour. Rather, this thesis puts forward that professional norms form part of the social organisation regulatory actors are embedded in, and thus contribute to the framing of their perception of their own interests. These perceptions of what constitutes strategic behaviour inform their behaviour in the institutional frameworks provided by tasks, which shape coordinative behaviour. This explains why the coordination patterns observed in the case of food risk assessment and drug safety monitoring differ despite similar professional norms: The institutional frameworks and frames for action provided by a knowledge generation task differ from the ones provided by a one-off decision-making task (see Chapter 1, 2 and 3), hence setting the involved regulators into different relations with each other.

The chapter also demonstrates that the inspection task of the FVO indeed results in a hierarchical coordination pattern. The FVO audit process entails detailed inspections of national practices followed by strict reporting of non-compliances and practices which do not follow guidelines. In contrast to the maritime safety case (see Chapter 4), however, the inspections of an EU regulatory body do not result in contestation on part of regulatory actors in the UK and Germany. Rather, German and British authorities perceive the FVO visits to their countries to add value to their own work: They perceive FVO inspections to provide them with an expertise that they lack, thereby providing them with an opportunity for improved control over their own territory in the context of social relations that are characterised by a highly decentralised industry and administrative system. They hence think of the transnational coordination process to be helpful for them in the specific context of the social relations they are embedded.

This provides us with an excellent point of comparison to coordinative behaviour in the case of maritime safety, where the UK and German authorities contest the hierarchical coordination pattern shaped by EMSA's inspection task. This can be explained by the different social relations that regulatory actors are embedded in across these two fields, which inform national authorities' perceptions of the value of the task carried out by an EU regulatory body: In the case of maritime safety, the authorities in the UK and Germany evaluate EMSA's inspection task from the vantage point of the international regime that they are highly engaged with, and which presents the focal point of their work. In the case of food control authorities, on the other hand, authorities in the UK and Germany assess the value of FVO inspections from a context in which they face the challenging responsibility to oversee a very complex, decentralised industry and administrative apparatus. This demonstrates that social relations fundamentally inform national authorities' evaluations of transnational coordination processes that are shaped by the specific task that is being carried out. Different sets of social relations hence represent different bases from which national authorities 'calculate' the perceived worth of their engagement with transnational processes.

Chapter 6

Banking Regulation and Supervision

The case study on transnational coordination in banking regulation and supervision provides as with an opportunity to study the effect of a standard-setting task on coordinative behaviour. The European Banking Authority (EBA)[251] brings together national banking regulators in order to agree on common technical rules, and to facilitate the shared supervision of banks in order to mitigate cross-border risks: Whilst the majority of banks in the EU are only active at the national (or even local) level, around 40 of the approximately 8000 credit institutions operating in the EU have large-scale cross-border operations (for example, see CEPR, 2011),[252] which, in turn, account for more than two thirds of the assets of the European banking sector. With regard to the EBA's standard-setting task, then, shared technical rules that guide the practices of banks and banking supervisors are seen not only as a driver towards the leveling of the playing field in an integrated market, but also as a means to achieve greater safety in a context

[251] The EBA was predeeced by the Committee of European Banking Supervisors (CEBS) from 2004 until 2011.

[252] Also, see the hearing with José María Roldán, then Chair of CEBS, European Parliament, Committee on Economic and Monetary Affairs, Brussels, 10 October 2005; and speech by Andrea Enria, Chairperson of the EBA, 'The crisis in Europe, the impact on banks and the authorities response', Università degli Studi di Trento, 20 February 2013.

in which banks can freely operate across borders without restrictions, whilst regulatory regimes remain fragmented along national lines. The EBA also has the task to facilitate the day-to-day supervision of cross-border banks: The banking supervisors of the original 'home' country and of the 'host' countries of subsidiaries of cross-border banks (such as HSBC or Deutsche Bank) need to collaborate if they want to obtain a full picture of the health of a given financial institution.

As laid out in Chapters 1 and 2, we can expect that a standard-setting task creates an arena of contention: Since the rules that are agreed upon bind all further actions of the involved regulatory actors, we can expect national authorities to attempt to influence the end result in their favour. In such a case, then, the main line of conflict runs between national regulators –rather than between national authorities and EU bodies– which play the role of adversaries in the institutional framework provided by standard–setting task. The extent to which national regulators perceive it to be valuable to influence proceedings, in turn, can be expected to be informed by the social relations they are embedded in.

The case of banking regulation and supervision is an excellent means to investigate coordinative behaviour for two further reasons. Firstly, the case is particularly intriguing since the formal authority of the EU regulatory body under scrutiny increased significantly during the time period that was studied when the European Banking Authority succeeded the Committee of European Banking Supervisors in 2011. According to the argument of this thesis, social relations and tasks fundamentally shape coordinative behaviour of national regulators –rather than the formal authority of the EU regulatory body they meet in. If this is indeed so, the coordinative behaviour of the involved national regulators should not have been affected by this change in formal status of the EU regulatory body. Secondly, it provides as with an opportunity to further scrutinise how coordinative behaviour is affected when an EU regulatory body has two differing regulatory tasks: Next to technical standard-setting, the European Banking Authority (and formerly the Committee of European Banking Supervisors) also has the task to facilitate the coordination of supervision of cross-border banks in so-

called 'supervisory colleges'. We can hence study whether the behaviour of the involved regulators indeed differs when they are carrying out different tasks as the argument of this thesis puts.

6.1 Social Relations and Tasks in Banking Regulation and Supervision

UK and German banking regulators are embedded in differing sets of social relations. Each of them has a specific regulatory philosophy about how risks from unsound banks should be managed. These philosophies, in turn, are tightly bound to the training their staff have –which is embedded in wider administrative traditions of each country– as well as the nature of their banking industries. In line with the argument of this thesis we can expect that these social relations inform which added value they perceive to gain from engagement with transnational coordination in CEBS/the EBA. British and German regulators are also tightly bound into social relations in their country with regard to the potential pressure that is exerted upon them by governments to avoid bank failures that would result in a taxpayer funded bailout of a given bank, particularly in the aftermath of the 2008 crisis (Section 6.1.1).

CEBS/the EBA, in turn, have the key tasks to set technical regulatory standards and to facilitate the day-to-day supervision of cross-border banks. Technical standard-setting provides an institutional framework that creates an arena of contention, which needs to be resolved in the coordination process. The task to facilitate the day-to-day supervision of cross-border banks, in turn, is essentially an information-exchange task in which information about the soundness of a cross-border bank is exchanged to form a picture about the health of a banking group as a whole. At face value, this could be expected to lead to mutual exchange and provide an arena for the finding of agreement. In order for this coordination pattern to be observed, however, national banking supervisors need to proactively engage with this task, which –as this thesis argues– will only happen if they value the task for their own work (see Section 6.1.2).

6.1.1 Social Relations in the UK and German Banking Supervision Regimes

The social relations that the UK and German authorities are embedded in differ markedly in many respects. The long-standing caricature of their two regulatory philosophies usually displays the British way of doing things as 'light-touch' as opposed to a strictly rule-bound German regulatory style.[253] This picture is perhaps firmly rooted in the past; indeed, the regulatory and supervisory structures for the banking sector in the two countries have been argued to have become more similar as a result of international and EU harmonisation efforts (see, for example, Lütz, 2004) and due to some shared dominant ideas of what constitutes good practice: Both regimes introduced integrated financial regulators around the start of the new millennium, and both became keen defenders of principles-based regulation.[254] Nevertheless, implementation of international and supranational rules necessarily happened under adaptation to specific national circumstances (*ibid*.). The evolvement of both regimes has been very dynamic and escapes straight-forward classification into 'light-touch'/interventionist or principles-based/rules-based labels. This is especially so due to the complexity of establishing a predominant regulatory approach or 'philosophy' in each country: Views of national regulators about how best to manage risks have consistently interacted with and have been shaped by the ideas of other national regulators, especially in the forum of the Basel Committee. At the same time, political pressure on national regulators in this field is significant. This has been particularly visible in the aftermath of the crisis of 2008.

The recent financial crisis has led to a starkly different response in the two countries: The British Financial Services Authority (FSA) engaged in extensive soul-searching after the crisis, leading to a reformulation of the philosophy underpinning financial regulation in the UK (FSA, 2009). Moreover, the FSA was disintegrated into the so-called 'twin-peaks

[253] For an overview of the development of the German and British regimes, see Moran, 1991, 1994; and Müller, 2002.
[254] Principles-based regulation uses broad principles -rather than detailed rules- to guide regulatory behaviour (for further discussion, see, for example, Black, 2008; and Black, Hopper, and Band, 2007.

model',[255] thereby giving the tasks of banking regulation and supervision to the Prudential Regulation Authority (PRA) within the Bank of England, which started operating in April 2013 (Treasury, 2011).[256] In Germany the aftermath of the crisis has largely been characterised by stability and to an extent the Federal Financial Supervisory Authority (BaFin)[257] perceives the virtues of its own approach confirmed through the crisis.[258]

In that regard, the discussion about the relative importance of capital adequacy requirements and calculable risk measures on the one hand, and 'softer' qualitative risk management tools (i.e. the evaluation of the internal control system of banks, the qualifications of the people in charge etc.) on the other hand has been one of the main issues which exemplify the differing regulatory philosophies of national authorities: The so-called Basel II agreement represented a crucial juncture from its predecessor as it introduced 'qualitative risk management' measures (Tarullo, 2008; also see Lütz, 2004, for a brief explanation). A crucial underlying assumption hereby was that ultimately banks know how to manage their own risks and that

[255] For an overview of the different organisational approaches to financial regulation see Goodhart, 2000; and Llewellyn, 2006.

[256] The FSA was established after the election victory of New Labour in 1997 as an 'integrated' regulator, in which the organisational structure did not reflect the sectoral divisions of the financial industry (i.e. the banking, insurance and securities sectors) (for a discussion of the potential merits of this organisational approach, see Briault, 1999, 2002). As of April 2013, the FSA was disintegrated along a twin-peaks model, in which banking oversight is organisationally separated according to prudential and conduct of business oversight (for further discussion of the FSA's disintegration, see Black and Hopper, 2012).

[257] When the BaFin was created in 2002, the three separate regulators for each financial sector were brought together under one roof. Although formally an 'integrated' regulator, BaFin remains divided along the lines of the three financial sectors as a result of this. BaFin is an independent agency, which operates under the auspices of the Ministry of Finance. BaFin and the Ministry of Finance (and the Bundesbank) thereby meet in 'Forum for financial market supervision'.

[258] Notwithstanding the considerable changes introduced by Basel III/Capital Requirements Directive IV (CRD IV, Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment forms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC).In relation to seeing its own approach confirmed, for example, consider the following excerpt of a speech by Jochen Sanio, then President on BaFin: "It would be an error to think that the deficits in the global regulatory regime were all a regrettable lapse – oops, we are sorry, we didn't take this and that into account. Quite the opposite: Many gaps in the supervisory structure were deliberately created by stakeholders holding an interest in this – of course without the premonition of the terrible consequences that would result many years down the line. An especially unpleasant issue in this regard has been the effect of an intense competition among the financial centers, which has too often led to an intense competition over the most lenient national regulatory rules – a 'race to the bottom'. It is not a coincidence that this term originates in the English language, which also provided the world with the notion of 'light touch regulation' […], which, however, is currently on the retreat" (translated by the Author, German original in speech 'Die Fortentwicklung der Bankenaufsicht', 28.05.2009, Frankfurt am Main.In relation to the stability of the German regime after the crisis, it is important to note that there was extensvie debate about giving the Bundesbank a more involved role in banking supervision (see Engelen, 2010), which, however, was not further pursued.

supervisors 'merely' need to verify the adequacy of their internal control systems. Basel III, on the other hand, has firmly re-established and expanded the usage of quantitative risk measurements, thereby especially establishing it in the area of liquidity risk measurement.[259]

In a nutshell (and hence simplifying matters), in the recent past the British approach has been focused on capital adequacy and quantitative measures,[260] whereas BaFin has emphasised the importance of non-quantifiable risks and qualitative risk management approaches.[261] Such crucial differences in philosophies about how best to manage risk frame the assessment about the value of the engagement with transnational coordination processes on part of UK and German regulators. The emphasis on new quantitative measures in Basel III (Brzenk, Cluse, Leonhardt, 2011) is thereby not necessarily aligned with the BaFin's risk management paradigm (*ibid*.; also see BaFin, 2013, p.11f); whilst, however, these provisions where once again 'watered' down in favour of the German – rather than the British approach– in the EU negotiations about the CRD IV (Howarth and Quaglia, 2013).[262]

The framing of their engagement with the EBA's (and previously CEBS') tasks is also informed by their regulatory practices, which, in turn, are embedded in particular sets of social relations found at the domestic level. For example, the FSA and now the PRA create their own risk models to verify the results of banks' internal risk management models. In this regard, they are also prepared to demand from a bank to hold more capital if its own model diverged from the results of the bank's calculations (compare to FSA, 2012; PRA, 2013). This approach hence implicitly assumes that in some instances the supervisor is better able to assess the risks posed by the

[259] See Liquidity Coverage Ratio (LCR) and Net Stable Funding Ration (NSFR) under Basel III. Interviewees have at least partly attributed this to the political level which has come to see banks as incapable of managing their own risks after the crisis.

[260] Interviewee B2, B5, and B6. Also see FSA speeches, such as Adair Turner's Mansion House Speech on 20 October 2011, or Hector Sants' speech at the Cityweek Conference on 7 February 2012. Also see Ferran, 2012, p. 18. In this regard, the UK's approach (especially after the crisis) has been aligned with the US and Switzerland (which is also characterized by a financial 'giants' that are very large in relation to the economy of the country as a whole) (*ibid*.).

[261] As, for example expressed in BaFin's tools in 'MaRisk' ('Minimum requirements for risk management') which assesses a bank's risk management processes. See, for example, AK BA, 2010, p.6.

[262] In this interview, the head of BaFin's banking supervisory division points out the merits of a qualitative approach.

particular business model of a financial institution than this financial institution itself (PRA, 2013, p.17).

The BaFin approach differs in this regard: The philosophy behind its practices has been the idea that banks are generally better at assessing their own soundness than banking supervisors are. Regulator-led calculations to verify data provided by banks are only carried out in a focused and targeted way if concrete doubts about the bank's internal control processes emerge. In this regard, BaFin has taken a very process-oriented approach, in which the evaluation of the competence of a bank's staff has been key. This BaFin 'philosophy' of how safety is best achieved (i.e. by verifying the internal control systems of banks in a qualitative manner) is embedded in wider the social organization of German administrative traditions: Many staff members have a background in legal training and do not have experience of working in the banking sector. Complex modeling and 'judgment-based' forms of supervision require technical expertise and intimate knowledge of business models, which is usually gained by working within the banking industry.

In the UK, it is indeed common to gather experience within the regulator and the industry, and staff might be seconded for this purpose. This is seen as necessary for effective risk management by the industry and the regulator (Black, 2012, p. 1046), which is indeed quite different in Germany: The 'revolving door' principle is frowned upon in the German context; instead, a clear delineation between governmental authority and the industry is seen as vital (see Lütz, 2004).[263] BaFin's regulatory approach is also embedded in a very particular industry structure, in which a few privately owned 'giants' (especially Deutsche Bank) exist alongside many small and mid-sized private, savings and co-operative banks (see, for

[263] Whereas transitions from senior BaFin and Bundesbank staff to the industry are not unheard of, the public debate generated by this should not be underestimated and the likelihood of a subsequent move back into the supervisory realm is much lower. For example, when the former head of BaFin's banking unit (Helmut Bauer) left the authority to work for Deutsche Bank in regulatory affairs, the German media reported on this with a critical angle (see *Spiegel Online,* 19.01.2008, 'Pikante Personalie: Banken-Aufseher wechselt zu Deutscher Bank'). Reportedly, this was also heavily criticised in the German industry as a former supervisor -who is familiar with business models etc. of banks- was going to work for one of their competitors.

example, IMF, 2011).[264] These social relations are vital for framing the value of engagement with CEBS' and the EBA's tasks on part of British and German banking regulators: New technical standards can demand change that would require a transformation of practices that are deeply rooted in domestic social relations.

Next to their domestic setting UK and German banking regulators are also embedded in social relations of international regulators efforts. Ever since the failure of *Herstatt* bank in 1974,[265] the Basel process has provoked debates amongst national officials as to how cross-border risk is best managed (see Tarullo, 2008, p.1ff; and Goodhart, 2011, for historical overview). Debates on banking regulation thus have a distinct international character, whereby national regulators consider whether certain ideas and practices can work internationally *and* in their respective jurisdictions. In this respect, it is vital for the analysis presented here to consider that discussions about technical standards in CEBS/the EBA cannot be regarded in isolation as national officials (often the same individuals) flesh out international deals in Basel. In the European context the Basel rules are then (re-)negotiated in the Council (in conjunction with the European Parliament, after receiving a proposal from the Commission) in order to implement the Basel rules in the EU, as was the case with Basel III and the Capital Requirements Regulation (CRD) and Directive in spring 2013.[266] Technical rule-making in the EBA hence potentially presents the possibility for 'reclaiming' some ground that was lost at previous rounds of negotiation.

[264] Demands of German small local savings and co-operative banks have become a key issue at the international and European level negotiations (Quaglia, 2010; Tarullo, 2008, especially p.69, p.115ff, Verdier, 2009, pp.130-143).

[265] The privately owned German bank *Herstatt* went bankrupt on 26 June 1974. On the same day, banks in other countries had released the payment of Deutsch Marks in exchange for US dollars (to be delivered in New York) to *Herstatt.* As the involved banks were operating in different time-zones, *Herstatt* ceased its operations between these payments. Consequently, the counterparty banks did not receive their US Dollars in exchange for their earlier payment. The G-10 countries formed a committee as part of the Bank of International Settlements as a consequence. This was the beginning of the Basel Committee on Banking Supervision. For a comprehensive overview of the development and substance of the international framework, see Tarullo, 2008.

[266] The CRD IV/CRR package was adopted in June 2013. See European Commission (2013b) for an overview to what extent the EU legal package differs from Basel III. (see Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment forms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC; and Regulation No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation No 648/2012.

This needs to be taken into account for understanding how British and German regulators evaluate their engagement with the EBA's technical rule-making task. Hence, these social relations can be expected to inform the assessment of the value of engaging with CEBS/the EBA's tasks on part of British and German regulators.

6.1.2 Tasks of CEBS and the EBA

EU cooperation in the field of banking started in the 1970s when the first principles agreed upon by what is now the Basel Committee were transferred into binding EC law.[267] In order to "ensure the proper implementation" of this Directive a committee of representatives from the EC Member States and the Commission with advisory functions was set up (the Banking Advisory Committee), to which the Commission provided a secretariat.[268] Transnational coordinative structures in banking regulation are hence far from novel. However, a major change in this transnational bureaucracy did not occur until the early 2000s, when one part of the Banking Advisory Committee became the European Banking Committee (EBC), the members of which were mostly drawn from national finance ministries (and central banks or supervisory authorities in some cases) (see Quaglia, 2008, p.565ff; 2010, p.48ff for a more comprehensive overview). The other half of the former Banking Advisory Committee convened to become the Committee of European Banking Supervisors (CEBS),[269] which held its first meeting in London in 2004. The EBC was responsible for defining broader objectives on the basis of EU banking legislation, and CEBS was to fulfil the task of formulating technical guidelines on the basis of these broader standards. This institutional architecture derived from the so-called Lamfalussy process that had originally been adopted in order to drive forward halted integration in the securities sector (European Commission, 1999; Lamfalussy Report, 2000; Quaglia, 2008, 2010). This structure was

[267] Directive 77/780/EEC (First Council Directive of 12 December 1977 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of credit institutions).
[268] *Ibid*., Art.11. It had acted as comitology and advisory committee.
[269] Established by Commission Decision 2004/5/EC.

then also adopted in the field of banking (as well as the insurance sector) in order to increase the coordination of regulatory practices across persistently differing national regimes,[270] in addition to providing the Commission with an expert advisory body.[271]

Before long, however, the financial crisis of 2008 resulted in further organisational change in these transnational coordination structures. In November 2008 the Commission mandated a High-Level Group chaired by Jacques de Larosière to make recommendations on how to reform the system. The 'de Larosière Report' suggested establishing a 'European System of Financial Supervisors' (De Larosière, 2009), which indeed started operating in January 2011. It consists of the 'European Supervisory Authorities' (ESAs) and the 'European Systemic Risk Board' (ESRB).[272] The ESAs are three supervisory authorities created for the supervision of each of the financial sectors, which in the case of banking regulation and supervision is the European Banking Authority (EBA), which based in London.[273] The EBA represents a continuation of the work done by CEBS, albeit with more resources and authority at its disposal (whilst also being entrusted with some additional responsibilities). This renders the banking case an excellent opportunity to explore to what extent it is really social relations and tasks that inform and shape coordinative behaviour of national regulators in EU regulatory bodies, rather than the latters' formal authority (as often asserted, for example, see Busuioc, 2013; and Wymeersch, 2012) .

In order to carry out its tasks, CEBS largely relied on national officials to handle the substantive issues in working groups convened from national officials: Its major task in this regard was the setting of technical regulatory

[270] *Ibid*., Recital 5.
[271] *Ibid*., Recital 4.
[272] Regulation No 1092/2010 of the European Parliament and of the Council of 24 November 2010 on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board.
The ESRB is another body charged with analysing risk that transcends national and sectoral boundaries. It is under the responsibility of the ECB, and is entirely concentrated on the task of macro-prudential supervision (whereas the ESAs need to focus on macro-, and micro-prudential, and conduct of business supervision) (*ibid.,* Art.3). In cooperation with the ESAs and national regulators the ESRB is meant to focus on the identification of systemic risk (i*bid*., Art.3, Art.15.).
[273] Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC.

guidelines, but also included the evaluation of national regulators' practices in peer reviews and the creation of a mediation panel to solve coordination problems between national authorities.[274] High-level officials from national supervisors represented the 'members' of CEBS and were responsible for taking decisions on the output of the committee (i.e. the technical guidelines), whereby consensus was the norm, despite the possibility to apply qualified majority voting to come to decisions (Quaglia, 2010, p.49). CEBS members met three to four times a year at the highest level, whilst the bulk of the extensive work on technical guidelines took place in working groups throughout the year. CEBS leadership was also drawn from national authorities on a non-full-time basis (the CEBS chair and vice chair), while the committee possessed a small number of its own dedicated staff: Its London secretariat consisted of a secretary-general, deputy secretary-general, and three bureau members (all appointed from amongst and by the CEBS members, i.e. national authorities' representatives).[275]

The most essential task of CEBS was to issue guidelines and recommendations for the practical application of shared high level standards, especially with regard to the implementation of the Capital Requirements Directive (the 'CRD', the implementing text of what was then Basel II).[276] It also needed to respond to 'Calls of Advice' from the Commission.[277] While resources of CEBS and national authorities participating in it were put under strain by the intensity of output needed to be produced by CEBS, the structure reportedly worked quite smoothly in term of 'getting things done' considering its small number of core staff (CEBS, 2007; 2007b; also see Ipsos Mori, 2007). Whereas CEBS guidelines took a non-binding voluntary role at first, a comply-or-explain mechanism was introduced in later years of its operations.[278] CEBS also made use of its expertise to forge a pioneering task for a transnational body with regard to

[274] See Protocol of the CEBS Mediation Mechanism, 25 September 2007. This mechanism then became more formalised in the 2009 reform of CEBS, see Art.19 and Art.21(4) in relation to supervisory colleges, Decision 2009/78/EC.
[275] Art.1,2 and 7 of CEBS Charter.
[276] Art.2, Decision 2004/5/EC; Art.3, Decision 2009/78/EC.
[277] Art.2, Decision 2004/5/EC; Art.2, Decision 2009/78/EC.
[278] Formally speaking the output of CEBS continued to be non-binding. However, Member States now had to be prepared to explain why they had chosen not to implement CEBS guidelines (or other measures). See Art.14, Decision 2009/78/EC.

day-to-day supervision of cross-border banks: The committee took up the task to facilitate the coordination of supervision of cross-border banks, for example, by carrying out peer reviews about the functioning of supervisory colleges (which bring together all banking supervisors involved in the supervision of a given cross-border bank) (CEBS, 2010).

In turn, the administrative capacity of the EBA has increased distinctly in comparison to CEBS: As of May 2013 EBA had around 100 staff members. The role of the CEBS chair is now performed by a full-time Chairperson.[279] A Management Board –responsible for steering the authority and its budgetary matters and consisting of the Chairperson and six members of the Board of Supervisors in rotating style–[280] and a full-time Executive Director fulfil the responsibilities of the former CEBS secretariat and bureau.[281] The EBA's Board of Supervisors –that takes decisions on legally binding technical standards– consist of high-ranking leadership personnel of national authorities. It meets at least four times a year;[282] however, the degree of deliberation here is limited as many meetings are relatively short teleconferences.[283] As was also the case in the CEBS system, the substantive work of the authority is carried out in working groups (and sub-working groups). Since the EBA has more staff to fulfil its task than CEBS did –and reportedly has a self-confident attitude as a 'fully-blown' authority–[284] it has the potential to be an influential actor in its own right. However, the EBA's workload far outstrips its capacities at the time of writing and national officials remain absolutely crucial for fulfilling its mandate (especially in regard of writing technical standards) (EBA, 2012b, p.9). As a UK official has noted "given the range of tasks that the EBA and the other European Supervisory Authorities have been asked to do, the only way they can possibly accomplish them is to continue to bind in the national

[279] Art.5, CEBS Charter, Interviews.
[280] Art.45, 47, Regulation No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/E.
[281] *Ibid*., Art.51.
[282] Art.1.1, Rules of Procedure of EBA Board of Supervisors.
[283] See Board of Supervisor meeting minutes. This was also pointed out by interviewees B12.
[284] As, for example, pointed out by interviewee B2 and B3.

supervisory authorities into their workings".[285] Indeed, some authorities – such as the German BaFin and British FSA/PRA– explicitly wish to limit the workforce of the EBA in order to remain closely involved in the drafting of a technical standard.[286] This gives us reason to believe that in the context of the specific social relations that the BaFin and the FSA/PRA are embedded in, they value the engagement with transnational coordination since it provides them an opportunity to influence the EBA's output in their favour.

The key task of the EBA is the setting of technical standards as required in the Capital Requirements Directive.[287] The nature of rule-making has changed in relation to the CEBS process since the EBA agrees on legally binding technical standards. The role of the EBA in this respect is to formulate 'regulatory technical standards', which are meant to be more detailed versions of the rules contained in the relevant legislation, a pertinent example of which is the definition of capital on which 16 out of the 23 draft technical standards opened for public consultation in 2012 focused (EBA, 2012, p.21).[288] The EBA also needs to agree on 'implementing technical standards',[289] which set out how secondary legislation should be implemented, a crucial example of which are standards of formats in which banks need to report various kinds of information to supervisory authorities (*ibid*.). These draft measures need to be endorsed by the Commission to become legally binding,[290] whereby, the Commission can make amendments to the proposed measures in coordination with the agency. The technical standards the EBA produces are directly effective at the national level, whereas the guidelines of CEBS had to be implemented at the national level. In its entirety, the rules produced by the EBA are hence termed the 'Single Rulebook'.[291] Moreover, draft measures of the EBA now express the decision of a single body –the EBA– rather than of CEBS, in which measures and recommendations could express the diverging views of members.

[285] This was expressed in a House of Lords Committee hearing by the then Deputy Chair of the EBA and Member of the Executive Committee of the FSA Thomas Huertas (see House of Lords, 2011, p. 15).
[286] Interviewee B4.
[287] And more recently the Capital Requirements Regulation.
[288] Art.10, Regulation 1093/2010.
[289] *Ibid*., Art. 15.
[290] *Ibid*., Art.10, Art.15.
[291] *Ibid.,* Recital 22.

As set out in Chapter 2, we can expect a standard-setting task to set up adversarial relations between the involved national authorities: The decision on a standard affects all further actions of a national authority and thus provides an incentive to influence the end results in one's favour. As a result, contention between national authorities is likely to arise, which can be expected to be resolved through processes of bargaining and deliberative persuasion in which each authority attempts to influence the given standard. As set out in the argument of the thesis, we can hence expect the coordination pattern under CEBS and the EBA to be similar –despite the different level of formal authority they possess– as they both have (or had) a standard-setting task. In CEBS, the comply-or-explain mechanism rendered its task effectively into a formal rule-making task. However, contention and bargaining under the EBA system can be expected to have increased in intensity due to the higher formality of its output: Having taken on a formal character, the stakes for national authorities are now higher than under the CEBS system, which is indeed reflected in the FSA/PRA's and BaFin's provision of additional staff for to the transnational process.[292]

The EBA –as CEBS– also has the task to facilitate the coordination of the supervision of cross-border banking groups, whereby national supervisors have the task to exchange information on the soundness of the particular branch of a cross-border bank that operates in their country. The involvement of the EBA has accrued a more formal nature in comparison to CEBS. In order to facilitate an effective functioning of supervisory colleges, the EBA has now also been granted the right to participate in supervisory college meetings and related college activities, such as joint on-site inspections carried out by national authorities.[293] At face value, this accrues to a simple information-gathering and exchange task that could be expected to lead to mutual exchange and provide an arena for the finding of agreement. However, this task is carried out in a very particular set of social relations –namely the pressure of governments on banking supervisors to

[292] See AK BA, 2010b, p.8; AK BA, 2011, p.8 for Germany, and FSA, 2010, p.12 for the UK.
[293] Art.21(1), Regulation 1093/2010. Also, the former mediation mechanism of CEBS has now become formalised under the EBA (*ibid.,* Art.19). Moreover, the authority can also ask a college for further deliberation if a "decision would result in an incorrect application of Union law or would not contribute to the objective of convergence of supervisory practices" (*ibid.,* Art.21(2)(e)).

avoid a bank failure at all costs– which gives us reason to expect that the functioning of coordination is not straightforward in practice.

6.2 Identifying the Coordination Pattern between Banking Regulators

In line with the argument advanced by this thesis, we can expect a standard-setting task to result in contention between national regulators that is solved through bargaining and persuasion. Since regulatory practices in banking are deeply embedded in the social relations at the domestic level, we can expect that the FSA/PRA and BaFin perceive the value of the engagement with this task to be a chance to influence the end result in their favour (see Section 6.2.1). The task of coordinating day-to-day supervision of cross-border banks in supervisory colleges, in turn, might be expected to provide an arena for finding agreement through the exchange of information. However, it is questionable to what extent national banking supervisors indeed value this task –and hence engage with it- given the social relations they are embedded in with regard to this task (i.e. the pressure on regulators to avoid a bank failure at all costs) (Section 6.2.2).

6.2.1 Technical Standard-Setting: Facilitating Contention between National Regulators

Indeed, we find that national authorities attempt to convince each other of the merit of their respective ideas and practices in a deliberative process in specialised CEBS/EBA working groups. Differences in views amongst national regulators which need to be mediated in this mechanism include such questions as whether to apply more quantitative risk management tools –as often favoured by the UK regulator– or more qualitative tools, as preferred by the German regulator. National authorities try to influence the end-result in their favour to align them to their existing ideas and practices. High capacity regulators –such as the UK and German ones– attempt to

exert this influence by supplying high numbers of staff with authoritative expertise on specific matters to CEBS/EBA working groups.

The role of CEBS and EBA staff in this process is to facilitate the different views represented within this deliberative process in order to ensure that agreement is reached. In this regard, they have adopted an approach of strategic pragmatism to ensure timely and workable solutions, rather than intervening in deliberations as an additional actor with a specific view. Tools used in this regard include an early identification of contentious issues, re-phrasing issues in an uncontroversial manner or the proposition of interim solutions. CEBS/the EBA have hereby focused on creating consensus, rather than intervening into the on-going debate about the most effective risk management tools. CEBS and the EBA staff make use of the resources at their disposal in order to facilitate consensus, such as their better overview and information of positions across all national regulators.

Technical standard-setting at the transnational level is an arena of contention since a common decision needs to be taken that restrains all further action of national regulators. These frame their engagement with this transnational process through the filter of their different national risk management paradigms and practices that are embedded in domestic social relations. In this light, British and German regulators have been adamant in securing influence on the technical rule-making process in CEBS and the EBA, especially under the raised circumstances of binding technical rules in the new system:

> In […] CEBS BaFin sings as part of the choir of European supervisors. However, when the accommodation of European harmonisation with German interests is concerned, BaFin sometimes sings an audible solo.[294]
>
> [The Capital Requirements Directice IV regulation package] is currently one of the most important topics in banking supervision. In the years ahead, the EBA will be having to draft technical standards for all the supervisory processes – for the Capital Requirements Regulation alone, there will be more than 100 of

[294] Translated by the author. Original: "In […] CEBS singt die BaFin im Chor der europäischen Aufsichtsbehörden. Wenn es aber darum geht, europäische Harmonisierung und deutsche Interessen in Einklang zu bringen, stimmt sie bisweilen auch ein starkes Solo an" (Jochen Sanio, President of BaFin at the time, Bafin, 2003, p. 3).

> these. *We must ensure that legitimate German interests remain safeguarded here* [emphasis added].[295]

> […] I cannot stress enough the importance of the changes to the European regulatory architecture. The PRA [...] [is] now operating as an extension of a broader European policy-making framework. Therefore, the effective engagement with the European process is paramount to their success. Critically, we need to win the argument in Europe that supervisors need to have firm-specific discretion and that regulations need to be tailored towards local circumstance. If this does not happen, the European framework will become discredited.[296]

In this regard, officials note that technical rule-making in CEBS/the EBA is an arena in which 'lost ground' at the Basel or Council level can be attempted to be redeemed, as expressed by a BaFin official:

> Even if you had to give in when a few broader issues are concerned, you can still make up for that when agreeing on the detailed questions.[297]

Regulators such as BaFin and the FSA/PRA have differing views on how best to manage risk, which are attached to the social relations they are embedded in at home. They are hence intent on influencing the results in their favour. In practice, national officials report that in order to convince other supervisors of their approach it is vital to present a well-argued, coherent, workable idea. This, in turn, is usually only possible if a national supervisor has particular expertise in an area, for example, due to working on an issue on a national basis before it becomes an issue the European level. In this regard for example, British regulators could convince others of the idea of using regulators' own models to verify banks' internal stress test in the Basel III negotiations because they were able to show a concrete model they had developed. "Once you present a coherent model, it will be

[295] BaFin, 2012, p. 28.

[296] Speech by Hector Sants, then Chief Executive of the PRA, to the BBA entitled 'The Future of Banking Regulation in the UK', BBA Annual Conference,Guildhall 2011.

[297] Interviewee B2, BaFin official. A concrete example in this respect was given as the following: "Take the example of the leverage ratio [...]: Even if you could not prevent that a fixed capital add-on results from the leverage ratio, you can still make sure it is more like what you wanted –namely that it is a corrective device- [...] in the technical standard by setting the reporting requirement for this. Original in German: "Selbst wenn ich bei ein paar Grundsatzfragen nachgeben musste, kann ich durch das Festlegen von Detailfragen noch einige nationale Interessen festsetzen. Nehmen wir mal das Beispiel von der Leverage Ratio. […] Wenn ich schon nicht verhindern konnte, dass tatsächlich eine feste Kapitalanforderung aus der Leverage Ratio entsteht, kann ich aber dafür sorgen, dass das was ich in die Verhandlungen einbringen wollte, nämlich, dass es eine Korrekturgöße sein soll […] dann in den technischen Standard einbringe, wie die Berichtspflicht aussehen soll.

very difficult for anyone else to counter this unless you form an immediate counter coalition".[298]

In order to present such a coherent idea, interviewees agree that one needs to write a substantial part of the measure to be adopted: "Only he who writes stays in the process".[299] This, in turn, usually requires the need to chair a working and/or sub-working group on the matter. The FSA/PRA and BaFin have made their desire to occupy these positions explicit:

> Let us be clear: There is no alternative to the European System of Financial Supervisors. Europe is a common economic area for which we will need in due course a common rule book. This is also in the interest of the German financial industry. [...] In this connection it is important for us to bring our influence to bear in all ways and to contribute our expertise: for example in the Boards of Supervisors, through working together in working groups in which the technical standards are developed, by occupying top positions and by providing the best possible advice to the chief political negotiators in the Council. [...] BaFin will assist the work of the ESAs and the ESRB, but will also keep a critical eye on them.[300]

(Sub-)working group chairmanships are distributed according to expertise of specific individuals or national authorities. In this regard, officials from the 'Big Five' (Spain, Italy, France, Germany and the UK) are frequent holders of such positions.[301] This is as result of their large expertise (in turn related to their substantial industries) and the related administrative capacities: The expertise expected to chair a working group usually requires the ability to evaluate an issue (such as the definition of capital or a common reporting framework) from various angles, which is often not feasible for an individual. In this regard, officials rely on work conducted by colleagues in their home authority for this purpose. As expressed by a UK official "those Member States […] that are willing and able to put capable staff on the working parties have a considerable opportunity to influence the results".[302]

[298] Interviewee B5 former BaFin official.
[299] Interviewee B2 (BaFin official), the German original was expressed as "wer schreibt, der bleibt".
[300] BaFin, 2012, p.28. Also, see AK BA, 2010b, p.8; AK BA, 2011, p.8 for Germany, and FSA, 2010, p.12 for the UK.
[301] However, officials from smaller authorities, such as the Dutch, Belgian , Finnish and Swedish authorities (and to a more limited extent the Irish regulator) have been in crucial positions over the years as well (see CEBS, 2004, p. 8ff; 2005, p.11, 13; 2006, p.32; 2007c, p.41; 2008, p. 32; 2009, p.55 for an overview of the chairmanship of the highest level of working groups).
[302] This was expressed in a House of Lords Committee hearing by the then Deputy Chair of the EBA and Member of the Executive Committee of the FSA Thomas Huertas (see House of Lords, 2011, p. 15).

This is usually not possible for smaller authorities. However, it is reported that deliberate attempts are made to give chairmanships to smaller authorities, especially from the 'new' Member States.[303]

Issues of contention are hence identified and resolved through the working group process, whereby the text is passed back and forth between sub-groups and working groups. Usually an agreement has hence been struck once the text reaches the potential voting situation amongst CEBS members and now the EBA's Board of Supervisors. If the Commission worries about the compatibility of a measure with EU law it will usually voice its view at this stage, rather than when the EBA submits a draft measure to be endorsed by the Commission to become legally binding.[304] CEBS/EBA staff, in turn, have not been active brokers in this process in the sense of advocating the value of some risk management tools; rather, they have taken a pragmatic approach to establishing agreement between national officials, especially due to the necessity to come to a decision under set timeframes: In this regard, areas of contention have, for example, been "re-phrased until the problem disappears".[305] Alternatively, the lowest common denominator has been found or principles broad enough to allow discretion in the tools to be used to reach an end have been formulated. For example, in its Guidelines of Hybrid Capital Instruments (which refers to instruments which have features of equity and debt, hence requiring clear definitions of when they are deemed to be capital by regulators) broader principles were agreed upon instead of clearly delineated rules with regard to the ability of hybrids to absorb losses.[306] This decision was justified by a cost-benefit analysis of principles as opposed to 'rules', thereby showing a

[303] See for example the Chairmanships held by Poland (CEBS, 2007c, p. 41), Hungary and Malta (CEBS, 2008, p. 32). Interviewees report, however, that this has been a challenge due to a lack of staff and expertise in the 'new' Member States.

[304] At the time of writing, only one draft standard had been passed to the Commission, which endorsed it without changes. This was the Commission Delegated Regulation (EU) No 152/2013 of 19 December 2012 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on capital requirements for central counterparties.

[305] Interviewee B2, BaFin official. German original "das Problem wegformuliert".

[306] CEBS Implementation Guidelines Hybrid Capital Instruments, 10 December 2010 (see p.8 – especially para.40 for summary intelligible for non-experts). However, this is not to argue that CEBS/EBA rules always favour principles-based regulation, see for example para.41 of the same Guidelines. Rather, this seems to be highly issue depended (i.e. whether there is support for and agreement about more detailed rules and whether the issue at stake is not too complex to be covered in a prescriptive form).

crucial role for CEBS staff and working group chairs (and now the EBA staff) to prompt a reasoned weighting of different options available when controversial issues are concerned without taking an explicit stance rooted in a particular regulatory philosophy.

CEBS/the EBA thus make use of the resources available to them to foster agreement in a pragmatic fashion. A key activity hereby on part of CEBS and EBA staff has also been to identify contentious issues at the very beginning of the process of devising an output in order to avoid any last minute difficulties in adopting a text, as done in the drafting of the CEBS's technical advice to the European Commission on options and national discretions, which aimed to identify possible areas in which the granting of national discretions in the CRD could be reduced: The working group here started with a thorough investigation of the national discretions in place in all countries in order to identify precisely what the key issues of contentions were from the very beginning.[307] This, however, did not succeed in relation to BaFin's demands with regard to the supposed specificities of the German banking sector and the political economy attached to it: The need to keep a special status for German (and Austrian) co-operative banks was a central point of disagreement when CEBS was drafting this technical advice, whereby no agreement could be reached and the German position remained isolated without resolving the issue.[308] Indeed, as in the CRD IV as well, the specific needs of co-operative banks remain to be taken into account in an EBA draft Regulatory Standard on Own Funds Requirements, which is specifically crucial for BaFin, which has been vocal in advocating a definition of capital which does not disadvantage the specific business model of its cooperative banks in all regulatory fora.[309] Extensive engagement with the transnational process hence provides value to BaFin by allowing it to maintain practices that are embedded in very specific social relations in the domestic setting.

[307] See text of the Advice, especially with regard to the questionnaire created by CEBS to establish the nature of national discretions. This was also confirmed by interviewee B9, former CEBS and Dutch official.
[308] See, for example, p.60 of the Advice text.
[309] See EBA near-final draft Regulatory Technical Standard on Own Funds Requirements, see Recital (4). Also see AK BA, 2009, p.4; AK BA, 2010, p. 6, for German regulatory position.

Staff of the EBA have also offered guidance and interim solutions in the longstanding unresolved debate amongst experts as to how to define capital (EBA, 2012b). Moreover, the EBA has offered interim solutions when a particularly contentious issue is concerned, namely supervisory and financial reporting (for example, see EBA, 2011, p. 3):[310] The attempt to harmonise supervisory and financial reporting from banks to supervisors across the EU (COREP and FINREP) exemplifies the difficulties in coordinating different risk management paradigms, which are embedded in particular sets of social relations.[311] A key matter in this regard has been the large differences in national traditions in this field, which are inevitably tied to wider social relations, such as particular accounting standards, and an emphasis on quantitative or more qualitative approaches to banking supervision. For example, when CEBS was working on formulating the Guidelines on common supervisory reporting (COREP), the direction that was taken relied on a quantitative approach, which has been seen critically by regulators which favour more qualitative tools, such as BaFin.[312] Although agreement on the reporting guidelines could be reached, it needs to be taken into account that decision-making in CEBS still happened under a different pre-text due to the non-binding nature of its output: Whereas Guidelines could be agreed upon, implementation across countries varied. The FSA only implemented COREP and FINREP to a very limited extent at the time (CEBS, 2007, especially p.46) which allowed it to collect significantly fewer data points than other national authorities (FSA, 2007b, p.7, p. 24). This was more in line with its overall risk management philosophy at the time (FSA, 2006, p. 12f, p.33). BaFin implemented COREP partially but refrained from making FINREP mandatory for its industry (BaFin, 2012b, p. 5), whereby it had especially spoken out against the heavily prescriptive rule-like nature of the framework as a form of unacceptable "maximum harmonization" (BaFin, 2005, p.45f). The reform of COREP and FINREP now fleshed out in the forum of the EBA will hence

[310] Also, all interviewees pointed this area out has being particularly difficult to come to agreements on.
[311] COREP refers to the common reporting of supervisory information, such as the reporting of own funds by banks to supervisors. FINREP refers to the reporting of financial accounting data (including the balance sheet) by banks to their supervisors.
[312] Interviewee B12, EBA official.

require radical changes in reporting practices in countries like the UK and Germany (and much less so in countries such as Belgium which implemented most aspects of these frameworks in previous years).[313] Consequently, an agreement on these technical standards has reportedly been specifically difficult under the new EBA regime. In this light, the staff of the EBA advanced a pragmatic interim solution when FINREP is concerned, which permitted the issue to be decided at a later point while the Commission prepares new legislative proposals on the matter in order to avoid stalemate (EBA, 2011, p.3f). The staff of the EBA, then, primarily intervenes pragmatically to ensure that output is delivered according to the deadlines of the given legal requirements, rather than advancing a specific regulatory approach.

The facilitating role played by the EU hub of national authorities has changed with the switch from CEBS to the EBA: The EBA has around a hundred staff to take a more proactive role in formulating technical rules, and the current Chairperson Andrea Enria is vocal in pushing for less discretion in rules and more convergence in practices.[314] This potentially opens a new fault-line between the EBA staff, on the one hand, and national officials on the other hand. Tasks of the EBA in which the authority acts as a source of expertise in its own right – during the aftermath of the crisis most crucially its role in the 'stress-testing' of banks– mean that there are possibilities for establishing its 'actorness'.[315] However, in order to carry out stress-tests of banks the EBA remains dependent on data provided by

[313] For an analysis in this regard when Germany is concerned, see Cluse and Wolfgarten, 2012.

[314] For example, with regard to the supervisory review process (Pillar 2 of Basel) in which regulators assess the soundness of a bank in light of its business model, Mr Enria –Chairperson of the EBA at the time of writing- has put forward to use EBA as a tool for more convergence in the way this is carried out across countries (see speech by Andrea Enria entitled 'The future of EU regulation', 29 June 2011, London).

[315] Art.22(2), Art.23, Regulation 1093/2010.

A 'stress-test' verifies the soundness of a bank against various scenarios of heightened risk (such as the impact of the collapse of a systematically important financial institution on a particular bank). In this regard it needs to be pointed out that CEBS had been carrying out stress-tests since 2009. However, the increased responsibilities and public visibility of the EBA should not be underestimated when stress-tests carried out by the EBA are compared to CEBS exercises. The 2011 stress-test of the EBA was specifically controversial and its results were questioned by the banking sector and experts in the field. As many German banks showed to have a shortfall of capital in the test, the results were especially challenged by the German industry and regulator. For example, 'European bank stress test results raise doubts, hopes', *EurActiv,* 18 July 2011; see Jenkins and Atkins, 2011, 'European banks have €115bn shortfall', *Financial Times,* 8 December 2011; Storn, 2011, 'Die Schwächen des Stress Tests', *Zeit Online,* 9 December 2011).

national authorities, which has contributed to the problems occurring in the first rounds of these exercises.[316] The methodology to be used in these stress tests has remained a source of tension between countries favouring stricter or more lenient tests (House of Lords, 2011, p.13). This, in turn, has arguably had the effect of lowering the EBA's reputation as hub of expertise in its own right.[317] Nevertheless, it has become clear that the authority does not shy away from making use of gathered data to perform its own analyses as a means to further its official objectives (such as harmonisation of practices across countries). This has, for example, been expressed in the exercise of calculating the capital requirements of the same bank by using different approaches as found in the practices of national regulators, thereby showing that these can lead to very different requirements for banks (Enria, 2012). Whereas interviewees have indeed commented upon the 'self-confidence' of the EBA as an actor in its own right, the restrictions posed on the EBA in terms of resource constraints in a time of high work pressure (i.e. the adoption of the CRR/CRD IV package which requires the EBA to adopt around 100 technical standards)[318] are likely to restrain potential fault-lines between the European authority and its national counter-parts. Increasing staff numbers for the EBA would be likely to change this, whilst, however, it is doubtful that large national supervisors will change their view on "the eternal question of the staff".[319] After all, national regulators like the PRA and the BaFin engage proactively with the transnational process –which creates capacity in the absence of sufficient formal authority of the EBA– since they can get something out if it: It provides them with a chance to maintain their practices that are attached to very specific social relations at the national level.

This section of the chapter has demonstrated that the standard-setting task of CEBS/the EBA shapes a coordinative pattern that is characterised by

[316] This has also resulted in the decision of the EBA to cancel its 2013 stress-test due to differences in national approaches (and hence the data delivered to the EBA to carry out stress-tests) in order to await further harmonisation as a result of recent legislative efforts and the Banking Union.
[317] See *supra* note 62 and 63.
[318] See *supra* note 7.
[319] As expressed by Interviewee B4.

contention between national authorities, which is resolved through bargaining, deliberation and the pragmatic input of CEBS/the EBA. German and UK authorities engage heavily with this transnational process since it provides them with an opportunity to safeguard their established practices –which are embedded in social relations at the domestic level– to the greatest degree possible. In this regard, the pragmatic approach of CEBS/the EBA to facilitate coordination by providing solutions that are workable in differing settings of social relations is valued by national authorities. This part of the chapter has also shown that this coordination pattern remained very similar under CEBS and the EBA. This provides further evidence that it is indeed tasks and social relations –rather than the authority of a given EU body- that drive the coordinative behaviour of national authorities.

6.2.2 Cross-Border Supervision in Colleges: CEBS and the EBA as Encumbered Facilitators of Contention

Next to technical standard-setting, CEBS/the EBA also have the key task to facilitate the coordination of day-to-day supervision of cross-border banking groups in so-called supervisory colleges. This provides an excellent opportunity to explore the coordinative behaviour of the same set regulatory actors under a different task and potentially different social relations that are directly relevant to this particular task. Supervisory colleges have a distinct place in the work of CEBS/the EBA since all issues arising in transnational coordination are magnified in their realm: Concrete collaboration is needed in order to coordinate the supervision of a cross-border bank. In order for coordination to function, the involved banking supervisors need to supply comparable types of information to the coordination process, they need to have similar understanding as to how to interpret it and when to act on it. This is especially so since the EBA was established since national authorities now need to decide jointly on the adequacy of the capital of cross-border banks within the given college based on a common risk assessment.[320] Supervisory colleges pre-date the financial

[320] This was introduced in Art.129(3) of the revised Capital Requirements Directive (CRD), approved by the European Parliament on 6 May 2009 (2009/111/EC), which applied from 31 December 2010. In the most recent updates of the CRD ('CRD IV'), the relevant provisions can be found in Art.72, 84,

crisis and have also been set up at the international level (D'Hulster, 2012). Hereby, the exchange of information, the reaching of common understandings of how to interpret it, and when to take action have been highly challenging for banking supervisors: Worries about the confidentiality of data (as, for example, it might be leaked to the press) and national data protection laws can be an impediment to free exchanges of information. Also, the use of different reporting standards and risk models can render it difficult for regulators to make sense of each other's data and overall approach to risk management (D'Hulster, 2012, p. 305).

CEBS started to take a proactive approach to alleviating the above difficulties by observing colleges and by formulating 'best practices' and detailed guidelines. In this regard, CEBS took a "pioneering role" in attempting to facilitate transnational coordination in this regard (*ibid*. p. 313). The EBA has continued this approach and has been given more wide-ranging authority to facilitate coordination between national supervisors. However, these enhanced powers have not been able to counteract the social relations that national authorities are embedded in with regard to the task of coordinating day-to-day supervision of cross-border banks: They have come under severe pressure from their governments to avoid bank failures at all costs. National supervisors do not perceive to gain an added value through coordination in supervisory colleges with regard to these social relations: The open exchange of information with other national authorities has the potential to become detrimental to this objective that emanates from the social relations they are embedded in at home, even though engagement with transnational coordination is the only possible means to gauge the full picture of the financial soundness of a cross-border bank on the whole: If, for example, a home regulator shares concerns about the health of a given bank with a host supervisor, and this host supervisor subsequently ring-fences the operations of the subsidiary of this bank operating in its country, the bank could get into financial difficulties in its home country.

92, 100(1)(a) and 100(a). Also, see CEBS Guidelines for the joint assessment and joint decision regarding the capital adequacy of cross-border groups (GL39), 2010. At the time of writing, the EBA is consulting on the predecessor of these Guidelines in form of binding technical standards.

The work of supervisory colleges is often characterised with difficulties to solve coordination problems: Pervasive issues in this regard are problems with effective communication, particularly under time constraints. Reportedly, it can be difficult to communicate and jointly take decisions within the strict time limits of EU requirements. An example in this regard is the so-called model validation process, whereby banks can use their own models to estimate some forms of risk if these models comply with certain rules, and if they are authorised by their supervisor: In relation to cross-border banks, all national authorities that are involved in the supervision of the this bank need to agree on whether the model is adequate for the estimation of risk. As a result, BaFin has sometimes gone ahead alone and sought host supervisors agreement to a particular model validation only afterwards, while the FSA has sometimes gone significantly over the time requirement to be able to communicate with host supervisors (i.e. supervisors which supervise subsidiaries of a bank in their territory) before validating the internal model of a bank (CEBS, 2009b).[321] Especially when BaFin is concerned, misunderstandings due to lack of frequent communication have been a problem according to host supervisors (*ibid*., p. 13). The French supervisor reported that misunderstandings during a joint model validation arose since BaFin was not using the college as main tool for communication in some cases (*ibid*.). Moreover, according to supervisors, language barriers can be an issue in college work (*ibid*., p. 11). Also, different supervisory philosophies (and hence different tolerance levels for the failure of banks) and a lack of common terminology render coordination in the day-to-day supervision of banks difficult (D'Hulster, 2012, p. 305f). Differences in supervisory approaches lead, for example, to significant differences between risk-weighted assets across similar forms of banks (Basel Committee, 2013), showing why exchange between supervisors with regard to the soundness of a given bank can be difficult.[322]

> We see these differences in our daily engagement with supervisory authorities across the EU. Our experience in supervisory colleges

[321] As laid out in the CEBS Guidelines on the implementation, validation and assessment of Advanced Measurement (AMA) and Internal Ratings Based (IRB) Approaches.
[322] Speech by Andrea Enria, Chairperson of the EBA at the time of writing, at the 4th Santander International Banking Conference, Madrid, 18 October 2011.

> have, for instance, shown that these differences can range from technical issues such as scoring scales used to measure and categorise risks, to more fundamental distinctions such as in the methodologies used to define capital requirements.[323]

In order to alleviate these problems, CEBS/the EBA has the ambitious task to facilitate coordination between national authorities in the college setting. Some of the methods employed in this regard are the Supervisory Disclosure Process and 'peer review', which are mechanisms to enable national regulators to study each other's' practices in a horizontal fashion, thereby providing for an increased understanding of how other regulators approach prudential oversight. These two mechanisms are complemented by trainings conducted by CEBS/the EBA (including seminars for officials that fulfil the same role in their respective home authority, see, CEBS, 2006), the facilitation of staff exchanges on part of the EU authority (set up in 2005 under CEBS), the provision of online discussion forums and query systems (CEBS, 2006), and virtual networks of experts, for example to share reporting practices (*ibid*.). CEBS has also engaged in efforts focused particularly on the functioning of supervisory colleges by observing college meetings and publishing good practices and guidelines for setting up the college process. Indeed, CEBS played a very active role in pushing for the establishment of supervisory colleges (which were called 'operational networks' in the forum of CEBS at the beginning) and can hence be seen as a major driver towards the institutionalisation of this cross-border supervision model, thereby playing a pioneering role in this field in global comparison.[324] This included a detailed peer review covering 17 colleges to assess whether the CEBS guidelines on colleges were are adhered to, thereby being able to provide evidence-based 'good practices' on the basis of the results of the peer review (see CEBS, 2010). CEBS thus employed its overview of practices across national regimes to facilitate the functioning of

[323] *Ibid*.

[324] See speech by Arnoud Vossen, then Secretary General of CEBS entitled 'Towards a New Architecture for European Banking Supervision', Euro Finance Week 2009, Frankfurt, Germany. The setting-up of supervisory colleges then became compulsory in the revision of the Capital Requirements Directive often referred to as 'CRDII, especially see Art.42, 42a, 129, 131, 131a and 132, Directive 2009/111/EC of the European Parliament and of the Council of 16 September 2009 amending Directives 2006/48/EC, 2006/49/EC and 2007/64/EC as regards banks affiliated to central institutions, certain own funds items, large exposures, supervisory arrangements, and crisis management.

supervisory colleges. Indeed, national officials state that college processes enable them to learn about other authorities' regulatory approaches. As a BaFin official noted:

> In general, one also needs to say that the national supervisory review process –so the approach taken to supervision- differ. So you might have a clash between more quantitative and more qualitative approaches. But I'd say in this respect colleges have been a great asset in terms of fostering a better understanding of the various approaches.[325]

In trying to establish a 'common supervisory culture', being a motor towards similar practices and providing detailed guidelines for the functioning of colleges and a peer review, CEBS/the EBA carried out a lot of work which is absent in international colleges. A particularly problematic issue in the functioning of colleges at a global level is the absence of a mediator in case of conflict between supervisors (D'Hulster, 2012, p. 303), which has been remedied in the EU: CEBS established a mediating role for itself and this mechanism was formalised in the EBA. In case of disagreement in the college setting, the EBA's decisions are binding on the national regulators.[326] The mediation panel hereby consists of the EBA's chairperson and two members of the Board of Supervisors (i.e. two heads of national regulators).[327]

Also, EBA staff can now take part in all college meetings and indeed does so in the case of 'priority colleges' (monitoring the largest banking groups) (EBA, 2012).[328] The EBA has become increasingly involved in the second year of its operation, whereby the EBA staff reportedly attended 77 college meetings (EBA, 2012, p.26). Moreover, EBA officials showed their determination to make a constructive contribution to the functioning of colleges by making use of their observations, such as by publishing a good practices guide relating the joint decision of a group's capital adequacy (*ibid*., p.27). CEBS and the EBA make use of its specific form of expertise in

[325] Interviewee B3, BaFin official.
[326] Art.21(4), Regulation 1093/2010.
[327] See Decision of the European Banking Authority adopting the Rules of Procedure of the *Mediation* Panel.
[328] See Art.21(10), Regulation 1093/2011. Informally, colleges had already invited CEBS Secretariat members to attend some of their meetings before EBA staff was granted this right formerly, see Speech by Arnoud Vossen, then Secretary General of CEBS entitled 'Towards a New Architecture for European Banking Supervision', Euro Finance Week 2009, Frankfurt, Germany.

this realm: After all, CEBS and now officials of the EBA enjoy a bird's eye view without a direct link to the interests of the respective industries and pressure from governments which provide the ultimate 'safety-net' for their banks. As a former Chair of CEBS stated "What's the role of CEBS in all this? The Committee is neither a home or host authority."[329] Moreover, the EBA has also played a role in providing 'peer group information' about large cross-border groups in order for supervisors to be able to make more meaningful comparisons.[330] This can be useful for supervisors such as BaFin, as it is essentially only the home supervisor of one large cross-border bank (Deutsche Bank), which renders it difficult to have reference points when making supervisory observations and decisions.[331]

Despite these formal powers of the EBA, however, in practice CEBS and the EBA's role in affecting coordinative behaviour has been extremely limited. For example, due to a lack of staff and a focus on the adoption of technical standards, the mediation mechanism had only been used once at the time of writing.[332] Even the presence of enough EBA resources and expertise, however, would not ensure that the EBA could act as influential facilitator: Coordination problems are not solved in this realm despite the work of CEBS and the EBA since national authorities are not willing to engage with the transnational process to the necessary extent. This is a result of not perceiving this particular coordination task to be valuable as informed by the social relations they are embedded in with regard to this coordination task.[333] The incentive structure provided by the social relations at home –the political pressure to avoid the failure of banks– is essentially set against the open sharing of information between home and host regulator (be it in a college setting or on a bilateral basis). The home

[329] As expressed by José María Roldán, then Chair of CEBS, at the Conference on supervisory convergence in Europe, Den Haag, 3 November 2004.
[330] Speech by Arnoud Vossen, then Secretary General of CEBS entitled 'Towards a New Architecture for European Banking Supervision', Euro Finance Week 2009, Frankfurt, Germany.
[331] As pointed out by Interviewee B1, industry representative.
[332] This process was just on-going as the research for this chapter was being finalised; hence, interviewees were not able to speak about the process and no documents were available.
[333] Please note that college related tasks in relation to Euro-Zone banks will shortly be taken up by the European Central Bank in relation to its new mandate proposed under the Single Supervisory Mechanism (SSM). In this regard, the incentive structures arising from the fiscal responsibility of a 'home' government for its bank are due to be counteracted through a single resolution mechanism (for example, see Howarth and Quaglia, 2013b, 2014; also see House of Lords, 2012; and Schoenmaker, 2010).

regulator has an incentive to keep information about a potentially deteriorating health of a parent institution to himself for as long as possible due the worry that the host regulator might ring-fence its subsidiary as soon as becoming aware of potential problems, thereby possibly even creating a serious liquidity issue for the overall banking group that might not otherwise have arisen. The host regulator, in turn, has an incentive to exaggerate the risks emanating from the subsidiary in order to trigger a further supply of capital to the foreign operations on part of the parent company (for a detailed analysis, see D'Hulster, 2012; Herring, 2007). (Banks, in turn, might be able to exploit these incentive differences between home and host regulator, see, for example, Holthausen and Rønde, 2004).

> When push comes to shove –meaning the announcement of negative information about one's own banks– then us national supervisors prefer to keep to ourselves. As host supervisor you can never be sure whether the home supervisor tells you the whole sad truth about the parent bank. That is understandable: The home supervisor always needs to expect that the host supervisor –whom he just informed so extensively on such a collegial basis– will take immediate steps that will endanger the whole banking group, such as a ring-fencing of the host country operations. So a healthy dose of suspicion is the natural mentality.[334]
>
> What's tended to happen now is regulators get very nervous about other regulators having the same information that they have because they think they are going to second-guess the decisions that were made.[335]

In this regard, industry representatives report that especially since the crisis hit supervisors have been keen to extract information from the given bank directly; i.e. host supervisors approach the parent of the bank directly instead of contacting the home regulator and home regulators contact

[334] Speech by Jochen Sanio, then president of Bafin, entitled 'Die Fortentwicklung der Bankenaufsicht', at the Conference 'Corporate Governance bei Banken', KPMG Audit Committee Institute, Frankfurt am Main, 28 May 2009. Translated by the author, original: "Wenn es ans Eingemachte geht, sprich: die Bekanntgabe von Negativinformationen über die eigenen Banken, dann geben wir als nationale Aufseher lieber die Auster. Als Gastlandaufseher kann man sich nie sicher sein, ob der Heimatlandaufseher einem die gesamte traurige Wahrheit über die Lage der Mutterbank sagt. Verständlich ist das: Der Heimatlandaufseher muss immer damit rechnen, dass der Gastlandaufseher, den er gerade so kollegial und umfänglich informiert hat, sofort etwas unternimmt, was die ganze Bankengruppe in den Untergang treiben könnte, etwa ein ‚ring fencing' der Gastland-Operation. Also ist ein gesundes Misstrauen die natürliche Geisteshaltung."
Also, see FSA, 2009, p.99, for expression of the same problem from a practitioner's point of view.
[335] Interviewee B1, industry representative.

foreign subsidiaries directly instead of relying on the host regulator's knowledge about the subsidiary's health.

> So you get someone saying, 'oh, I can't believe how bad this is, we found this really awful problem with Deutsche Bank' and then someone else will say 'oh yeah, we found an even worse problem', and actually none of them really know what's going on, and they always try to outdo each other.[336]

> Where are improvements needed? I have already made public statements reflecting the fact that EBA considers that the level of information exchange between supervisory authorities was not sufficient in recent months, as liquidity stresses in the system increased. The EBA has been clear to supervisors on the need to provide other college members with timely and sufficiently granular information concerning the liquidity and financial position of banking groups so as to ensure that home and host authorities have a clear and current understanding of the risks.[337]

The lack of proactive engagement –and problem-solving– when this transnational process is concerned hence needs to be understood in relation to the perceived interest of national banking supervisors to avoid the failure of one of 'their' banks: The exchange of information in supervisory colleges could endanger the financial viability of a banking group: If for, example, the home regulator (such as BaFin in the case of Deutsche Bank) shares information about concerns of the soundness of a particular bank with its colleagues from authorities that supervise parts of the same banking group in their country, the latter could potentially ring-fence the operations of the subsidiaries operating in their country. This, in turn, could bring the operations of the bank in its home country into financial difficulties, which could –in the worst case scenario– lead to a government funded bailout of this bank. That national authorities perceive their interest to be the safeguarding of information –and as a result do not value the transnational coordination activities of CEBS and the EBA to warrant sufficient engagement– can only be understood in the context of the social relations they are embedded in at home: The link between banks and 'their' governments when financial aid is concerned means that governments have

[336] *Ibid*.
[337] Speech by Andrea Enria, Chairperson of the European Banking Authority, at the 4th Santander International Banking Conference, Madrid, 18 October 2011.

put enormous pressure on banking supervisors to avoid a potential bank failure at all costs.

Banking supervisors are interdependent in relation to the supervision of cross-border banks and have a functional rationale to engage with coordination (see Schoenmaker and Oosterloo, 2005): Only open sharing of information can result in an aggregate picture of the financial health of a cross-border banking group, which, in turn, is vital to all involved regulators (as a result of which they indeed attempt to obtain this information directly from banks). However, it is not these functional pressures, but the unfavourable assessment of transnational coordination on parts of national regulators as informed by the specific social relations they are embedded in, that drive their coordinative behaviour. The proactive attempt of CEBS and the EBA to counteract the ensuing coordination problems cannot offset national regulators' perception of their own interest that derive from deeply embedded social relation at the national level.

This part of the chapter provides an example of a case in which national regulators do not value the coordination task of an EU regulatory body sufficiently to solve coordination problems: In the context of the social relations they are embedded in at home –the pressure to avoid a bank failure at all costs– national authorities assess this task unfavourably. As a result, the efforts of CEBS and the EBA to solve coordination problems through their activities are relatively ineffective.

6.3 Conclusions

This chapter confirms that a standard-setting task results in a coordination pattern of contention, bargaining and deliberative persuasion: UK and German authorities try to convince other national regulators of the value of their approach to banking supervision by supplying skilled staff that tries to provide the 'best arguments' to the working groups of CEBS/the EBA, which

draft the technical standards that are later voted on by the Board of Supervisors. Since, however, regulatory practices in this realm are deeply embedded in the domestic setting, contention is at times difficult to resolve. As a result, the staff of CEBS/the EBA act as pragmatic facilitator of the standard-setting process, whereby they advance practical solutions for fostering agreement, rather than advocating a particular vision of sound risk management themselves. The banking regulators of the UK and Germany engage proactively with this transnational coordination process since they value it in relation to the social relations they are embedded in: Their regulatory practices are attached to the administrative traditions of their countries as well as their banking industries, which renders changes difficult to carry out, as well as extremely costly (on material and immaterial level). Hence, the UK and German authorities engage with CEBS/the EBA's standard-task –thereby creating its capacity to set standards in the first place– since they value the opportunity to influence the end results in their favour. The pragmatic facilitator role of CEBS/the EBA hereby enters their positive evaluation of this task since the EU regulatory body usually tries to find compromises which allow national authorities to keep deeply embedded practices intact.

The case study also demonstrates that national authorities indeed do not engage heavily with a transnational process if they do not value it from the vantage point of the social relations they are embedded in: CEBS/the EBA also have the task of facilitating the coordinated supervision of cross-border banking groups in so-called supervisory colleges. In contrast to technical standard-setting, however, these efforts are relatively ineffective and UK and German supervisors do not engage with the processes to a significant degree. Although banking supervisors are interdependent in relation to the supervision of cross-border banks –and are thus exposed to a functional pressure to coordinate– they often fail to do so since they do not value this task as informed by their social relations: The crucial social relations in this regard are found in the link between failing banks and their governments, which, in turn, have put severe pressure on their banking supervisors to avoid a bank failure at all costs in the aftermath of the 2008

financial crisis. In the setting of these social relations, there is an incentive for the home and the host supervisors of a cross-border bank not to share information about the financial soundness of this bank due to fears of the subsequent actions of their counterparts. Such an action could, for example, be a ring-fencing of resources on part of the host regulators when they get worried about the state of a given bank. In turn, this can cause the home branch of the bank to get into financial difficulties in the first place, potentially requiring a 'bail-out' of its government.

The chapter shows, then, that the same set of actors can be embedded in different social relations with regard to different tasks, hence leading them to value one transnational coordination process, but not another: Whilst UK and German banking supervisors perceive the engagement of standard-setting in CEBS/the EBA to be valuable to their work in the context of the social relations they are embedded in, they do not perceive the facilitation of coordinated supervision of cross-border banks to be valuable enough to engage with this transnational process to a significant extent.

Chapter 7

Conclusion

This thesis has demonstrated that national regulators engage extensively in transnational coordination processes with their sister authorities. In doing so, they render it possible for EU regulatory bodies to fulfil their tasks and thus crucially support potential bureaucratic 'rivals' in their work. In light of what we know about the motivation of governmental authorities' to protect their turf, this is surprising. It was hence examined what determines the coordinative behaviour of national regulators at the transnational level. The EU governance literature has developed three lines of reasoning in this regard, namely that coordinative behaviour is driven by professional norms, functional pressures and the 'shadow of hierarchy'. The thesis demonstrated that all three literatures highlight aspects which are important for understanding coordinative behaviour. However, they underestimate the extent of the coordination problems inherent in these processes (which are pointed out by the relevant public administration literature), and over-characterise coordination processes, thus failing to account for the extensive variation in coordination patterns that was observed in this study.

The thesis accounts for this variation by demonstrating that the coordinative behaviour of regulatory actors in the EU is determined by the task they fulfil at the transnational level –since tasks provide specific institutional frameworks for their interactions– and their strategic

considerations that are informed by the social relations they are embedded in: After all, regulators want to get something out of their 'investment' at the transnational level. The thesis argues that tasks and social relations need to be recognised as determinants of coordinative behaviour since they allow us to explain the highly varied patterns of coordination that were observed in the empirical research carried out for this project: In some cases coordination was largely orchestrated by EU bodies (leading to rather hierarchical coordination patterns), in others coordination was characterised by bargaining and deliberative processes between national regulators. In yet other cases, coordination happened largely through competitive dynamics or mutual exchange and adjustment between national authorities. This thesis suggests that the different tasks and the differences in social relations that the involved regulatory actors are embedded can explain such variation, where the three above approaches have tended to focus on the similarities of transnational coordination processes across policy areas and national regulators. The first section of the Conclusion reiterates these findings of the study and elaborates on the manner in which the identified determinants of coordinative behaviour contribute to the relevant literature (Section 7.1).

The thesis also demonstrates that British and German regulators are heavily engaged in transnational coordination processes, thereby contributing crucially to capacity building that renders the management of 'European' risks without a 'European' state possible. Whilst the thesis does not analyse the effectiveness of coordination efforts as such, it nevertheless demonstrates that formal authority, expertise and resources on parts of EU bodies are not necessary in order to create capacities at the transnational level: As long as national authorities perceive the engagement with coordination activities to add value to their own work –however they define it– their participation can contribute crucially to creating 'European' capacities where these do not formally exist. This insight also has implications for the study of transnational coordination efforts at the international level, where coordination efforts are much more dependent on the willingness of national authorities to create capacities beyond their

jurisdiction. Equally, these findings are of interest to the study of coordination processes in public administration in general, especially with regard to the formulation of the conditions in which inter-organisational coordination can function. These wider contributions of this thesis are elaborated upon in the second section of the chapter (Section 7.2).

7.1 What Determines Coordinative Behaviour at the Transnational Level?

The empirical findings of this thesis demonstrate that coordination patterns differ vastly across policy areas and the involved national authorities (see Section 7.1.1). The thesis argues that existing explanatory approaches cannot adequately account for this variation. Rather, the observed differences can be explained by the different tasks regulatory actors carry out, as well as the different social relations they are embedded in (see Section 7.1.2).

7.1.1 Observing Variation of Coordination Patterns

The empirical findings of this study demonstrate the existence of a wide array of coordination patterns at the transnational level: Some coordination patterns are based on horizontal exchanges between national regulators, others on vertical relations between EU bodies and national authorities. We observed the occurrence of contention between the involved actors in some cases, whilst we found a focus on agreement between the involved authorities in others.

We found a coordination pattern mainly based on horizontal exchanges between regulators in banking regulation and supervision, drug safety, as well as food risk assessment. Whereas coordination between banking regulators in the forum of the EBA was shown to be riddled with contention and disagreement between the involved national regulators, the relations between food risk assessors and pharmaceuticals regulators in the forum of EFSA and EMA were instead characterised by the areas of

agreement between them (see Table 7.1). Mechanisms through which contention was reconciled and agreement was reached, however, differed crucially across all three cases (see Table 7.2): Coordination between banking regulators is characterised by bargaining and deliberative processes in which they attempt to convince each other of the value of their practices in the (sub-)working groups of the EBA. In the case of food risk assessment the coordination process is defined by mutual exchange of their practices and scientific outputs. This is often followed by mutual adjustment to each other's scientific positions. In drug safety monitoring, in turn, the coordination process is defined by epistemic competition, in which the perceived 'best' model of data-gathering and evaluation sets the informal coordinated standard that other national authorities strive towards. In this case, then, coordination functions through competition in which the 'best' model wins, thus driving potential changes in practices among regulators in order to compete with the dominant model. Hence, even in cases where coordination is mostly based on direct relations and exchanges between national authorities in the forum of an EU regulatory body, we find an extraordinary variety in the functioning of the coordination process.

Table 7.1: Observed Coordinative Relations between Regulatory Actors

	Agreement	**Contention**
Horizontal Exchanges	Drug safety monitoring Food risk assessment	Banking regulation and supervision
Vertical Exchanges	Food controls	Maritime Safety

A coordination pattern mostly based on vertical relations between the given EU regulatory body and national authorities was found in

maritime safety and food controls (see Table 7.2). The coordination process in these cases was characterised by the central role the staff of the involved EU regulatory bodies play in defining coordinated practices and driving change in the practices of national authorities. In maritime safety the modification of behaviour is largely based on the formal enforcement mechanism of the EU system (i.e. infringement proceedings). In the case of food controls, on the other hand, it is mostly based on persuasion of national authorities on part of the FVO before infringement proceedings become necessary. Whereas the UK and German maritime safety authorities contest the role of EMSA in this hierarchical coordination pattern, such contestation could not be identified among food control authorities in these two countries. Hence, we also find variation in coordination processes in cases in which coordination is based on vertical relations between EU bodies and national authorities (see Table 7.1).

Table 7.2: Observed Coordination Patterns

Bargaining and deliberation	Epistemic competition	Mutual exchange and adjustment	Hierarchy
Banking regulation	Drug safety	Food risk assessment	Food controls Maritime safety
Banking regulators attempt to convince each other of their regulatory approaches in deliberative processes in the EBA's working groups to avoid the costs of adjustment.	Drug safety regulators compete to become the dominant model of data gathering and exchange to avoid the costs of adjustment.	Food risk assessors exchange information and adjust to each other's scientific outputs to maintain their reputation.	The FVO and EMSA (in conjunction with the Commission) define and enforce coordinated practices. Enforcement happens through 'soft' persuasion in food controls and through 'hard' legal enforcement in maritime safety.

Moreover, national authorities make use of and engage with transnational coordination processes in a variety of ways: Whereas food control authorities in the UK and Germany use the work of the FVO to improve

control over their own territory, maritime safety officials in the UK and Germany make use of EMSA's coordination activities as an assurance that control is sufficiently exerted in other authorities' jurisdictions. In drug safety, the UK regulator uses EMA processes to establish its model as dominant 'gold standard', whilst German authorities use it to gain access to an expertise that is perceived as superior and to modify practices to remain competitive with the dominant model. British and German food risk assessors, in turn, utilise their coordination activities in EFSA to reinforce public trust in their scientific outputs. The level of engagement of national authorities in transnational authorities was hereby also observed to differ: Whereas German and British authorities engaged with transnational processes very proactively in most of the studied cases, their involvement was less pronounced in the case of the coordination of the day-to-day supervision of cross-border banks. Overall, then, the way in which coordination functions varies greatly across policy areas and national authorities.

7.1.2 Explaining Coordinative Behaviour: Tasks and Social Relations

This thesis suggests that previous explanatory approaches cannot fully account for this vast variation in coordination patterns. It argues that the tasks of EU regulatory bodies –which are usually carried out by national officials coming together in the forum of these EU bodies– shape the coordinative behaviour of regulatory actors, and thus help us to explain variation: These tasks provide institutional frameworks, which set up specific relations between the involved authorities. In doing so, they provide specific incentive structures for strategic behaviour and provide particular frames for action. What 'strategic behaviour' means for the involved regulators –and whether they perceive their engagement with these transnational tasks to be 'worth it'– is informed by the social relations they are embedded in their domestic setting and beyond. These social relations act as interpretative filter through which national authorities perceive the world, as well as constituting their main frame of reference, and thus need

to be seen as vehicles for interest formation. Since national regulators are the 'operative arm' (compare to Wilson, 2000 [1989], pp.31-110) of this transnational bureaucracy, they need to perceive their engagement with transnational coordination to add value to their own work (i.e. the main regulatory work they perceive themselves to be engaged with). The thesis hence stipulates that strategic concerns are the main determinant of the coordinative behaviour of the involved regulators, whereby 'strategic behaviour' is shaped by tasks and informed by social relations. Since tasks and social relations vary greatly across policy areas and national authorities, they can account for the observed variation.

Professional Norms as Driver of Coordinative Behaviour?

As was outlined in Chapter 1, the constructivist literature on EU governance emphasises that coordinative behaviour of regulatory actors at a transnational level is mainly driven by professional norms (for example, Eberlein and Grande, 2005; Majone, 1997; Joerges and Neyer, 1997). As a result, this literature has tended to focus on the conformities of coordination processes across vastly different policy areas and national authorities as it puts forward that mutual exchange, learning and deliberation are key mechanisms across different policy areas and involved authorities (for example, see the analyses of 'experimentalist governance' across vastly differing policy areas in Sabel and Zeitlin, 2010). In this view, the motivation of regulators to invest time and resources to transnational processes is mainly determined by peer pressure in their professional communities (Majone, 1997, p.272). This thesis instead argues that transnational coordination processes are characterised by variation, which cannot be adequately accounted for by solely focusing on professional norms as determinant of coordinative behaviour.

The comparison between coordination processes among drug safety authorities and food risk assessors (see Chapter 3 and 5 respectively) seeks to substantiate this insight further: The scientific communities in the two involved cases can be deemed to have relatively similar professional norms, but the coordination process in the two cases differs. In the former case it is

characterised by epistemic competition, while being defined by mutual exchange and adjustment in the latter case. Undoubtedly, the processes also bear similarities: In both cases the main interactions occur on a horizontal level between national authorities and the involved actors are seeking agreement, rather than being in contention with each other. Mutual exchange, learning and deliberation and peer dynamics certainly occur in the processes in both cases and the professional norms of the involved actors are likely to inform their behaviour in crucial ways. However, if professional norms were indeed the main determinant of coordinative behaviour it would be unlikely for transnational coordination processes to be characterised by such variation, especially in cases where the professional norms of the involved authorities are supposedly similar. Arguably, the emphasis on professional norms neglects that interactions between regulators at the transnational level are shaped by the specific institutional frameworks –the tasks of EU regulatory bodies– which set them into specific relations with each other.

The findings of this thesis also suggest that the focus on professional norms neglects that the involved national authorities are embedded in social relations beyond these norms: The assessment of the perceived value of transnational coordination on part of British and German authorities was shown to be crucially informed by their social relations in the domestic settings. Concerns about their reputation among political actors and the public (in case of food risk assessors) and the specific systems of data gathering and evaluation which are deeply embedded in national structures (in case of drug safety regulators) informed national authorities' perceptions of their own interests in these cases. In this regard, this thesis conceptualises professional norms as part of the social organisation that regulatory actors are embedded in, thus putting forward that they can indeed be crucial: As 'cultural biases', they form part of the interpretative filter through which national authorities see the world (see Douglas, 1986; Wildavsky, 1992; Thompson *et al.,* 1990). As such, however, they do not determine coordinative behaviour per se; rather, they need to be seen as part of the factors which inform actors' perceptions of their own interests.

The professional ethic of 'doing their jobs well' is hereby crucial for most regulators (Brehm and Gates, 1997).

(Perceived) Functional Pressures as Determinant of Coordinative Behaviour?

Another school of thought discussed in Chapter 1 emphasises that (perceived) functional pressures determine coordination behaviour. In this view, the perception of being interdependent with regulators in other countries prompts national authorities to coordinate their practices in the forum of EU bodies (for example, Van Boetzelaer and Princen, 2012). Indeed, this thesis also finds evidence in this regard: For example, the UK and German maritime safety authorities evaluate EMSA's tasks positively – despite their contestation of the inspection system– since they perceive EMSA to add value to their work by ensuring that authorities in other countries are taking their work seriously. In their view, this helps to avoid that they carry out their work to in vain under conditions of interdependence (see Chapter 4). British and German food risk assessors, in turn, clearly perceive themselves to be interdependent with their colleagues with regard to the maintenance of their reputation and this motivates their willingness to engage extensively in coordination processes in EFSA (Chapter 5). Such (perceived) interdependencies hence form part of the social relations that national authorities are embedded in.

However, we also observe proactive engagement –or at least absence of contention– in cases where it is more questionable whether the involved actors perceive themselves to be interdependent. This is especially true in the case of food risk controls, where the daily work of authorities is not dominated by reflections about interdependence with authorities in other countries. Rather, the complexities of overseeing a large network of control authorities –and their respective interdependencies– seem to be at the forefront of the minds of officials in overseeing authorities. Nevertheless, they engage with the FVO inspection process to a great extent and perceive this to be helpful. This finding is better explained by the specific set of social relations they are embedded in than by perceived interdependencies.

Also, we observe a lack of engagement with coordination when interdependence is likely to be perceived by the involved national authorities: In this regard, the case of banking regulation and supervision presented in this thesis is instructive (Chapter 6): It is unlikely that banking regulators perceive themselves to be interdependent in relation to technical rule-making at the transnational level, but not with regard to the day-to-day supervision of specific cross-border banks (which could then explain their proactive engagement in the former, and absence of investment in the latter activity). Rather, this difference can be explained by UK and German authorities' assessments of the value that each transnational coordination task can add to their work in the context of the social relations they are embedded in: In the case of standard-setting, these are their practices that are deeply embedded in national administrative structures and industry structures. With regard to cross-border supervision, these are the relations to their governments and the pressure that is exerted by them to avoid a bank failure at all costs. In this regard, the functionalist approach –as well as the constructivist approach– overestimate the extent to which national authorities' coordinative behaviour is determined by factors beyond their country, such as transnational interdependencies and professional communities. This thesis shows that national regulators remain mostly embedded in their home countries: After all, the resources and authority that is granted to them are usually dependent on the maintenance of the social relations they are embedded in domestically.

Overall, this thesis advances that we need to understand *how* the coordination process functions (i.e. which pattern of coordination emerges as a result of a particular task) in order to understand *why* national authorities are willing to engage with transnational processes: Their assessment of which value a particular task can add to their own work is informed by the social relations they are embedded in, which are often found at the national level. The functionalist approach does not provide us with tools to observe *how* coordination functions or why regulators that perceive themselves as interdependent do not engage extensively in

transnational coordination processes. In this regard, it struggles to account for the variation of coordination patterns that were identified in this thesis.

'Shadow of Hierarchy' induced Coordinative Behaviour?

Chapter 1 points out that whilst EU regulatory bodies lack authority and resources, they operate within the legal system of the EU, which has been argued to cast a 'shadow of hierarchy' that can potentially induce transnational coordination (Eberlein 2010b; Héritier and Lehmkuhl 2008, 2010; Scharpf, 1997). Indeed, the thesis shows that transnational coordination can be affected by the institutional framework of the EU: In maritime safety, relations between regulatory actors were shown to be strained by the Commission's zealous enforcement of EU maritime safety law (see Chapter 4). Whereas this 'shadow of hierarchy' was very explicitly perceived as such by national maritime safety authorities, it did not induce mutual exchange between national authorities. To the contrary, it inhibited mutual exchange in the forum of EMSA due to a fear of being found to have incompliant practices. Acceptance of EMSA inspections and engagement in coordination in its forum was shown to happen despite –not as a result– of the enforcement possibilities of the Commission because the British and German authorities perceived EMSA's work to add value to their activities by providing operational support and ensuring the overall effectiveness of the European port state control regime. In all other studied cases, concerns about Commission enforcement or the possibility for policy-makers to get involved in the detailed formulation of shared practices could not be detected.

In this regard, the thesis puts forward that the 'shadow of hierarchy' is not a primary determinant of the coordinative behaviour of national authorities in the EU: Rather, the institutional frameworks provided by tasks and the social relations regulators are embedded in shape and inform coordinative behaviour. This is not to say that the institutional system of the EU is not crucial. The maritime safety case study clearly demonstrates that the possibilities of hierarchical enforcement and policy-making on part of the European Commission can have an impact on the relations between the

regulatory actors that are involved in transnational coordination. However, the institutional frameworks provided by tasks need to be seen as more significant as a determinant of coordinative behaviour than the broader institutional framework set by the legal system of the EU: As put forward in Chapter 1, the carrying out of tasks is an *activity* during which preferences are formed and re-assessed on a continuous basis (Cohen, March and Olsen, 1972, p.2). In that regard, then, coordinative behaviour needs to be seen to be determined by processes in which the officials are *actively* engaged in, rather than institutional frameworks which remain a distant and abstract concept to officials involved in transnational coordination processes: In maritime safety, the 'shadow of hierarchy' was explicitly perceived by the involved national regulators because it had a very concrete impact on them on a regular basis: The European Commission enforces vigorously in this field as a result of the social relations that regulatory actors operate in when maritime safety is concerned. With regard to the European Commission this means that it can justify its *raison d'être* in relation to the IMO by enforcing rigorously. In other cases, however, action on part of the European Commission does not directly affect national authorities on a frequent basis. As a result, the 'shadow of hierarchy' remains abstract for national authorities and does not primarily drive their coordinative behaviour.

Overall, strategic –or interest-driven– behaviour on the other hand was indeed shown to be crucial throughout the thesis: National regulators engage in coordination if they perceive this to add value to their work and they respond strategically to the incentives emanating from the institutional frameworks provided by tasks of EU regulatory bodies. Rationalist accounts of bureaucratic behaviour (for example, Niskanen, 1994 [1971]), however, tend to regard interests as exogenously given, and do not consider how rational pursuits are constrained by institutional frameworks, such as tasks and social relations. They largely regard governmental authorities as motivated by preferences for more resources. Indeed, these aspects feature in the observations of this thesis: For example, British and German maritime authorities explicitly consider which EMSA activities can provide cost-

savings to them and approve of those that do (COWI, 2008). Pharmaceutical regulators agree that they have a very concrete (and material) reason to engage with EMA's work: National authorities receive money from the European agency if they take over the rapporteurship of pharmaceutical company's market authorisation applications for a new drug.[338] Food control officials were observed to at times consider the advice of the FVO as 'free' expertise that they might otherwise have to pay for. In a wider sense, the engagement of British and German authorities with one-off decision-making and standard-setting tasks at the transnational level provide them with an opportunity to avoid the material costs of having to modify their practices in favour of new formal or informal standards.

At the same time, this thesis shows that the 'cost-benefit' analyses of engaging with transnational coordination activities on part of national authorities are far more complex than pertaining to material considerations and cannot be detached from the social relations they are embedded in. Interests, then, are here not conceptualised as exogenously given: Whilst coordinative behaviour is seen as strategically driven, the thesis puts forward that we need to understand what the regulatory actors perceive to be their 'interests' (Wildavsky, 1987, 1992, 1994). This, in turn, is a complex mix of material and immaterial benefits they can derive from transnational coordination, depending on the tasks they are carrying out at the transnational level and the social relations they are embedded in. Arguably, the potential costs and benefits –in the widest sense– include such a plethora of aspects that we can only understand them by in-depth study of the particular social relations a given regulator is embedded in: What might be perceived as costly –be it in material, reputational or other ways– by one authority, might not be perceived as such by an authority that is embedded in different social relations.

The comparison between coordination in maritime safety and in food controls presented in this thesis is enlightening in this regard (see Chapter 3 and 5 respectively): Although the EU regulatory body has an inspection task

[338] Art.62(3), Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

in both cases –and coordination is thus largely based on a hierarchical pattern– the involved regulatory authorities assess the work of these EU regulatory bodies very differently in light of the specific social relations they are embedded in. In maritime safety, the context of a highly global regulatory regime renders the work of an EU body in this field questionable to British and German authorities, which contest the role of the EU in the field. Nevertheless, they assess EMSA –and their engagement with it- positively because they can derive distinct material savings from its work and because it provides them with reassurance that their colleagues in other countries are also doing their jobs accurately under conditions of interdependence. In the case of food safety control authorities, on the other hand, authorities in the UK and in Germany do not contest the work of the FVO. Rather, in the framework of the social relations of a heterogeneous, decentralised industry and administrative control system, they perceive the work of the FVO as helpful in gaining better control over this industry and the local authorities that they oversee. Hence, in order to understand what strategic coordinative behaviour indeed means, we need to comprehend what the involved authorities perceive to be their core work, and to what extent they regard transnational coordination to add or to distract from it. 'Adding value' to their core work is inextricability linked to the safeguarding of their autonomy, for example, by helping them to carry out their work in a better way (such as in food controls) or by maintaining their reputation (as found in food risk assessment) (Wilson, 2000 [1989], p. 179ff). Coordination is hence not inextricably linked to the loss of autonomy –as a result of which coordination between governmental authorities is usually is seen to be difficult (*ibid.,* p. 192ff)– but can also be a means to enhance it.

7.2 Contributing to Wider Debates about Coordination in Government

The thesis demonstrates that capacities to manage 'European' risks without a 'European' state are created not *despite* but *because* national authorities

are embedded in their domestic social relations. This helps us to specify the conditions in which transnational administration can function. It also has wide-ranging consequences for the study of transnational coordination at the international level, in which formal hierarchical structures are absent (see Section 7.2.1). The thesis also has implications for the study of coordination in public administrations within the national realm. Indeed, perceived interdependence and formal authority might be less important for engaging particular organisational units in coordination efforts than their perception of whether coordination adds value to their day-to-day work (see Section 7.2.2).

7.2.1 Capacity Building at a Transnational Level

The thesis demonstrates that national authorities are willing to engage proactively in transnational coordination if they perceive this to add value to their work in the context of the social relations they are embedded in. The implication of this finding is that the building of capacity to manage cross-border risks does not necessarily require allocation of formal authority and resources to the supranational level. This perhaps does not seem surprising since we know from the literature on coordination and control in public administration that 'hierarchy' is by no means the only available form of exerting control in a bureaucratic system (for example, Hood, 2000; Ouchi, 1979). However, in relation to an emerging 'European' bureaucracy this is especially significant since the findings of this study show that the creation of 'European' capacity to manage 'European' risks is not incongruent with interests that emerge from the domestic social relations that national authorities are embedded in. Rather, national authorities are often willing to engage –thus creating capacity– not *despite* but *because* of their national settings. In this regard, this thesis helps us to specify the conditions for the functioning of a transnational administration, which sets standards, monitors practices and modifies behaviour as one administrative apparatus at the transnational level (compare to Hood *et al.*, 2001), instead of administering the regulation of a given industry separately in each Member

State (Hood, 1976, p.17): Transnational administration functions if the involved national authorities can make use of their activities at the transnational level to enhance their work at home. The observations made in this thesis give us reason to believe that this is usually the case when national authorities perceive the work of EU regulatory bodies to provide them with expertise they lack, if they value the reassurance that other regulators are carrying out their work adequately, or if the engagement with coordination provides them with a chance to maintain their current practices or their reputation.

In the EU governance literature, 'networks' of national authorities are often described as a means of the Commission to use national administrative capacities (Wilks, 2005; also see Eberlein, 2008). Whilst this view is supported by the empirical evidence presented here, our findings add another dimension to this issue: The implications of the argument of this thesis is that national administrations might indeed *also* be able to use transnational processes to enhance their own capacity to carry out their work effectively. Transnational coordination helps British and German authorities, for example, to maintain public confidence in their work. In drug safety, German authorities gain access to additional expertise that they could not create within their domestic social relations. Food control authorities use the FVO audit process to increase control over their own territory. In this regard, one might argue that these processes are concerned with mutual capacity building of bureaucratic actors (also see Bach and Ruffing, 2013), rather than the 'Europeanisation' of national bureaucracies (see Knill, 2001). It might hence not be the relevant question to ask whether the creation of EU regulatory bodies strengthens the European Commission (Keleman, 2002) or the Member States (Kreher, 1997). Rather, it arguably needs to be seen to result in an overall strengthening of bureaucracies, and particularly highly specialised authorities. The concern of governments – such as demonstrated in the Dutch subsidiarity review (Ministerie van Buitenlandse Zaken, 2013) – might thus be adequate from the point of view of political actors to the extent that they are concerned about the 'uncontrolled' autonomy of regulatory authorities. However, it remains

questionable whether this concern should indeed be focused on the creation of EU agencies as strengthening of the 'EU bureaucracy', rather than also being concerned with the strengthening of national authorities. The flip-side of this insight –which is likely to please national governments– is that transnational administration can function without transferring more resources or powers to the EU-level if national authorities can make use of transnational processes for their 'national' work.

This is linked to the perennial question of the 'effectiveness' of transnational coordination processes in bringing about 'coordinated' practices. In this regard, the EU governance literature has largely focused on the formal institutional and organisational set-up of EU regulatory bodies and their networks of regulators (for example, Eberlein and Grande, 2005). Weaknesses in the formal set-up –such as the lack of authority and resources of the involved EU bodies– are often seen as impediment to 'effective' coordination (Coen and Thatcher, 2008, p.67f). The findings of this study suggest, however, that the effective engagement of national authorities with transnational coordination activities are not dependent on the formal authority of the EU body in which they meet, but on whether they perceive the task they carry out at the transnational level to add value to their regulatory work at home.

This is exemplified in the case of banking regulation and supervision (see Chapter 6): The way coordination functions –and why national authorities choose to engage or not to engage with transnational processes– remained very similar under CEBS and the EBA, although the latter has significantly more resources and authority than the former used to have. The findings of this study raise the question whether effectiveness is also –if not primarily– a question of whether national authorities perceive the tasks of EU bodies to add value to their own work. This implies that crucial changes to coordination patterns and the level of engagement of national authorities –and hence potentially effectiveness– can be expected if the *task* of and EU body and/or the *social relations* that a national authority is embedded change, rather than if the formal authority of an EU body is altered. Additional comparative research on cases where such a change took

place is needed in order to substantiate this insight further. Overall, however, the different interpretation of this aspect on part of the EU governance literature and this thesis is also likely to lie in a different interpretation of 'effective' coordination. The cited literature usually emphasises that effectiveness is to be equated with fully coordinated (i.e. 'harmonised') practices. This thesis, however, sees coordination as a dynamic feedback loop in which practices are never 'coordinated' as such; rather, they can only ever be in the process of being coordinated (see Section 1.3.2).

The insight that formal authority is not necessarily crucial in determining coordination behaviour renders transnational coordination at the international level into a particularly tough –and hence valuable– field for further investigation of the argument developed in this thesis: The lack of formal authority on part of international bodies is usually seen as a major hindrance in their ability to convince national authorities to support their work. If the formal authority of international regulatory bodies is indeed less crucial for observing proactive engagement on part of national authorities than whether these authorities perceive the task that is carried out transnationally to add value to their own work at home, we might be able to explain some of the variation in the level of engagement of national regulators in international coordination processes. A valuable starting point in this regard could be the comparative study of international coordination processes in the banking, securities and insurance sectors, which take place in the Basel Committee, the International Organization of Securities Commissions (IOSCO), and the International Association of Insurance Supervisors (IAIS): Proactive engagement of national authorities has been strongest in banking, less developed in the field of securities and until recently underdeveloped in the insurance sectors. Whilst differing functional pressures for international coordination are frequently cited as main determinant of coordinative behaviour in this regard (for example, Davies and Green, 2008), an investigation about the extent to which the observed differences can be explained by tasks and social relations could

further elucidate transnational coordination in these cases, as well as the argument that was developed in this thesis.

Further depth to this analysis could be added by the comparison of transnational coordination at the international and at the EU level in each of these financial sectors: National authorities have been more proactively engaged in EU-level efforts in the securities and insurance sector than they have been at the international level. This provides an opportunity to evaluate the respective role of functional pressures and formal authority of coordinating bodies on the one hand, and regulatory tasks and how they are assessed by the involved regulators in light of the social relations they are embedded in on the other.

7.2.2 Coordination Processes in Public Administration

Whilst this thesis has focused on the specific context of coordination at a transnational level, coordination processes are of course far from unique to this arena. Indeed, coordination between different constituent units might be deemed to be at the core of the functioning of public administration: Within 'national' bureaucracies, different offices, ministries or administrative sub-units can have responsibility for the same –or over-lapping– issues, thus requiring them to coordinate (Hood, 1976, p. 17f; Wilson, 2000 [1989]). This is especially so in relation to the highly specialised bureaucracies we observe today. Equally, coordination between authorities that oversee policy implementation and 'street-level' bureaucrats is likely to remain a perennial issue in public administration. The findings of this study arguably expand upon the inhibiting and enabling factors of coordination between organisations or organisational units in the broadest sense.

A key insight of organisation studies with regard to coordination has been the importance of the recognition of mutual interdependence on part of the involved organisational units (for an overview in this regard, see, Alexander, 1995, p. 31ff). Rather than focusing on the importance of (perceived) interdependence, this thesis focuses on the strategic aim of

organisational units to enhance their own work through their coordinating activities as informed by the social relations they are embedded in. This provides an angle that can potentially help us to enhance our understanding of why administrative units across all levels of government do or do not engage proactively in coordination in cases where coordination has been mandated. The empirical research conducted for this thesis on German and British regulatory regimes provide examples in this regard: For instance, the overseeing food control authorities in Germany seem to engage proactively in coordinating their activities in a cross-*Länder* working group since FVO audits started to focus on audit systems of countries, rather than inspecting individual businesses. They perceive their coordination with colleagues from other German regions to aid them in receiving good evaluations from the FVO, as well helping them to control the food control systems in their respective *Länder* more effectively.

Arguably, the approach developed in this thesis could hence provide us with fresh insights into why, for example, governmental units seem to engage proactively in particular coordination efforts –such as 'joined-up governance' or 'whole-of-government' initiatives, as well as coordination between interdependent implementation agencies- whilst not doing so in others. In contrast to the study of transnational coordination between regulators which are very similar in relation to their expertise and responsibilities, the study of coordination between governmental units which exhibit crucial differences –for example, ministerial units from different policy areas with fundamentally differing forms of expertise and professional norms- would allow us to specify the scope conditions of the argument developed in this thesis. If the argument holds under conditions of involved administrative units that exhibit crucial differences, we would expect them to engage proactively in coordination if they perceive the particular coordination activity they are involved in to add value to their main line of work –as perceived through the particular context of social relations they operate in on a daily basis– even in the absence of hierarchical pressure and perceptions of interdependence.

Overall, this would imply that the structuring of coordination activities needs to start with the core questions of what the involved organisational units see as their main task and in which setting of social relations they carry it out. In other words, in order to understand why coordination functions –and to structure coordination in a manner in which it is workable– we need to consider what the involved organisational units value; rather than merely focusing on the objectives of the given coordination process. In this regard, the thesis helps us to elucidate the conditions for intra-organisational administration: When coordination is an auxiliary task existing to the 'core business' of an organisation, the engagement with coordination processes depends on the involved organisations ability to use coordination to support them in their core business. In principle, this should be possible even in situations where organisations are not interdependent (or do not perceive themselves as such) or where they are potential rivals in a given field.

Arguably, 'adding value' to their core business is what Wilson means when he refers to the drive of bureaucratic actors to maintain their 'autonomy' (Wilson, 2000 [1989], p. 179ff): When organisations are able to use coordination in order to maintain or to enhance their autonomy, inter-organisational administration has a chance to function. What is surprising is that this should even be possible when rival governmental authorities are concerned: The support of EU regulatory bodies on part of national authorities is a case in point. This is the case when an authority perceives other potential threats –such as political interference or loss of public support- to its autonomy to be greater than its 'rival' agency. As pointed out by Wilson, coordination with other governmental authorities is often associated with precisely this kind of loss of public support or with political interference (*ibid.*, p. 190f). This thesis adds to this 'Wilsonian' insight that coordination can indeed be a means to *safeguard bureaucratic autonomy* vis-à-vis the 'non-bureaucratic' world, rather than only being associated with its loss.

Appendix

List of Interviewees (anonymised)

Interviewee D1, former pharmacovigilance official of the MHRA (then MCA) and representative to EMA (then EMEA), scientific expert in pharmacovigilance. Interview conducted on 15 December, 2011.

Interviewee D2, pharmacovigilance official of the PEI and representative to EMA, scientific expert in pharmacovigilance. Interview conducted on 20 December, 2011.

Interviewee D3, pharmacovigilance official of BfArM and representative to EMA, scientific expert in pharmacovigilance. Conjoint e-mail interview with interviewee D4, responses received on 27 January, 2012.

Interviewee D4, pharmacovigilance official of BfArM, scientific expert in pharmacovigilance. Conjoint e-mail interview with interviewee D3, responses received on 27 January, 2012.

Interviewee D5, pharmacovigilance official of EMA, former official at the European Commission (DG Sanco) and the MHRA. Interview conducted on 3 February, 2012.

Interviewee M1, official of the *Dienststelle Schiffssicherheit* (Ship Safety Division). Interviews conducted on 26 September, 2012, and 19 December, 2012.

Interviewee M2, former official of EMSA, official of the Maritime Directorate of Luxembourg. Interview conducted on 31 October, 2012.

Interviewee M3, official of EMSA, former national representative to the IMO and official of the MCA. Interview conducted on 28 November, 2012.

Interviewee M4, former official of EMSA and the European Commission (then DG TREN), expert in maritime law. Interview conducted on 29 November, 2012.

Interviewee M5, official at the UK Department of Transport and representative to EMSA. Interview conducted on 30 November, 2012.

Interviewee M6, official of the European Commission (DG MOVE) and representative to EMSA. Interview conducted on 7 December, 2012.

Interviewee M7, former official of EMSA (Administrative Board), former official at the UK Department of Transport. Interview conducted on 12 December, 2012.

Interviewee M8, official of the *Dienststelle Schiffssicherheit* (Ship Safety Division). Interview conducted on 19 December, 2012.

Interviewee M9, port state control inspector of *Dienststelle Schiffssicherheit* (Ship Safety Division). Interview conducted on 19 December, 2012. The author also accompanied the inspector on a six hour port state control inspection in the port of Bremen on 19 December, 2012.

Interviewee M10, official of the MCA. Interview conducted on 10 January, 2001.

Interviewee F1, official of EFSA (Advisory Forum), food safety expert. Interview conducted on 17 January, 2014.

Interviewee F2, official of EFSA, food safety expert. Interview conducted on 22 January, 2014.

Interviewee F3, official of the BfR and representative to EFSA, food safety expert. Interview conducted on 3 February, 2014.

Interviewee F4, official of the FSA and representative to EFSA. Interview conducted on 4 February, 2014.

Interviewee F5, former official of the FVO, official of the European Commission (DC SANCO). Interview conducted on 5 March, 2014.

Interviewee F6, official of the FVO. Interview conducted on 6 March, 2014.

Interviewee F7, official of the European Commission and representative to EFSA (DG Sanco). Interview conducted on 10 March, 2014.

Interviewee F8, official of Thuringia Ministry for Social Affairs, Family and Health (food controls). Interview conducted on 13 March, 2014.

Interviewee F9, official of the European Commission (DG Sanco). Interview conducted on 13 March, 2014.

Interviewee F10, official of the FVO, former official in food controls in Bayern and Hesse. Interview conducted on 13 March, 2014.

Interviewee F11, official of the Hessian Ministry for the Environment, Climate Protection, Agriculture and Consumer Protection (food controls). Interview conducted on 17 March, 2014.

Interviewee F12, official of the BMELV (Federal Ministry of Consumer Protection, Food and Agriculture). Interview conducted on 17 March, 2014.

Interviewee F13, official at the FSA (food controls). Interview conducted on 19 March, 2014.

Interviewee F14, official of the BVL (Federal Office for Consumer Protection and Food), food controls. Interview conducted on 4 April, 2014.

Interviewee F15, official of the Ministry for Climate Protection, Environment, Agriculture, Nature and Consumer Protection of North-Rhine-Westphalia. Interview conducted on 9 April, 2014.

Interviewee B1, industry representative (government and regulatory affairs unit at a major bank). Interview conducted on 11 April, 2013.

Interviewee B2, official of BaFin (International Policy Division). Conjoint interview with interviewee B3 conducted on 2 May, 2013.

Interviewee B3, official of BaFin (International Policy Division). Conjoint interview with interviewee B2 conducted on 2 May, 2013.

Interviewee B4, official of the European Commission (DG MARKT), former observer at CEBS. Interview conducted on 2 May, 2013.

Interviewee B5, former official of BaFin and the CEBS secretariat. Interview conducted on 2 May, 2013.

Interviewee B6, former official of CEBS, the FSA and the European Commission (DG ECFIN). Interview conducted on 3 May, 2013.

Interviewee B7, former official of CEBS and the EBA, official of the Dutch Central Bank. Interview conducted on 10 May, 2013.

Interviewee B8, former official of the *Deutsche Bundesbank* (German Central Bank) and representative to CEBS. Interview conducted on 28 May, 2013.

Interviewee B9, former official of CEBS and the Dutch Central Bank. Interview conducted on 31 May, 2013.

Interviewee B10, official of the EBA, former official at the Bank of Italy. Interview conducted on 27 June, 2013.

Interviewee B11, former official of the FSA, BaFin and CEBS, former industry representative. Interview conducted 11 July, 2013.

Interviewee B12, official of the EBA, former official of the French Financial Markets Authority. Interview conducted on 17 July, 2013.

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