EU policy enforcement through EU agencies and networks of national authorities

Case studies of aviation safety and medical products regulation

Laurens van Kreij

Provided by thesis specialist Ridderprint, ridderprint.nl
Printing: Ridderprint
Layout and design: Jildou Hengst, persoonlijkproefschrift.nl

EU policy enforcement through EU agencies and networks of national authorities

Case studies of aviation safety and medical products regulation

EU-beleidshandhaving door EU-agentschappen en netwerken van nationale autoriteiten. Case studies van luchtvaartveiligheid en de regulering van medische producten

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de
Universiteit Utrecht
op gezag van de
rector magnificus, prof. dr. H.R.B.M. Kummeling,
ingevolge het besluit van het college voor promoties
in het openbaar te verdedigen op

vrijdag 26 januari 2024 des middags te 12.15 uur

door

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geboren op 10 maart 1994
te Oss

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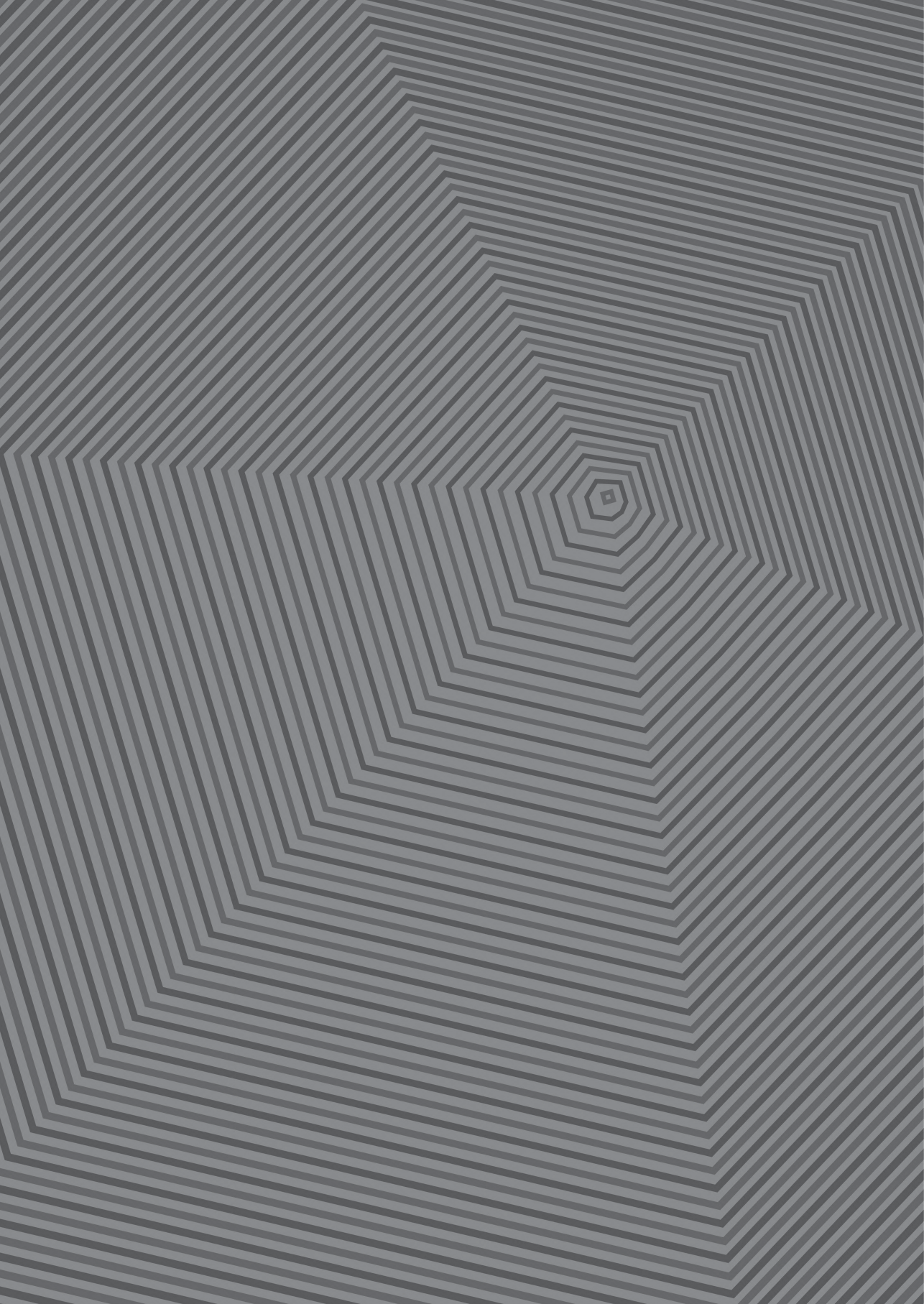

Chapter 1

Introduction

1.1. Institutions for EU policy enforcement

In his 2014 book, the British legal scholar David Howarth set out to reconceptualize the work that lawyers do. The title of his book leaves little room for doubt: in 'Law as engineering', Howarth argues that it is accurate as well as constructive to liken the work of lawyers to the work of engineers. Like engineers, lawyers identify problems, specify objectives, generate solutions, and pick the right solution to resolve those problems. And above all, both lawyers and engineers work on systems used by people – from which stems a responsibility to design the best systems possible.

Now try to imagine being an engineer yourself, and assume responsibility for the systems that make people and organizations follow rules. For a moment, you are engineering the institutions that enforce rules upon citizens and corporations. As with many other institutions, enforcement institutions originate in a particular design, and for a moment, you are in charge thereof. How would you go about? Two perspectives can guide you (Harlow & Rawlings, 2009). First, enforcement has to be effective. Enforcement is literally about *giving force to* a particular norm, and many will argue that institutions have to be effective at doing so. Enforcement is then seen as instrumental to the effectuation of rules, and institutions can be measurably better or worse at doing so (Accetto & Zleptnig, 2005). According to the second perspective, however, the state-mandated *use of force* cannot just be effective – enforcement should also remain well embedded in the complex set of norms that circumscribe it. Enforcement, after all, is conducted by and within democratically legitimated institutions that seek to strike a balance between public interests and those of individuals. As an engineer, you would ensure that enforcement abides by the standards that constitute public power and constrain its exercise. Enforcement, in other words, has to be legitimate.

It must be daunting, even for the best engineers, to construct well balanced enforcement institutions – and not least because the above two perspectives may be fundamentally different ways of understanding rules and their enforcement. Luckily, however, engineers almost never make all-encompassing trade-offs on their own, and neither do lawyers. Enforcement institutions are not designed all at once, but shaped step by step, like many engineers working over time to devise large and complex technical systems. Institutions, including those for policy enforcement, consist of multiple layers being added, modified and removed over a longer period of time, by a great number of people representing a great variety of interests.

This dissertation is about understanding the design of two new types of enforcement institutions – institutions established by the European Union (EU) and increasingly involved in enforcing its regulatory policies. One type are EU agencies; the other type are EU networks of member states' national authorities. More and more often these institutions are relied upon

to help ensure compliance with EU policies. This dissertation seeks to better understand how the EU's engineers went about in creating them.

The nature and role of regulatory policy

Before zooming in on enforcement by EU agencies and networks of national authorities, it helps to discuss the type of policies they enforce and role of such policies in contemporary societies. In many parts of the world, rules play a considerable role in everyday economic life: individuals, and corporations in particular, are required to follow a host of legal norms and interact with a range of government agencies interested in them doing so. These rules and regulatory agencies are emblematic of a specific type of government policy: when governments rely on behavioral rules and (semi-)independent government agencies to administer them, governments engage in the making of *regulatory* policies (Jordana & Levi-Faur, 2004, 2005). The prevalence of rules and agencies indicates just how important regulatory policy has become: regulation is one of the most important tools in the contemporary government toolbox as well as a main feature of contemporary global markets.

In Europe, however, regulation has not always been as important as it currently is. For several decades after the Second World War, states primarily relied on income redistribution and macroeconomic management by government ministries. The state became an all-encompassing 'planner, direct producer of goods and services, and employer of last resort' mostly through instruments such as public expenditure and company ownership, and not so much by means of rules (Majone, 1997b, p. 141). Regulatory policies became more relevant when the welfare state was in decline. The 1970s were marked by high unemployment and inflation, and the state and its enterprises were considered to fail in reaching their objectives. As business privatization was central to the transition that followed, public ownership could no longer be the main instrument for controlling businesses affecting the public interest (Majone, 1996b; Majone, 1997b). The supply of goods and services would be left to private corporations, and through regulation, the state would limit itself to guiding the economy instead (Levi-Faur, 2005; Jordana & Levi-Faur, 2004, referring to Braithwaite, 2000).

The rise of regulation as a main tool for economic intervention thereby marks the transition from the welfare state to 'the regulatory state' (Majone, 1994): to control the economy, governments devised rules as well as (semi) independent agencies to administer them. And as regulation became more relevant, academics also came to better understand its various dimensions. Regulation is indeed commonly understood to involve authoritative state rules (Jordana & Levi-Faur, 2004), but instruments of a different nature can perform regulatory functions as well. Broader definitions of regulation thus include instruments such as private contracts, the disclosure of information, economic incentives, and even mixes of these instruments (e.g. Van Erp et al., 2019). Academics have also researched regulatory agencies, and investigated the

causes and implications of their proliferation as well as their varying designs (e.g. Busuioc et al., 2011; Verhoest et al., 2012). Regulation, however, is by no means the domain of states alone. Many non-state actors can engage in regulation, including private actors such as corporations, but also non-governmental, international and supranational organizations (Van Erp, 2020).

Existing institutions for EU policy enforcement

The EU is one such regulatory actor and will be the focal point of this dissertation. The EU has even been referred to as a regulatory state in itself, given its limited budgetary capacity and its extensive reliance on regulation (e.g. Majone, 1996a). Indeed, the influence of EU rules is felt across a growing number of policy areas (De Moor-Van Vugt & Widdershoven, 2015), and perhaps most tangible are substantive EU norms that detail how organizations ought to behave. Think of the General Data Protection Regulation (GDPR), the EU instrument that prescribes how organizations – from multinationals to local sports clubs – ought to handle personal information. Or consider the EU rules on energy labels, to be applied by vendors on certain products so that consumers know about their energy efficiency. The number and detail of such EU behavioral norms seems to have grown over the past couple of decades, and they are not seldomly met with skepticism for disrupting existing regulation at the national level. Academics speak of the Europeanization of national rules and policies – and in case of the GDPR, even of 'EU law brutality' (Papakonstantinou & De Hert, 2022).

The EU, however, has also become more and more invested in *ensuring compliance with* those behavioral rules. In order to do so, the EU initially relied on its member states to make individuals and their organizations abide by EU norms, and these member states were relatively free to decide how they went about (Adriaanse et al., 2008; De Moor-Van Vugt & Widdershoven, 2015). Since the 1980s, however, the tide has turned: following mounting concerns about actual compliance with substantive norms, institutions at the national and EU levels started to ensure that behavioral rules be put into practice. EU legislators as well as the Court of Justice of the European Union (ECJ) formulated norms for how member states ought to enforce EU policies (De Moor-Van Vugt & Widdershoven, 2015), and the (European) Commission stepped up its game to make sure that also member states implement EU (enforcement) standards themselves (Börzel, 2003).

New institutions for EU policy enforcement

The new mandates of these existing institutions already significantly changed the way EU norms are realized. It meant, after all, that member states became less autonomous in organizing the use of coercion vis-à-vis 'their' citizens and businesses. However, another development in the context of EU policy enforcement has implications that are at least as profound. Not only did the EU tighten the mandates of existing EU and national institutions to improve compliance with EU norms; the EU is also engaging in building enforcement institutions that are distinctly

new. It involves, as it were, the construction of new layers of institutions. As mentioned, the institutions central to this dissertation are EU agencies, and EU networks of national authorities (Scholten, 2017). EU agencies, first, exist already since the 1970s, but have proliferated in the course of the last thirty years (Egeberg & Trondal, 2017). EU legislators establish them for a circumscribed set of tasks in a specific policy domain, and in doing so, EU agencies tend to operate (semi-)independently from other organizations. Importantly, these institutions are increasingly empowered to ensure that individuals and organizations comply with EU rules (Scholten & Luchtman, 2017). The second type of institution increasingly involved in EU policy enforcement are networks of national authorities. These networks are primarily composed of member states' national enforcement authorities, who coordinate their actions – like sharing case-specific information, or taking enforcement action vis-à-vis individuals or organizations within their respective jurisdictions. Formal EU networks of national authorities are a relatively new phenomenon, but many are involved in EU policy enforcement (Scholten, 2017).

The involvement of EU agencies and networks changes the fabric of policy enforcement – in the EU as well as in the member states. These new institutions, after all, manifest themselves among several others whose involvement in enforcement is well established. This dissertation addresses these changes and aims to unravel why EU legislators establish EU agencies and networks of national authorities for EU policy enforcement. What motivates EU legislators to create these institutions and endow them with enforcement tasks? Such changes deserve close attention because they may have far-reaching implications for the position of citizens and companies as well as for the authority of states and the EU.

Implications of new institutions for EU policy enforcement

At least three implications make enforcement through EU agencies and networks worthwhile studying. First, direct enforcement through EU institutions has implications for our understanding of the EU, and in particular for our understanding of the EU as an international organization (Scholten, 2022). Some key EU legal doctrines, of course, already did their part: the ECJ's rulings that EU law is an autonomous, directly effective, and supreme legal order prompted many to disqualify EU law as international law and see the EU as a federal system or something *sui generis* instead (see e.g. Weiler, 1991; Von Bogdandy, 2012). EU agencies and networks being involved in the direct enforcement of EU law, however, may further complicate conceptualizations of the EU as an international organization. One characteristic of international law, after all, is that it commonly lacks a comprehensive set of centralized executive enforcement mechanisms – mechanisms that traditionally only existed in national systems (Röben, 2010). The United Nations' Security Council was exceptional in this respect, but generally, enforcement of international law was limited to enforcement vis-à-vis contracting states (Philpott, 2020). As discussed, this also used to be the status quo in the EU: with the exception of competition law, member states organized enforcement vis-à-vis nationals, and the EU would enforce vis-

à-vis its member states. The establishment of EU enforcement agencies and networks changes this status quo and may thereby also affect our understanding of the EU. These institutions constitute the EU's own executive enforcement mechanisms, which render its characterization as an international organization more problematic and that of a federal system more fitting.

Direct enforcement by EU institutions also challenges conventional perceptions of sovereignty and statehood. Until the Second World War, sovereignty was broadly considered as absolute, which meant that the sovereign had supreme authority over all matters, including domains such as the economy, monetary policy, and defense (Philpott, 2020). European integration already challenged this absolute character as member states could be sovereign in some domains (defense) without being sovereign in others (competition law) (De Witte, 1995). One could argue that the establishment of EU enforcement agencies and networks reaffirms the relative nature of sovereignty: in addition to the transfer of competencies in areas such as financial and competition policy, the EU is becoming increasingly sovereign for the enforcement of such policies. Yet direct enforcement by EU agencies and networks may also more profoundly affect our understanding of sovereignty, as it touches upon the very concept of authority itself. For long, the EU's authority used to specifically connote *normative* authority: as discussed above, the EU mostly engaged in making substantive, behavioral norms. Through procedural rules for how member states ought to enforce norms, and more so through the establishment of EU institutions with direct involvement in enforcing policies, the EU seems to assume a more comprehensive form of authority – one that comprises *factual* power in addition to *normative* power; one that comprises the power to command as well as the power to coerce obedience.

Enforcement through EU agencies and networks, lastly, also raises issues of legitimation. Authority, after all, implies something more than the power to make rules and to coerce compliance; it also assumes 'some mutually acknowledged source of legitimacy' (Philpott, 2020). Law is one source of legitimacy in many modern societies, whereby some body of (constitutional) law constitutes and constrains the power to make norms and coerce compliance. Yet political sources of legitimacy are at least equally relevant, and the literature distinguishes three: input legitimacy, throughput legitimacy, and output legitimacy (Scharpf, 1999; Schmidt, 2013). These sources of legitimacy connote participation in decision-making, deliberation during decision-making, and the performance of decision-making outcomes. It is often argued that the EU has a rather technocratic decision-making mode and thus legitimates its decisions primarily in terms of their problem-solving performance (e.g. Scharpf, 1999). One can argue, however, that EU decision-making resulting in EU enforcement agencies and networks should do better for these institutions to qualify as legitimate. It concerns, after all, the EU's ability to engage in coercion – which requires a solid embedding, not just in law, but also in the societies against whom such coercion could be used. As mechanisms for legitimizing public power tend

to be more established in states, an inquiry into the reasons for *centralizing* such public power in the EU becomes more pressing.

By better understanding the role EU of agencies and networks of national authorities in the enforcement of EU policies, this dissertation allows us to improve our knowledge of the EU system as a whole, to better appreciate EU authority and sovereignty more generally, and to review the legitimation of more centralized policy enforcement. Identifying EU legislators' reasons for involving EU agencies and networks in policy enforcement, however, is a prerequisite for assessing its implications. The decision-making processes leading to those novel EU enforcement institutions are thus central to this dissertation. Why do EU legislators rely on EU agencies and networks for policy enforcement in the first place? The fact that these novel enforcement institutions are such a profound overhaul of the EU's enforcement architecture raises questions about the institutions that preceded them. Were they insufficient? How do novel enforcement institutions relate to them? Furthermore, a technocratic view of EU decision-making warrants a close look at the actors that influence the creation of EU enforcement agencies and networks, as well as the motivations that these actors have. What motivates EU legislators to opt for EU enforcement agencies? Did they indeed choose for EU agencies and networks in order to improve the problem-solving performance of EU policy enforcement? Or did they legitimate the creation of these institutions in a different way? These and similar questions are central in the chapters to come, which seek to map how policy-makers went about in establishing EU agencies and networks for EU policy enforcement.

This introductory chapter has four more sections. Section two hereafter discusses existing scholarship, and illustrates this dissertation' academic and societal relevance. The research question and central concepts are presented in sections three and four. Section five, in turn, discusses methodological considerations behind the comparative case study research design and the selection of cases for this dissertation. Section six, lastly, gives a short overview of the chapters to come.

1.2. Relevance of this dissertation

Academia has had a sustained interest in the enforcement of regulatory policies for more than 40 years (Faure et al., 2009, p. 161). Yet there is still potential for more contributions on the specific topic of enforcement by EU agencies and within networks of national authorities. This section discusses some focal points in the existing literature, how this dissertation has the potential to add to them, and what makes an answer to the abovementioned questions societally relevant.

Academic relevance

With its focus on EU agencies and networks of national authorities, this dissertation adds to the large body of literature on the more established (EU and national) institutions involved in enforcing policies. As member states have long been the main enforcers of EU policies, much of the existing scholarship concentrated on the EU's legislative and judicial prescriptions for enforcement by the member states and how the latter enforce EU policies vis-à-vis their citizens (e.g. Vervaele, 1999; Voermans, 2005; Versluis, 2003; Adriaanse et al., 2008), and on enforcement vis-à-vis member states regarding the implementation of EU rules (e.g. Börzel, 2001; Falkner et al., 2005; Thomann & Sager, 2017a, 2017b). In addition, ample attention has been paid to differences across systems of (national) law for EU policy enforcement (e.g. Faure, 2004; Faure & Weber, 2017; Hayden, 2022; Van den Bergh, 2013; Van den Bergh & Visscher, 2008; Drake & Smith, 2016). This does not mean, of course, that other EU institutions with enforcement functions have escaped scholarly attention. Many have studied the EU's transnational arrangements for the enforcement of (national) policies, (e.g. Marguery, 2018; Luchtman, 2020; Bloks & Van den Brink, 2021; Graat, 2022), the role of the Commission (e.g. Falkner, 2018; Batory, 2016; Andersen, 2012; Börzel, 2003; Tallberg, 1999) as well as the constitutional and institutional context of enforcement in the EU (e.g. Van den Brink et al., 2015). EU agencies, in turn, have been studied to a considerable extent (see below), but attracted considerably less scientific attention for their involvement in the enforcement of EU policies (see however Luchtman & Vervaele, 2014; Scholten & Scholten, 2017; Scholten & Luchtman, 2017; Scholten, 2017; Wissink, 2021; Karagianni, 2022; Joosen & Zhelyazkova, 2022). Likewise, attention for networks of national authorities is growing, but scholarly interest for their role in the enforcement of EU policies has been modest (Mastenbroek & Martinsen, 2018). This dissertation contributes to filling this gap.

The contribution of this dissertation also lies in its focus on policy areas that have received less attention. The literature on enforcement tends to focus on a distinct number of policy areas (see Treib, 2014), including notably the areas of environmental policy (e.g. Vos et al., 1993; Faure, 2004; Martens, 2006; Wennerås, 2007; Tosun, 2012); economic policy and competition, and consumer and financial services policies (e.g. Wechsler, 2016; Van den Bergh, 2013; Faure et al., 2009; Jones & Sufrin, 2014; Monti, 2007; Wilks, 2007; Hayden, 2022; Scholten & Ottow,

2014); (im)migration and border control (e.g. Fernández-Rojo, 2021; Nagy & Nicolosi, 2021), as well as anti-fraud policy (e.g. Pujas, 2003; Quirke, 2010; Vervaele, 2013; Vervaele & Luchtman, 2015; Simonato et al., 2018). Other policy areas tend to receive less academic interest for the way policies are being enforced. Enforcement of EU transport policies and EU medical products policies, for example, has not received a great deal of attention (see however Permanand et al., 2006; Schout, 2008; Groenleer et al., 2010; Permanand & Vos, 2010; Jarman et al., 2021; Schmitt et al., 2017; Chamon & Wirtz, 2017). This dissertation focuses on these policy areas, both for methodological reasons (see below), and because it helps filling a gap in the existing body of scholarly literature.

This dissertation furthermore contributes to the growing body of explanatory (and mainly institutionalist) literature on the establishment of EU institutions, including EU networks and EU agencies. On the one hand, and as will be discussed extensively in the chapters to come, much about these institutions is already known; institutionalist debate on EU legislators' reasons to create EU agencies and networks goes back about 25 years (e.g. Majone, 1997a; Dehousse, 1997). Some institutionalists have even already raised the specific question why EU legislators differentiate between EU agencies and EU networks of national authorities (Kelemen & Tarrant, 2011; Tarrant & Kelemen, 2017; Blauberger & Rittberger, 2015, 2017). On the other hand, however, institutionalist scholarship limitedly distinguishes between enforcement and other functions performed by these organizations. When explaining delegation to EU agencies and networks of national authorities, institutionalist scholars do focus on organizations engaged in agenda-setting (e.g. Pollack, 2003) and implementation (e.g. Heidbreder, 2017), but few contributions focus on enforcement specifically. Also, potentially relevant differences *between* such functions tend to be disregarded.

Only a very limited number of studies have explicitly addressed the specific explanatory question why EU agencies, and EU networks of national authorities, perform functions for the enforcement of EU policies (or not). Schout (2008), first, studied the institutionalisation of the EASA and the elaboration of its inspection powers. Schout specifically argued that the EASA's establishment originated in the shortcomings of its predecessor, the problems with which 'were many' (p. 267). He found that the decision-making process resulted in an EU agency because of strong preferences within the Commission, the unfeasibility of other options, and the belief that 'Member States had to be put at a distance' because of earlier issues in the implementation and application of aviation policy (p. 269). Schout furthermore found that the need for the EASA's inspection powers was fed by sensitivities that frustrated previous inspection arrangements, and 'widely shared frustration with the EU's internal market for aviation' (p. 275). Scholten and Scholten (2017), second, addressed the increasing number of EU enforcement agencies through the perspective of the neo-functionalist European integration theory. As EU agencies gain enforcement powers in addition to rule-making powers,

Scholten and Scholten specifically asked whether this constituted a novel type of functional spillover, and whether 'the expansion of EU direct enforcement competences occurred due to functional necessity (pressures originating from previous integration bargains) or specific developments (exogenous pressures)' (p. 931). The authors indeed found that in the majority of cases they studied, 'functional needs are at the core of why enforcement competences of the EU have grown', and that no EU enforcement agency 'was found to trace its roots solely to exogenous pressures', which leads them 'to conclude that we are indeed witnessing a new type of functional spillover', i.e. policy-cycle functional spillover (p. 937). Maggetti (2019), lastly, conducted an exploratory study into the case of energy regulation. He focussed on the EU Agency for the Cooperation of Energy Regulators – that did not obtain the enforcement powers it would theoretically be likely to have. Maggetti argues that energy stakeholders mattered, and business interest representatives in particular. He shows that business interests were overrepresented in the network that preceded and overlaps with the EU agency in question, and that the representative of 'the most important stakeholders as regards business interests in the energy sector expressed a clear opposition to the attribution of enforcement powers' (pp. 465-466). He argues that the pre-eminent role of business interest groups in the area of energy potentially enabled them 'to concretise their preferences for the non-attribution of enforcement powers to the sector-specific EU agency' (p. 472).

All in all, this overview underscores the academic relevance of further investigating EU agencies and networks and their role in EU policy enforcement, particularly in policy areas that have received relatively little scholarly attention. At the same time, there is a rich literature that can be built upon for answering such questions: particularly a combined reading of the legal literature on EU policy enforcement and the institutionalist literature on EU agencies and networks more generally could deliver highly relevant insights. This dissertation relies on both strands of scholarship to answer calls for more explanatory work on the institutions enforcing EU policies specifically (Scholten, 2017; Mastenbroek & Martinsen, 2018).

Societal relevance

The societal relevance of this dissertation is twofold. First, this dissertation helps society get a better grasp of EU politics. The popular view on EU politics is that decision-making processes are untransparent, technocratic, and thus void of a solid democratic foundation. At the same time, many stress the democratic aspects of EU decision-making: following the EU's founding treaties, for example, only *elected* officials from the European Parliament and the Council of Ministers make EU policies and the institutions that enforce them. This dissertation may transcend the juxtaposition between these views and help the public get a more nuanced view on the EU decision-making process. By studying the creation of EU agencies and networks of national authorities, this dissertation shows how EU decisions come to be, and how they are the result of a complex interaction between technocratic, electoral, and many other types

of motivations. The chapters to come provide greater transparency about the EU legislative process and the many more or less democratic considerations that play a role.

This dissertation also aims to assist decision-makers in developing future EU policies and institutions for EU policy enforcement. Subsequent chapters unravel some of the conditions under which EU enforcement institutions were established and designed in the past, and why these institutions have been reformed in later stages. This dissertation uncovers problems that policy-makers have encountered in the past, and shows how they set out to deal with them. While I do not seek to evaluate the success of such policy reforms, information about the reasons for policy change can be of help to decision-makers creating or reforming enforcement institutions in similar policy areas. Knowing what drove the establishment and design of EU enforcement institutions in the past can be of benefit for the creation, (re)design and assessment of similar institutions in the future.

1.3. Research questions and aim

This dissertation thus gathers scientific knowledge about the creation of EU enforcement agencies and EU enforcement networks, to thereby improve our understanding of EU policies and politics more broadly. To achieve that aim, this dissertation revolves around the following central research question:

> *Why do EU legislators establish EU agencies and networks of national authorities for the enforcement of EU policies, and why do they differentiate between these types of institutions?*

This central research question is broken down into four sub-questions, which are addressed in the four chapters to come. Taken together, these chapters help to answer the central research question.

The first prerequisite step is to map and assess the relevance of the existing scientific knowledge. Chapter 2, therefore, is a theoretical chapter that reviews the extant political sciences and legal literature on the EU and EU policy enforcement, and on EU agencies and networks of national authorities. In addition to these novel institutions, chapter 2 also discusses the more traditional role of the member states in enforcing EU policies. Chapter 2 revolves around the question:

> *What insights from legal and political scholarship help to understand EU legislators' choice for enforcement by EU agencies, EU networks of national authorities, or the member states?*

Chapter 3 then builds upon this initial theoretical exploration and zooms in on networks of national authorities. Some of the theoretical perspectives discussed in chapter 2 are refined and expanded upon to study two cases of networks enforcing EU policies. EU legislators established these two networks, even though the establishment of EU agencies would have been very likely, as agencies had been created in policy areas very similar to the ones at hand. The sub-question underlying chapter 3 therefore asks:

> *Why do EU legislators establish new networks of national authorities for EU policy enforcement, even though EU agencies with enforcement tasks already exist in highly similar policy domains?*

Chapter 4 then shifts focus to the very similar policy domains in which EU legislators established EU agencies. Having examined the creation of networks, chapter 4 thus studies two cases of EU agencies with a role in enforcing EU policies. It specifically focuses on the contrasts between EU enforcement agencies on the one hand, and the pre-existing member state model for EU policy enforcement on the other. Again, chapter 4 refines and expands upon some of the theory discussed in chapter 2. Chapter 4 specifically seeks to answer the question:

> *Have existing institutional paradigms on governance and enforcement in the EU influenced the establishment and design of EU enforcement agencies, and if so, how?*

Chapter 5 then engages in a comparative analysis of all four cases that were studied earlier. It thus draws a comparison across the two cases of EU networks and the two cases of EU agencies. In order to do so, chapter 5 focuses on one specific aspect that may help to explain why EU legislators differentiate between these two types of institutions. Chapter 5 asks:

> *To what extent do differences among regulated industries have an effect on the choice between EU enforcement agencies and networks of national authorities?*

Chapter 6 is the last chapter of this dissertation. It discusses the answer to the central research question and concludes.

1.4. Key concepts

Some concepts used in the research question require additional clarification. First, I provide my conceptualization of enforcement of EU policies. Then, I set out what I mean by an EU agency, and what I mean by a network of national authorities.

EU policy enforcement

EU policy enforcement is a key concept that requires clarification. Its definitions in various bodies of literature, however, vary greatly. Enforcement is sometimes defined in terms of the instruments public authorities have at their disposal, whereby some reduce enforcement to sanctioning (Maggetti, 2019), whereas others also include various forms of supervision (e.g. Vervaele, 1999). Another part of the literature defines enforcement in terms of the function it serves, such as ensuring compliance (Röben, 2010; Versluis, 2003), while many others do not provide an (explicit) definition of the concept at all.

Given the diversity among definitions in the literature, and because of the variety in the cases selected for this dissertation (see below), I maintain a broad definition of EU policy enforcement. I see EU policy enforcement as public action aimed at preventing or responding to emergencies or violations of EU norms by private actors (Röben, 2010). This public action typically involves the use of legal powers for 'monitoring, investigating and sanctioning violations of substantive norms' (Vervaele, 1999; Adriaanse et al., 2008), but may also involve other types of activity. In my definition, an institution is also involved in EU policy enforcement when it *may request or force other actors* to take action for preventing or responding to emergencies or non-compliance; when it *distributes information or other resources* prior to or as a result thereof; or when it *supervises how other institutions* enforce EU policies.

Two more remarks are in place. First, this dissertation is about enforcement for the realization *of EU policies*. I distinguish this from EU involvement in enforcement for the benefit *of national policies*. In this view, institutions such as the European Public Prosecutors Office and Europol are outside this dissertation' scope of interest: they are EU institutions, but primarily geared towards effectuating the substantive criminal laws of the member states. Second, this dissertation is about executive organizations engaging in enforcement action *ex officio*, and not about organizations that are passively involved. Courts can also enforce EU policies, but only come into play as dispute settlers when called upon by one or multiple parties. Given the distinct nature of courts and court organization, cooperation among them is outside the scope of this research.

EU agencies

An EU agency is the second key concept that requires clarification. I see an EU agency as a body that is established through (primary or secondary) EU public law, that has legal personality, and that operates with some degree of independence from political actors (Egeberg & Trondal, 2017; Chamon, 2016; Groenleer, 2009). This means that the agency's organization is formally separate from the Union institutions involved in making legislation. An EU agency is led by an agency director and some governing board – the members of which are often representatives of relevant national authorities, member states, the Commission and/or European Parliament (Thatcher & Coen, 2008). EU agencies furthermore tend to have some sort of specific and circumscribed mandate (Thatcher & Coen, 2008), and usually carry the explicit name 'agency', 'authority' or 'office'.

Networks of national authorities

A network of national authorities is the last concept defined here. I see an EU network of national authorities as a structure through which primarily member states' national authorities cooperate to execute a specific task (Mastenbroek & Martinsen, 2018). In the context of EU policy enforcement, this cooperation may consist of national authorities pooling resources or mutually adjusting their enforcement actions. Unlike an EU agency, then, decisions are not made by a single actor, but by two or more national authorities through (voluntary or obligatory) coordination. In this dissertation, furthermore, I focus on formal networks of EU authorities, which means that network membership as well as network cooperation is determined by EU (secondary) legislation. Networks usually carry the name 'network', can be supported by a small secretariat, and sometimes make use of an (automated) system to share case-specific information.

1.5. Research design and methodology

Having clarified the concepts key to this dissertation, this section discusses several methodological considerations. I first introduce the comparative case study research design that was used to examine and develop the theory. I then discuss the case selection processes, the cases that I selected, and the (comparative) analyses that I conducted for each of this dissertation's chapters. Lastly, I detail how I analyzed each individual case and how I gathered and managed by data.

Comparative case study research design

In order to explain why EU legislators establish EU agencies and networks of national authorities, I conducted four qualitative case studies and executed comparative analyses between them. The primary reason for relying on qualitative case studies is that the establishment of

institutions – such as EU networks and agencies – is usually preceded by complex decision-making processes. These decision-making processes are best analyzed through a rich and in-depth analysis. Case studies are a useful method to do so: they allow the researcher to examine the details of phenomena and provide a nuanced and thick description thereof (Bryman, 2012). In the context of this dissertation, case studies enabled me to capture the complexity of decision-making processes and the range of factors that influence it. Moreover, the small number of networks and agencies that are available for study (see below) and the overwhelming number of factors that play a potential role in each case makes that the capacity of conventional statistical analysis to adjudicate among rival explanations is limited (Collier, 1993; Lynggaard et al., 2015). A quantitative analysis would moreover artificially reduce the large number of factors that impact legislative decision-making in real-life. Case studies are therefore a suitable methodology to analyze the complexity of the legislative processes preceding EU agencies and EU networks.

This project studies and makes comparisons across four individual cases. In essence, a comparative case study design extends a study of one single case by adding one or multiple others (replication), and then comparing them by seeking contrasts, similarities or patterns (Campbell, 2010). The primary value of a comparative case study design is that it not only captures the complexity of the individual cases, but also derives conclusions across the individual cases to contribute to theory-building more broadly (Bryman, 2012). 'By comparing two or more cases, the researcher is in a better position to establish the circumstances in which a theory will or will not hold' (Bryman, 2012, p. 74, referring to Eisenhardt, 1989; cf Yin, 2018).

Case selection

Three reasons led to the selection of cases introduced below. First, and above all, the case selection had to include the phenomena of interest to this dissertation. Two such phenomena of interest are mentioned in the research question: the research question asks why EU legislators establish *EU agencies* for the enforcement of EU policies, and why EU legislators establish *EU networks* of national authorities for the enforcement of EU policies. I have therefore selected cases in which EU legislators established both types of institutions and, from their inception, tasked them with EU policy enforcement. As table 1.3 below shows, the case selection ensures that these types of institutions are represented. Subsequent chapters thus discuss the decision-making processes that led towards two EU agencies as well as two EU networks of national authorities.

The research question, however, also asks why EU legislators *differentiate* between EU agencies and networks for EU policy enforcement. This dissertation relied on the selection of *two pairs of most-similar cases* to examine the reasons for this differentiation. A pair of most-similar cases comprises two cases that are highly similar in many respects other than the phenomena of

interest. For this dissertation, this means that each pair of cases 1) has to comprise one case with an EU agency and one case with an EU network; and 2) that these cases should otherwise be similar in as many ways as possible. Such a case selection enables the researcher to isolate the reasons why EU legislators differentiate between EU agencies and networks for EU policy enforcement. After all, by keeping the differences between the cases in a pair to a minimum level, the researcher can identify the reasons why EU legislators have established different institutions nonetheless. Also, selecting cases that exhibit a different phenomenon of interest yet are otherwise as similar as possible minimizes the possibility that the researcher erroneously assigns explanatory value to differences between cases that are actually irrelevant. By selecting cases in which the circumstances of the decision-making process as similar as possible, the researcher is in a better position to flesh out the reasons why EU legislators chose one type of institution over the other.

Therefore, the second reason why I included the cases introduced below, is that these cases are highly similar in many respects, but differ when it comes to the phenomena of interest. In order to find those cases, I first identified the policy areas in which EU legislators established an EU agency with enforcement functions (see table 1.1 below).

Table 1.1. EU agencies likely to be involved in EU policy enforcement

Name	*Key legal acts (constituting agency and/or defining important aspects of enforcement role)*
European Anti-Fraud Office	Commission Decision 1999/352/EC, ECSC, Regulation (EU, Euratom) 883/2013; Regulation (EU) 1293/2013; Regulation (EU) 377/2014
European Aviation Safety Agency	Regulation (EC) 1592/2002; Regulation (EC) 216/2008; Regulation (EU) 2018/1139
European Banking Authority	Regulation (EU) 1093/2010
European Border and Coast Guard Agency (Frontex)	Regulation (EU) 2016/1624 ; Regulation (EU) 2019/1896
European Central Bank (Banking Supervision)	TFEU; Protocol (no 4) on the Statute of the European system of central banks and of the European Central Bank; Regulation (EU) 1024/2013;
European Fisheries Control Agency	Regulation (EC) 768/2005; Regulation (EU) 2019/473;
European Food Safety Agency	Regulation (EC) 178/2002
European Maritime Safety Agency	Regulation (EC) 1406/2002
European Medicines Agency	Regulation (EEC) 2309/93; Directive 2001/83/EC; Regulation (EC) 726/2004;
European Securities and Markets Agency	Regulation (EU) 1095/2010; Regulation (EU) 513/2011; Regulation (EU) 648/2012

Then, I looked for policy areas which were most similar to the ones above, but in which enforcement functions were attributed to an EU network of national authorities (see table 1.2 below).

Table 1.2. Formal EU networks likely to be involved in direct EU policy enforcement

Name	*Legal act constituting network and/or defining enforcement role*
AVMSD Contact Committee	Directive 2010/13/EU
Consumer Protection Cooperation	Regulation (EC) No 2006/2004
Customs and Common Agricultural Policy Enforcement Network	Regulation (EC) No 515/97
European Border Surveillance System	Regulation (EU) 1052/2013
European Competition Network	Regulation (EC) 1/2003
European Network of Civil Aviation Safety Investigation Authorities	Regulation (EU) No 996/2010
Food Fraud Network	Regulation (EC) No 882/2004
Forum for Exchange of Information on Enforcement	Regulation (EC) No 1907/2006
Medical Devices Coordination Group	Regulation (EU) 2017/745
Rapid Alert System for dangerous non-food products	Directive 2001/95/EC
Single Supervisory Mechanism	Council Regulation (EU) No 1024/2013

As tables 1.1 and 1.2 demonstrate, there are many policy areas that feature an EU enforcement agency, and there are many policy areas that feature an EU enforcement network. However, only some pairs can be made of policy areas that are roughly similar *and* feature both an EU agency and a network. And among the policy areas that do, the pairs of cases that are *most-similar* are in the area of medical products policies and in the area of aviation safety policies. In the case of EU medicines policy, EU legislators have vested enforcement tasks in EU agency – the European Medicines Agency (EMA). Highly similar to EU medicines policy is medical devices policy. In this case, however, EU legislators did not establish an EU agency, but agreed on an EU network of national authorities instead. A similar picture arises in the context of (civil) aviation safety regulation. For the enforcement of EU airworthiness policy, EU legislators decided to vest tasks in the European Aviation Safety Agency (EASA). Adjacent to airworthiness policy is the investigation of aircraft accidents and incidents. In that case, however, EU legislators decided to establish a network instead.

To the author's knowledge, there is no other pair of cases that exhibits both outcomes of interest, involves cases *that are more similar* than the cases selected, and that meet other preconditions. First, a couple comprising the European Border and Coast Guard Agency (Frontex) and the European Border Surveillance System was excluded as these institutions are not primarily engaged in enforcing regulatory policies vis-à-vis citizens and businesses of (and active within) the EU. Second, a case pair involving the European Food Safety Agency and the Food Fraud Network was excluded because the regulatory framework of the European Food Safety Agency is of a primarily administrative law nature, whereas combatting food fraud involves criminal law (of the member states). The cases selected for this dissertation are more similar in this respect, for they all involve regulation through administrative law. One other case pair, lastly, has been excluded because the cases do not sufficiently resemble the analytical distinction between the EU agency and the network of national authorities. It concerns the potential pair involving the European Central Bank (Banking Supervision) and the Single Supervisory Mechanism. The Single Supervisory Mechanism allows the national authorities to work together on a horizontal basis, but the European Central Bank remains responsible for the entire mechanism and has relatively strong powers to instruct national authorities (Duijkersloot et al., 2017). As the strong role of this EU agency in the network of national authorities obscures the analytical distinction between the two, including these cases may severely hamper the generalizability of any comparative findings.

The third reason for including medical products and civil aviation policies in this study is that it is academically relevant to do so. As mentioned above, the literature on EU policy enforcement tends to focus on a limited number of policy areas other than EU transport and health policies. As a consequence, EU medical products and aviation safety regulation have not yet received much academic attention. Including these policy areas in this dissertation turns out to be a welcome addition to the existing scholarship.

Selected cases and case analysis

Table 1.3 below thus shows the pairs of cases selected for this dissertation. Case pair 1 is about medical products. In the case of EU medicines policy, EU legislators established the EMA in 1995 to assess the safety of certain classes of medicine, and thereby help the Commission issue EU-wide licenses for those medicines. The EMA's enforcement tasks are to collect information about the safety of medicines on the market, and the agency can advise the Commission to amend, suspend or withdraw medicines licenses if need be. In the case of EU medical devices policy, EU legislators recently enacted the Medical Devices Regulations, with which they established two network arrangements. Within joint assessment teams, national authorities cooperate in the supervision of companies certifying medical devices before they come on the market. And as part of market surveillance coordination, national authorities cooperate to assess (serious) incidents with medical devices on the market.

Case pair 2 is about aviation safety regulation. The case studies in this pair are about EU airworthiness policy and EU civil aviation accident and incident investigation. In the case of EU airworthiness policy, EU legislators decided to establish the EASA in 2003. Since its inception the EASA has been responsible for issuing licenses for aircraft designs, and for enforcing airworthiness rules once aircraft are on the market. It specifically monitors compliance, and can amend, suspend or withdraw licenses if need be. In the case of EU aviation incident investigation, EU legislators decided to enact the European Network of Civil Aviation Safety Investigation Authorities (ENCASIA) in 2010. Through this network, national authorities share information about specific incidents and accidents, organize peer reviews and training, share resources, and provide mutual assistance during investigations.

Table 1.3. The four cases (and units of interest between brackets) studied for this dissertation.

	Case pair 1: Medical products	*Case pair 2: Aviation safety*
Networks	1. EU medical devices policy (two specific network arrangements)	2. EU civil aviation accident and incident investigation (the ENCASIA)
Agencies	3. EU medicines policy (the EMA)	4. EU airworthiness policy (the EASA)

These cases are discussed and compared in chapters 3, 4 and 5 to answer the central research question. Given the different sub-questions formulated earlier, each individual chapter has a distinct focus on two or more of the above cases. Chapter 3, first, focuses on the two cases involving networks of national authorities, even though it also addresses the differentiation between networks and agencies. Chapter 4 then focuses on EU agencies and discusses their establishment in the two cases of EU medicines and airworthiness policy. Chapter 5, lastly, draws upon all cases studies and engages in a comparative analysis of both case pairs.

The method for studying each individual case was process tracing. Process tracing 'is a research method for tracing causal mechanisms using detailed, within-case empirical analysis of how a causal process plays out in an actual case.' (Beach, 2017). This means I did not only aim to map the factors that were relevant for the establishment of an EU network, an EU agency or differentiation between the two; I also aimed to examine how these factors impacted policy-makers' preferences and how policy-makers went about in realizing them. In other words: I sought to identify both the causes for specific outcomes – commonly referred to as the congruence method (Beach & Pedersen, 2013; George & Bennett, 2005) – as well as the causal mechanisms that connect causes to outcomes.

Data collection and data management

To collect the data necessary for a reconstruction of actors' roles, relevance and preferences throughout the establishment processes of EU agencies and networks, I conducted archival research and semi-structured in-depth interviews. The archival research, first, consisted of a

systematic collection and analysis of all potentially relevant documentation. In order to identify such documentation, I have browsed and conducted search queries in general search engines, news databases, university libraries as well as the EU's online archives. Every document that could possibly contain relevant information for the case studies was stored and assigned a reference number (for an overview of all documentation, see appendix 1). Every document was subsequently scanned for its relevant parts, either manually or through the use of text search queries. Relevant information was then studied in detail and analysed mostly using coding software (QSR Nvivo). When documents contained references to other files that were not identified earlier, such other files would be assigned a reference number and be traced to the extent possible. If such referenced documentation was not publicly available, specific document requests would be submitted to the EU's archives. Physical visits to the EU libraries were not possible in the relevant stages of the research project due to restrictions following from the covid-19-pandemic.

Secondly, 36 semi-structured in-depth interviews were held with a range of stakeholders who were either directly involved in the decision-making processes themselves or had sufficient knowledge thereof (see appendix 4). 18 of the interviewees have held senior positions at a national authority; 8 had senior positions at an EU agency; 7 had senior positions in the Commission; 4 had senior policy-making positions at national ministries; 4 in the industry; 1 in the European Parliament; 1 in academia; 1 as an independent consultant. Several interviewees have had relevant positions in multiple organisations, and some interviews were relevant for more than one case study. Each case draws upon a nearly equal number of interviews, although it was more difficult to find interviewees for the cases of EU airworthiness policy and medicines policy as the EMA and the EASA were established several decades ago. I've also experienced difficulties finding suitable interviewees from the European Parliament. 26 people who were contacted dropped out at some point prior to finalization of the interview.

Leads for potential interviewees were found through LinkedIn, by studying relevant documentation, and through prior interviews. These potential interviewees were then approached via LinkedIn, e-mail or phone call. Before participating in this research project, all interviewees have given their explicit and informed consent on the condition that only a general professional affiliation and interview date could be used as a reference to the interview (see appendix 2). Unless interviewees specifically allowed me to do so, I could not directly quote interviewees. Interviews were conducted using topic lists (appendix 3) that were composed on the basis of the theoretical frameworks discussed in subsequent chapters. The average length of an interview was about an hour, although some lasted 0,5 hour and some 2,5 hours. Also, some interviewees were interviewed more than once. Most interviews were held via videoconferencing tools due to covid-19-related restrictions and a generally large physical distance between the interviewer and the interviewee. All interviews were recorded with

participants' permission, and interviewees did not have the possibility to check or correct the transcript after the interview had been conducted. The interviews were indexed and analysed similar to the other documentation studied for this dissertation (see above).

A research data management plan was drafted for this project. A first version of the plan was finalized on 17 December 2019 and updated on 1 March 2023.

1.6. The upcoming chapters

The upcoming chapters work towards answering the central research question. Chapters 2 through to 5, however, are also individually readable chapters as they are based on four original contributions that were published over the course of the last four years (see table 1.4 below). A short statement is included prior to the chapters to indicate that they differ from the original contribution.

Table 1.4. The four original contributions on which chapter 2-5 are based.

Chapter	*Original contribution*
2	Van Kreij, L. (2019). Towards a Comprehensive Framework for Understanding EU Enforcement Regimes. *European Journal of Risk Regulation*, *3*(10), 439–457. https://doi.org/10.1017/err.2019.52
3	Van Kreij, L. (2022). Enforcing EU policies: why do EU legislators prefer new networks of national authorities and not existing EU agencies?. *Journal of European Public Policy, 29*(10), 1568–1589. https://doi.org/10.1080/13501763.2022.2125045
4	Van Kreij, L. How do EU legislators design EU agencies with enforcement tasks? Case studies of the EASA and the EMA. S*ubmitted and under review*
5	Van Kreij, L. (forthcoming 2023). The choice for EU agencies or networks of national authorities: Exploring the relevance of regulated industry characteristics. In M. Scholten (Ed.), *Research Handbook on the Enforcement of EU Law.* Edward Elgar Publishing.

Chapter 2

Towards a Comprehensive Framework for Understanding EU Enforcement Regimes

This chapter is based on: Van Kreij, L. (2019). Towards a Comprehensive Framework for Understanding EU Enforcement Regimes. *European Journal of Risk Regulation*, *3*(10), 439-457. https://doi.org/10.1017/err.2019.52

Abstract

Next to member states, EU level organizations have come to play a larger role in the enforcement of EU policies during the last two decades. Analyzing the roles of member states, networks of national authorities and EU agencies in this stage of the policy cycle through multiple academic lenses could lead to a more comprehensive explanation and assessment of their design. This chapter sets elementary steps towards a framework that brings together prominent theoretical insights from the legal and political disciplines, to discuss their combined leverage for explaining these new modes for enforcement in the EU.

2.1. Introduction

The member states of the EU have long been primarily responsible for enforcement in the EU. By default, 'public action with the objective of preventing or responding to the violation' of a norm by citizens or businesses has been undertaken at the national level (Röben, 2010, p. 820). Through case law and legislation, the EU vests a responsibility to enforce EU law in the member states (De Moor-Van Vugt & Widdershoven, 2015), as is the case with the Environmental Crimes Directive (ECD) in the area of environmental policy. However, also networks of member states' national authorities, EU agencies and their many manifestations become increasingly involved in enforcement in the EU (Scholten, 2017). One example is the European Securities and Markets Authority, an agency that (among others) enforces EU law vis-a-vis credit rating agencies (Regulation (EC) 2006/2004). The Consumer Protection Cooperation (CPC) moreover, is a network of national enforcement authorities that provide mutual assistance and jointly engage in investigations upon cross-border infringements of EU consumer law.

Taking these innovations into account, EU policy-makers can decide to vest enforcement tasks in three different regimes: the member states, EU networks and EU agencies (Scholten 2017). EU policy documents however, neither capture the varying qualities of these regimes nor do they consistently motivate a choice between them (Commission, 2017a; Commission, 2017b; European Court of Auditors, 2018). While legal scholarship was quick to attribute functional motives to the EU's involvement with enforcement by the member states (De Moor-Van Vugt & Widdershoven, 2015), researchers of European networks, agencies and multilevel implementation have not yet specified the EU's motives for delegation of enforcement tasks specifically (Rittberger & Wonka, 2011). Nonetheless, increased understanding may lay a better foundation for and reasoning of the choice for a particular enforcement regime. Therefore, this chapter aims to find out why certain regimes are chosen over others. Referring to the examples above: why would tasks for the enforcement of EU consumer policy be conferred upon a network, whereas considerable powers for the enforcement of EU policies for credit rating agencies are given to an EU agency? And what explains that the EU continues to rely on and steer member state enforcement through secondary legislation?

This chapter takes stock of insights from legal and political scholarship to understand the EU legislator's choice for one or more of these three regimes for enforcement, and demonstrates that a combined account of both EU law and politics yields a more comprehensive picture. Taking relevant literature on European integration into account (Scholten & Scholten, 2017; Genschel & Jachtenfuchs, 2018), I alter the insights of rationalist studies of European regulatory networks and European agencies for enforcement in the EU. Thus, section 2.2. first illuminates the object of inquiry (EU involvement with member state enforcement, EU networks and EU agencies for enforcement). Section 2.3. then discusses institutional and policy-specific

conditions to demonstrate that room for choice between enforcement regimes remains. Therefore, sections 2.4. and 2.5. discuss functional and political rationales (see Rittberger & Wonka, 2011). Integrating insights from law and politics, I then propose a framework in section 2.6 which allows for a more comprehensive study of the choice for one or more enforcement regimes. Section 2.7. discusses the CPC and the ECD as empirical illustrations, as regimes for the enforcement of consumer protection and environmental policy respectively. I conclude thereafter.

2.2. Three regimes for enforcement in the EU

The EU has three enforcement regimes at its disposal, and each regime involves one (or more) public institution(s) on the national or EU level which, pursuant to EU law, jointly or separately perform(s) functions for compliance with EU law by citizens and businesses. As mentioned, the EU conventionally relies on the member states. This decentralized regime is also referred to as indirect, because the EU institutions do not monitor, investigate or sanction (collectives of) citizens themselves (Adriaanse et al., 2008), but rather leave that to the member states (Rowe, 2009). Although the latter were long autonomous in the formal and operational design of their enforcement systems, the EU increasingly controls member state enforcement through regulatory obligations. Case law of the ECJ sets general requirements (e.g. Von Colson and Kamann, 1984; Greek Mais, 1989; Spanish strawberries, 1997), while secondary and soft law instruments contain more detailed standards for (among others) the nature of sanctions to be imposed upon violation of an EU rule (criminal, administrative or private), the establishment and architecture of national enforcement authorities and the attribution and use of enforcement powers (Adriaanse et al., 2008).

However, EU policy enforcement is subject to increased centralization as two types of EU level organizations have become increasingly involved with the enforcement of EU policies in the past two decades (Scholten, 2017). *EU enforcement networks*, as mentioned, consist primarily of member states' national authorities engaging in bi- or multilateral cooperation for the enforcement of EU policies. They cooperate with varying degrees of intensity and on various matters: some pool staff or exchange best practices, whereas others share real-time supervisory information or engage in the (voluntary or obligatory) coordination of enforcement decisions. A network's nodes thus comprise national authorities but may also include EU agencies and the Commission. They exist formally when EU law explicitly provides for their enactment, although the Commission can participate in (informal) enforcement networks outside the scope of EU law.

Yet in other policies areas, enforcement responsibilities and instruments have (also) been attributed to *EU agencies* (Scholten & Luchtman, 2017). As mentioned, I define an EU agency as a body that is established through (primary or secondary) EU public law, that has legal personality, and that operates with some degree of independence from political actors (Egeberg & Trondal, 2017; Chamon, 2016; Groenleer, 2009). An example of an agency is the 2005 established European Fisheries Control Agency, set up to coordinate control and inspection by member states and later given the power to conduct inspections itself. Another example is the European Securities and Markets Authority, which can autonomously decide to fine credit rating agencies. EU agencies do not (yet) replace national authorities or their networks in their entirety (Thatcher & Coen, 2008).

Table 2.1. Configurations of regimes for EU policy enforcement

policy	*1*	*2*	*3*	*4*	*5*	*6*	*7*	…
EU agency				X	X	X	X	…
EU network		X	X	X		X		…
member states	X		X	X	X			…

However, this distinction between regimes is blurred in practice. First, regimes are not necessarily limited to enforcement tasks, but can simultaneously fulfil advisory or rule-making functions. Moreover, regimes can coexist within one policy (field) without consuming each other. Table 2.1 therefore demonstrates the minimum variety of potential configurations of increasingly centralized enforcement of EU policies, whereby each configuration displays a different distribution of some enforcement responsibility among one or more of the identified regimes. Only a few configurations included in table 2.1 currently exist. For instance, the member states are given certain circumscribed responsibilities for the enforcement of the mercury regulation (example of policy 1; Regulation (EU) 2017/852). For the enforcement of EU consumer protection policy (example of policy 3), the EU has vested tasks in the member states and a network (see section 2.7), while the member states and an agency (the European Securities and Markets Authority) enforce (different) aspects of EU law on credit rating agencies (example of policy 5; Regulation (EC) 1060/2009). Thirdly, there are various ways in which the EU spreads (formal) authority or (operational) enforcement tasks over multiple regimes. For example, an agency can hierarchically steer enforcement operations by national authorities (e.g. for EU policy on credit rating agencies); an EU agency and the national agencies can both have similar formal and operational tasks for enforcement of the same set of EU rules (e.g. for EU policy on airworthiness standards); or an agency can have specific operational powers to only support national authorities (e.g. the EMA) (Scholten & Luchtman, 2017).

Thereby, this typology demonstrates that enforcement in the EU is more nebulous than anticipated by other frameworks. Among others, it follows from the above that the enforcement

of one policy cannot well be described along top-down/bottom-up and task-specific/exclusive jurisdiction dimensions (Heidbreder, 2017). In case of crimes against the EU's financial interests for example, the EU firmly requires (top-down) that member states take enforcement action, but the latter enjoy a great deal of (exclusive) jurisdiction on the way they enforce, while their action is complemented by a (task-specific) EU agency that provides investigatory information and supports enforcement by national authorities (the European Anti-Fraud Office). Therefore, in spite of the above qualifications and the variety within each category, I maintain the broad-brush typology of member state, network and agency enforcement, because they serve well as analytical starting points for further investigation and because these categories underly the scholarship feeding into the perspectives discussed below (Thatcher & Coen, 2008). Hence, the following question arises: why do agencies have enforcement tasks for some policies, while networks of national authorities and/or the member states have a role in the enforcement of others?

2.3. Institutional conditions: actors and policy instruments

Two existing frameworks provide insights in EU policymaking and implementation – the process whereby EU policy is put into practice (Treib, 2014) – more broadly. Wallace (2010) outlines how EU policies are made through five policy-making modes, whereby each mode differs in 'roles and behaviour of the various key actors, in the approaches to policy dilemmas, and in the instruments intended to address them' (p. 90). For implementation specifically, Heidbreder (2017) specifies how the convergence of interests over a policy affects the authority of supranational bodies over the implementation, and outlines how ambiguity over the goals and means of policy implementation determines whether an implementing entity has full or only specific jurisdiction. Whereas these frameworks are useful to understand actor preferences for implementation in the broader context of EU policy-making, this chapter builds upon them for an understanding of the dynamics *specific to enforcement vis-à-vis (private organizations of) citizens*. Enforcement is particularly different from implementation because it presupposes a regulatory policy instrument with unambiguous (behavioural) rules and direct contact with policy target actors in case of non-compliance. This chapter discusses how these (and other) characteristics necessitate a revised framework for the choice between enforcement regimes.

This section discusses the relevant institutional and policy context. Who are the key policy-making actors that delegate enforcement to the member states, networks or agencies, and what constrains them? On the basis of EU law, I first introduce the (constellations of) key actors that choose between regimes. Thereafter, the section demonstrates how competences in the Treaty on the Functioning of the European Union (the TFEU) can constrain policy-makers' options for enforcement, as competence specificity varies considerably across policy areas.

The last part discusses how also the degree of ambiguity of EU policy-instruments can limit the range of available enforcement regimes.

What does the TFEU determine for enforcement? Key decision-making actors and competence

The Commission, the European Parliament and the Council of Ministers together delegate enforcement tasks to the above-mentioned regimes. Their respective influence differs per decision-making procedure: under co-decision (COD), the Commission has the sole right of proposing legislation after which the Parliament and the Council can amend, approve or reject. The TFEU can also prescribe the consultation procedure (CNS), in which the Commission sometimes shares its right of proposal with the Council, and whereby the Parliament is merely consulted. Compared to COD therefore, CNS leaves considerably less space for supranational preferences, while intergovernmental bargaining has a larger effect on the outcome. Section 2.5 demonstrates how the latter can be of particular importance for enforcement in the EU.

However, these decision-making actors are bound by the existence of a legal basis (a competence) for the establishment of any enforcement regime. Such regimes are ruled out entirely if a basis is absent, whereas legal bases that do exist might circumscribe a choice beforehand. The necessity of legal bases connects to the rule of law (Hill & Hupe, 2009) – only the law constitutes (and constrains) public authority (Wade & Forsyth, 2014) – and to the principle of conferral – competences not attributed to the EU remain with the member states. The TFEU provisions thus determine the ambit of EU governance (Bulmer, 1993): in what policy domains can the EU take action and what are the objectives? The collection of direct taxes for example, is outside the scope of EU authority, while competition policy is within. Additionally, the competences can determine qualitative aspect of EU governance (Bulmer, 1993): how are policy objectives achieved, what should a policy look like, and what forms of action (e.g. distributive, regulatory or enforcement) does it prescribe?

The specificity of TFEU competences varies and is moderated by case law. Several policy areas, e.g. internal market and air transport, exhibit openly-worded ('flexibility') provisions in which many forms of EU action can fit (articles 100(2) and 114(1); Weatherill, 2004). Moreover, ECJ case law in principle allows EU action if it *aims* to improve the functioning of the internal market – but achieves something else by effect (Tobacco Advertising II, 2003; Craig & De Búrca, 2015) – and recognized that EU action, including standards on enforcement (Commission of the European Communities v Council of the European Union, 2003; Craig & De Búrca, 2015), can be *implied* by a TFEU article. These openly-worded provisions seem suitable for enforcement regimes (Schütze, 2016), especially if such action is a necessary step in effectuating existing policy instruments or their goals (Accetto & Zleptnig, 2005). The TFEU is more specific only by way of exception: article 127(6) of the TFEU allows powers for financial supervision to be attributed to the ECB,

while for competition policy, the TFEU identifies the Commission (in cooperation with the national authorities) as primarily responsible for enforcement and provides for corresponding sanctioning powers (article 103). One finds more detailed competences for the Area of Freedom, Security and Justice (AFSJ): the TFEU specifies the instruments and organizations that can be enacted. However, more often than not, an available TFEU competence for EU enforcement action does not specify how enforcement should be organised.

How do policy rules impact enforcement? Harmonization of law

In addition, the unity of the rules to be enforced limits the range of available regimes. After all, enforcement presupposes an assessment of behaviour in the light of prohibitions or obligations, and involves a decision on enforcement action. However, a single conclusion about (non)compliance with EU law becomes problematic in the case of (multiple sets of) diverging substantive policy rules. Therefore, whereas conventional principal-agent theory predicts that high ambiguity results in delegation to an independent agent (Heidbreder, 2017, referring to Matland, 1995), this chapter maintains that a high degree of ambiguity of substantive policy rules hinders delegation of enforcement authority to an independent EU agency or a (strong) network of national enforcement authorities. After all, the parallel existence of multiple and diverging obligations, prohibitions or sanctions for the enforcement of a policy – usually stemming from the EU member states' laws – would render a judgement about (non) compliance, by one or a few enforcement authorities jointly, ambiguous. This ambiguity is reduced if the EU legislator decides to harmonize the laws of the member states. The more harmonized a body of obligations, prohibitions and/or sanctions, the more likely becomes enforcement by an agency or a strong network.

Thus, the EU legal framework denotes and binds key actors in their choice between enforcement regimes. The TFEU provisions determine which actors may devise enforcement and can limit their options with varying degrees of detail. Yet, even if competence is present, only a harmonized body of substantive EU law allows delegation to an agency or strong network for enforcement. However, competence and harmonized substantive policies seem to be conditions only: they leave further actor preferences for regimes undetermined. Therefore, the limited determinacy of EU law necessitates extra-legal perspectives to explain the choice between enforcement regimes.

2.4. Functional rationales

Functional rationales help to understand the choice between regimes (Rittberger & Wonka, 2011). They indicate how key actors consider the utility of a policy option: what respective use do the member states, networks and agencies have for enforcement? And, more generally, what is the function of enforcement within the EU? First, this section connects two distinct types of enforcement (functions) to EU policy-making modes distinguished by Wallace. Thereafter, the section builds upon the literature on European regulatory networks and EU agencies (Pollack, 2003; Kelemen & Tarrant, 2011; Kreher, 1997; Rittberger & Wonka, 2011), and proposes modifications for to explain the delegation of enforcement tasks specifically.

What are the functions of enforcement in the EU? Two types

Enforcement in the EU has at least two broad functions and one is enforcement of EU policies proper. Many EU-made policies employ legal rules as a key instrument to steer the behaviour of EU citizens and businesses (Young, 2010), whereby compliance with the rules is an implicit yet crucial part for achieving policy objectives. Rules are required both for combatting fraud with EU funds and typically for the EU's many regulatory policies. Considering enforcement's instrumental position to secure and effectuate these distributive and rules-based policies, I expect key actors' positions to resemble the mode in which they devise those policies more broadly. Within both the regulatory and distributive policy mode, the Commission acts as agenda-setter and defender of policy objectives while the member states' governments take some (political or operational) responsibility to implement policies or secure subsidies from the EU purse (Wallace, 2010). Moreover, given enforcement's position as the logical tailpiece of regulation (Scholten & Scholten, 2017), functional rationalities of necessity, effectiveness or efficiency (subsection 2.4) rather than political notions of identity and sovereignty (subsection 2.5) are likely to prevail during decision-making.

The second type is EU cooperation for (problems with) national enforcement. Decision-making thereon demonstrates characteristics of intensive transgovernmentalist policy-making, in which national preferences are both more articulate and more diverse, given the politically sensitive issues it concerns (Lavenex, 2010). Intra-EU cooperation for public security for example, is a primarily member state response to common pressures: integrated police and judicial cooperation followed increased cross-border crime resulting from removed national border controls, as part of the (earlier EU policy of) free movement within common market (Börzel, 2005; Lavenex, 2010). As for other policies devised through an intensive transgovernmentalist mode, decision-making on cooperation for enforcement can be characterized by a dominant Council and a subordinate Commission and Parliament, constrained by detailed legal bases (see section 2.3) (Wallace, 2010). Hence, although functional benefits of cooperation for enforcement can equally be present, political rationalities could prevail among the member states. After all,

the integration of state capacities for public order, national security or immigration control are amenable to a considerable deal of political saliency and sovereignty-driven electoral resistance (Genschel & Jachtenfuchs, 2018).

Which regime? Functional reasons for delegating enforcement tasks

The previous section indicated that functional reasons may underlie the integration of enforcement in the EU, in particular for the enforcement of the EU's own policies. Hence, functional rationalities may explain why policy-making actors adjudicate between the three regimes to delegate enforcement tasks to. Agencies, their networks and the member state regimes all have a different utility to perform enforcement functions (Kassim & Menon, 2003; Kelemen & Tarrant, 2011). This section discusses three functionalist models of delegation embedded in studies of European agencies and regulatory networks, that are most relevant in the context of enforcement in the EU (Mathieu, 2016; Rittberger & Wonka, 2011; Kassim & Menon, 2003).

First, delegation to European agencies – and networks of national authorities to some extent – results from a credible commitment to cooperation. Politicians generally delegate to independent agencies to isolate regulation from electoral or interest group pressure, and thus credibly bind themselves or each other to policy (Egan, 1998). The same reasoning applies to enforcement in the EU: member states may have difficulties in committing themselves to comply with EU law (Majone, 2000; Pollack, 2003) and to enforce it on citizens and businesses, and/or have a lack of trust in other member states doing so (Mathieu, 2016). In the face of national (economic) interests, delegation by the EU legislator of enforcement tasks to EU agencies prevents potential lenient enforcement by (weak networks of) member state authorities towards domestic companies or industries. Especially purely member state enforcement, which requires transposition through the (national) political process (Treib, 2014), can frustrate the enforcement of EU policies given opposition by domestic interest groups (Thomann and Sager, 2017). EU agencies (and strong networks) therefore, are credible enforcers in the face of national interests which could undermine the effectiveness of EU policy.

A second rationale that could impact delegation of enforcement tasks is a regime's reflection of the (geographical) heterogeneity among a policy's target actors. Blauberger and Rittberger assert that European regulatory networks are chosen over agencies because the former possess the operational resources and 'street-level expertise' for regulation that requires 'case-by-case implementation'. Those national authorities are thought to be in a better position to reflect the particularities of citizens and organizations in their respective jurisdictions (Blauberger & Rittberger, 2015; see also Hooghe & Marks, 2001). This argument is most appropriate for enforcement, which involves more direct contact with target actors than any other stage of the policy cycle. Moreover, the logic can differentiate between enforcement by the member states

or by agencies as well: a large heterogeneity among (especially locally operating) target actors may best be reflected by leaving enforcement to the member states, allowing adaptation to the national contexts (Thomman & Zhelyazkova, 2017). The target actors of the ambient air quality directive for example, are not specified and can thus include both natural persons and both small and large companies active in about any sector (Directive 2008/50/EC). Conversely, only an EU agency has the required proximity to entities in a pan-European sector with a relatively small number of similar companies, such as credit rating agencies.

A third reason for delegation lies in a regime's capacities to process enforcement information and reduce related transaction costs. Political actors have difficulties in gathering and processing all information relevant for determining a course of action, given similar interests (Pollack, 2003; Heidbreder, 2017). Delegation to independent agents can then have a twofold function when it comes to information: EU agencies and networks facilitate the exchange of information (Scholten, 2017; Majone, 1997; Busuioc et al., 2011; Versluis & Tarr, 2013) and – depending on their strength – bring together relevant stakeholders for problem or even solution definition (Dehousse, 1997; Zinzani 2012). In the specific context of enforcement, this could entail that networks and agencies share information on (the harmful consequences of) target actor behaviour to facilitate investigations into non-compliance in cross-border or Europe-wide situations by respective national authorities. Moreover, and provided that substantive law is harmonized sufficiently, agencies or networks can foster a mutual agreement on violations of EU law. For example, national authorities comprising the CPC are not only obliged to share of information on infringements of EU law and resulting damage, but are also ought to agree on enforcement action in a case of non-compliance. On the other hand, a unitary decision on enforcement is best taken by a single strong agency.

Thus far, I have identified three functional considerations that impact the choice to vest enforcement responsibilities in member states, an EU network of national authorities and/or an EU agency. These three regimes can reflect varying credible commitments to effective enforcement in the face of distinct national interests; varying needs to share information on non-compliant behaviour and facilitate agreement on sanctioning; and varying natures and sizes of target actor groups. Yet functional rationales alone may also be insufficient to understand the choice between enforcement rationales: if delegation was indeed functionality-driven, the EU legislator could simply delegate tasks to the Commission – an existing institution with considerable expertise that already prevents downwards regulatory competition among member states (Kelemen & Tarrant, 2011). In other words, functionality alone cannot explain the more nebulous and novel enforcement regimes under consideration (and outlined in section 2.3). Therefore, additional political rationalities are needed.

2.5. Political rationales

A given functional demand to integrate enforcement in the EU thus leaves questions of political supply unanswered. What are the costs and benefits of an enforcement regime in terms of resources and political identity? And how do the preferences of the member states, the Parliament and the Commission interact in this respect? As discussed in section 2.4, some political rationales may be particularly articulated when it concerns intra-EU cooperation for national enforcement. This section thus provides for a brief account of political preferences regarding enforcement, and outlines how the interaction among the key actors is crucial in the EU legislative decision-making process. Together with the institutional, policy-specific and functional rationales outlined above, their preferences determine the choice to delegate tasks to the member states, networks or agencies for enforcement in the EU.

What are the costs of enforcement regimes? Resources and sovereignty

Enforcement is expensive. As with other core state powers, such as military and the collection of taxes, enforcement is an essentially limited resource (Genschel & Jachtenfuchs, 2018). Whereas legal rules can last forever after enactment, their enforcement requires a continuous appropriation of limited public funds. Therefore, actors will try to render enforcement as efficient as possible, while arguing over the location of enforcement costs. When it comes to the choice between regimes, member state enforcement is rather costly: every member state has to devise an administrative and coercive apparatus to enforce EU laws, in order to remain in compliance with EU standards themselves (Genschel & Jachtenfuchs, 2018; Treib, 2014). Agencies however, and networks to some extent, allow resources to be exchanged or bundled: if these regimes allow the pooling staff, training and expertise, or if they perform (information-gathering) functions that would otherwise be performed by a multitude of member states' authorities themselves, these regimes could result in lower total costs for enforcement. Moreover, their enactment may allow the member states to redirect costs to the EU's budgets. The more a proposed regime presents efficiencies for the member states, the more they may be willing to support its establishment.

Additionally, the integration of enforcement can be costly in non-monetary terms. As the nation-state is traditionally connected to the provision of national security and the use of coercive power against its citizens, domestic electorates easily connect enforcement by public authorities to national community and self-determination (Lavenex, 2010). Conversely, Genschel and Jachtenfuchs maintain that European integration of such enforcement is a salient topic within domestic politics and is receptive to political mobilization against it (Genschel & Jachtenfuchs, 2018), but I would argue that this is particularly so when it concerns enforcement of policies made within a transgovernmentalist mode (see section 2.4 above). When it comes to a choice between regimes then, sovereignty-driven electoral resistance

against integrated enforcement in the EU may well correspond to the territorial divergence between an enforcement regime and the actors targeted by a policy. Domestic political groups will be less keen to accept enforcement by an EU agency or another member state's authority, if the targeted actors (such natural persons and (small) enterprises) behave locally and primarily within member state boundaries. Conversely, they are more likely to accept a distant EU enforcer against actors that operate across Europe and benefit from cross-border movement.

Actor interaction and distributional conflict

Taken together, the choice between enforcement regimes depends on the *collective position* of the member states and the preferences of the supranational institutions. First, as for intergovernmental bargaining generally, the preference of the Council depends on the relative division of preferences over the more and less powerful member states and the relative exposure to external pressures. The supranational preferences on the other hand, can assumed to be stable: the Commission generally seeks an expansion of powers to achieve its objectives and thus opt for a high degree centralization (Kelemen & Tarrant, 2011; Thatcher, 2011), while Parliament concurs for reasons of voter popularity and because EU organizations allow for better accountability relations (Kelemen & Tarrant, 2011; Thatcher, 2011). The institutions act in their self-interest and prefer the most centralized regime of an agency.

Thus, Kelemen and Tarrant assert that the degree of distributional conflict among member states is a key factor for the choice between regimes of interest (Kelemen & Tarrant, 2011) – and probably particularly so when it concerns a choice between regimes for EU cooperation for (problems with) national enforcement (section 2.4). In case of low distributional conflict (leaving more room for the Commission and Parliament preferences for centralization), enforcement tasks are more likely to be attributed to an agency. Delegation to the Commission is unlikely, given its lack of expertise and more general hesitation by the member states. Conversely, greater distributional conflict – e.g. where a sufficiently large group of states would incur high costs – decreases the chance of a strong agency and increases the likelihood of a network or weak agency (with little powers and autonomy), as they allow member states to retain their influence yet efficiently pool information resources and avert compliance costs (Kelemen & Tarrant, 2011; Scholten, 2017). The relationship between distributional conflict and member state enforcement however, is more ambivalent: although implementation costs increase, it provides more possibilities to wield political influence.

2.6. Towards an analytical framework

The central question of this chapter is: what rationales inform the choice between member state, network or agency for the enforcement? On the basis of the available literature, I have mapped rationales from various institutional, functional and political angles and discussed their applicability to the delegation of enforcement tasks to either of the three regimes. The arguments presented above allow us to construct a framework to determine which rationales could play a role in the choice for enforcement regimes. The framework is visualized in table 2.2.

Table 2.2. Rationales for three enforcement regimes in the EU * More articulated when cooperation for enforcement is functional for policies resulting from transgovernmentalist policymaking mode

	Member state regime	*Network regime*	*Agency regime*
Competence and legislative procedure depends on (presence and detail of) competence			
Harmonization of prohibitions, obligations and sanctions	more likely with low degree of harmonization	more likely with medium degree of harmonization	strong agency likely with high degree of harmonization
Proximity to the target actors of a policy	targets large and/or heterogenous group of actors operating locally	targets medium-sized and/or mixed group of actors operating regionally	targets small and/or homogenous group of actors operating Europe-wide
Information-sharing for problem and solution definition	information-sharing on non-compliance is not relevant	nature of (potential) violations and damage requires the sharing of information; and possibly also mutually defined enforcement action	nature of (potential) violations and damage requires single definition of (non)compliance and enforcement action
Credible commitment to effective cooperation	distinctly domestic interests are absent or less likely to hamper effective enforcement	distinctly domestic interests could, but probably do not influence effective enforcement	distinctly domestic interests are more likely to influence effective enforcement
Sovereignty-driven electoral opposition in domestic politics*	more likely in case of high electoral opposition against cooperation	more likely in case of medium electoral opposition against cooperation	more likely in case of low electoral opposition against cooperation
Supranational preferences and distributional conflict	more likely in case of high distributional conflict	more likely in case of medium distributional conflict	more likely in case of low distributional conflict
Resources	does not facilitate efficiencies	facilitates efficiencies	

It follows from this framework that a *member state regime* seems more likely with a low degree of substantive law harmonization. Given its capabilities, it is also more likely to be chosen when the policy involves large and/or heterogenous group of actors that operate locally and when cross-border information-sharing on non-compliance is not or less relevant. In addition, enforcement can be left to the member states when political actors do not perceive distinctly domestic interests to be present or less likely to hamper effective enforcement in the long run, and/or when there is high electoral opposition against cooperation or high distributional conflict. The *network regime*, secondly, occupies middle ground. The delegation of enforcement functions to networks is more likely when the applicable obligations, prohibitions and sanctions are harmonized to some extent. A network is suited to target a mixed group of actors operating cross-border but within a limited geographic range, and has the ability to share information on (potential) violations, damage and corresponding enforcement action involving several member states. Distinctly domestic interests could exist, but probably do not impede effective enforcement. Networks are more likely if there is some electoral opposition against or distributional conflict over enforcement cooperation. *Agencies* lastly, can only be delegated strong enforcement powers if substantive EU law is harmonized to a large extent. Agencies are only capable of targeting a relatively small and/or homogenous group of actors that operate across the continent, and/or whose violations and damage require a single problem and solution definition. Also, agencies are likely to be preferred if distinct national interests can impede effective enforcement, and if electoral opposition and distributional concerns are limited. The latter two regimes facilitate resource efficiencies.

However, this (primarily rationalist) framework requires some nuancing in light of several contextual factors (Egeberg & Trondal, 2017). First, enforcement regimes can inherit structures of organizational predecessors, which may account for incremental change rather than a sudden establishment or overhaul of enforcement regimes. Regimes can inherit pre-existing structures vertically – whereby an enforcement network may well turn into an enforcement agency over time (Scholten, 2017, referring to Levi-Faur 2011) – or horizontally, whereby the EU legislator stipulates enforcement tasks for a regime when that regime previously fulfilled little or no such functions at all (Scholten & Scholten, 2017). As a second group of contextualizing factors, crises and other contingent events may influence the timing of a (shift in) regime choice: the BSE or financial crises for example, correspond to the enactment of the European Food Safety Authority and the delegation of enforcement tasks to the ECB respectively (Egeberg & Trondal, 2017). Such events expose deficiencies in a current system, and may provide the impetus for reform (Mathieu, 2016). Lastly, one should account for model or example regimes that are appreciated within the broader institutional environment, which may inform the EU legislator's delegation preference. One mechanism through which the copying of regimes may occur, is whereby decision-makers are faced with uncertainty and hence mimic another policy

area's regime, that they consider successful or legitimate (Radaelli, 2000). I take these nuances into account throughout the illustration of the theoretical framework in the section hereafter.

2.7. Empirical illustrations

To illustrate the utility of the theoretical framework developed above, this section provides for two examples. How can the EU legislator's choice for a network and for the member states (the CPC and the ECD for the enforcement of EU consumer protection law and EU environmental law respectively) be understood, using the insights above?

Consumer protection enforcement through a network

What regimes did the EU choose for the enforcement of its consumer protection policies? The legislator initially chose the member states through a Directive on injunctions (Directive 98/27/EC), and later also established a network of national authorities. Since 2004, Regulation (EC) 2006/2004 (the CPC-regulation) requires that national liaison offices coordinate enforcement with offices in other member states (article 4). Coordination involves a mutual assistance system, allowing an enforcement body to request its counterpart in another member state to enforce on its behalf (article 8). The latter can refuse, e.g. if it finds that no intra-community infringement has taken place (article 15). In addition, the CPC-regulation required public authorities to have certain inspection powers and the ability to impose sanctions, either directly or through court proceedings. A real-time information database was set up as well (articles 6, 7 and 10).

Institutional conditions did little to structure the choice between enforcement regimes for consumer protection. First, article 114 of the TFEU – the current legal basis for the CPC-Regulation – is a widely-formulated provision for the harmonization of national laws for the functioning of the internal market (Craig & De Búrca, 2015) and is indeed not predisposed towards any enforcement regime. The Commission chose article 114 because it previously served as the legal basis for consumer protection rules in general (Commission, 2001b), for the earlier Directive on injunctions and for the enforcement of other internal market policies (Commission, 2003). Moreover, substantive consumer protection law was harmonized considerably prior to the establishment of the CPC-network. At the time of the Commission's proposal, at least fourteen instruments specified obligations and prohibitions for various aspects of business-to-consumer relations, including distant marketing (Directive 2002/65/EC) and prices indication (Directive 98/6/EC). Moreover, the Commission found the proposed increase in harmonization of substantive rules logically induced revision of the rules on enforcement (Commission 2001b, pp. 17-18, 2003, p. 3).

Secondly, actors indeed articulated the *functional capabilities of the regime* for the enforcement of consumer law as an EU policy proper. The ability to share information for the definition of enforcement problems and the proximity to target actors clearly informed the choice for a network. The Commission expected consumers and fraudulent traders to increase cross borders activity, due to the growth of online-shopping, the single currency and English as a more common language (Commission, 2001b, p. 17, 2003, p. 3). Additionally, it considered mutual agreement between the respective national authorities required for problem and solution formulation: the requested authority – in the state of the fraudulent trader – was best suited within its home jurisdiction and national culture to decide on enforcement action, while the requesting authority in the member state of the harmed consumer to be best placed to understand and judge the harm suffered (Commission, 2003, pp. 8-9).

Consequently, *political rationalities* were less prevalent during the decision-making process. The member states did not voice concerns in terms of a loss of power (Commission, 2003, p. 28), although the network clearly facilitated the Commission's preference for extension of its own influence. After all, the network would facilitate stronger Commission involvement and increased feedback from the member states, and allows it to participate when an infringement affects more than two member states (Commission, 2001b, p. 18; CPC-regulation, article 9). The Council was divided only over the costs for the adaptation of national enforcement structures: the Netherlands, Luxembourg and Germany would have to substantially adapt their national laws (Poncibò, 2012). Luxembourg and Germany thus emphasized the successful functioning of the existing systems of informal and judicial corporation, resulting in their abstention from the final vote (Council, 2004). Apart from national law adaptations, additional costs for national authorities arising from the network would be covered by the multi-annual EU budget for consumer policy.

In addition, the Commission occasionally referred to similar cooperation tools in other policy areas as a way to legitimize its preference for a network (Commission, 2001b). *Isomorphism* therefore seems to have played a role in the decision-making process, but it must be noted that EU agencies were a fashionable idea within that period of time as well (Groenleer, 2009) – and therefore, isomorphism seems a problematic explanation for a preference for a network over an agency. In addition, the *pre-existing structure* of an informal network was present, but the inheritance of core attributes was fairly limited. The CPC involves a considerably stronger cooperation mechanism than the bi-annual informal conventions of its predecessor.

Environmental protection through the member states

What regime did the EU chose for the enforcement of EU environmental policies? With the ECD, the EU legislator explicitly chose the member states. An EU agency and various networks existed already, but without responsibilities for enforcement; and although various EU regulatory instruments already contained clauses that vest some responsibility to enforce in the member states (Commission, 2007a), the EU firmly reinforced the choice for member state enforcement of environmental policy. The ECD enumerates various EU regulatory policies, the violation of which is to qualify as a criminal offence within the member states – given that violation has been committed with a certain severity of conduct (Directive 2008/99/EC, articles 2a and 3).

Although key actors articulated *functional arguments for increased enforcement* and although they could have delegated enforcement tasks to the *pre-existing network or agency structures*, *institutional and policy conditions* seem to have limited the range of available regimes. The Commission (2007b) indeed sought to increase compliance for more effective environmental protection (e.g. pp. 19, 21), and the member states governments likewise recognized the necessity and appropriateness of increased enforcement action (Council, 2008). However, article 175 of the TFEU establishing the European Community stipulated that '[w]ithout prejudice to certain measures of a Community nature, the *Member States shall* finance and *implement* the policy devised [emphasis added]'. Moreover, in terms of policy ambiguity, the sanctioning rules chosen for the ECD were too divergent as to facilitate a more centralized enforcement regime. Although some EU policy instruments, e.g. on the shipment of waste (Regulation (EC) 1013/2006) or the protection of species of wild fauna (Council Regulation (EC) 338/97), specify prohibitions and obligations for protection of the environment, diverging criminal law rules envisaged for sanctioning would hamper a single or joint decision on appropriate enforcement action. As the Commission recognized, the existence of discrepancies in the definition of environmental crimes and sanctions would cause problems when it comes to cooperation. Criminal law in Europe was (and remains) hardly harmonized, despite some effort by the ECD itself (Commission, 2007b).

Both empirical illustrations thus indicate that institutional and policy-specific considerations can, but need not limit the EU legislator's functionally informed choice between enforcement regimes. Given that decision-making revolved around the enforcement of an EU policy proper, functional and not political rationalities informed the preferences of the Commission and the Council. Although these preferences resulted in a network for the enforcement of EU consumer policy, the enforcement of EU environmental policy was left to the member states for the lack of a substantially harmonized body of rules on sanctioning. Thereby, I have illustrated the potential empirical utility of understanding the EU legislator's choices for vesting enforcement tasks in the member states and a network of national enforcement authorities.

2.8. Conclusion

The central question formulated at the outset of this chapter was: what rationales determine the EU legislator's choice for the member states, EU networks of national authorities and/or an EU agency for the enforcement of EU policies? Building upon earlier frameworks of EU policymaking and implementation, this chapter made a start by connecting various insights from law and politics to understand enforcement in the EU. I outlined how EU law establishes the Commission, the Parliament and the member states as decision-making actors on the one hand, and how it can readily influence their range of available enforcement regimes on the other. In turn, the chapter specified the functional and political logics that allow us to explain why the EU is increasingly involved in the enforcement of its policies and which regime is most likely to perform a particular enforcement function under particular circumstances. Lastly, I illustrated the framework's potential usefulness by means of an example of the CPC network and ECD.

Thereby, the combination of (legal and political) insights provides us with a richer understanding of the choice to delegate enforcement tasks to the member states, networks of national authorities or EU agencies. It also has potential for a normative assessment of a regime in light of rationales that preceded its enactment: *should* the EU enact a network or agency be to bring stakeholders together for unitary problem definition? And is the risk of downwards competition among member state authorities high *enough* to warrant an enforcement agency? This very knowledge about when to choose which regime for the enforcement of EU policies can then feed into the legislative process itself: it provides policy-makers the opportunity to adapt their regime choice to the relevant contextual factors of a policy and its environment, as provided for by this framework.

Nonetheless, the above needs refinement and expansion through application. To what extent can the above rationales indeed by identified in the legislative processes that led to (the delegation of enforcement tasks to) regimes? And when comparing multiple regimes, can we identify which rationales are necessary and sufficient conditions for a particular enforcement regime? The empirical illustrations of consumer and environmental protection alone do not teach us about the establishment of an agency or the attribution of enforcement tasks thereto. The EU legislator did not establish an agency, although distributional conflict between the member states over the centralization of enforcement was low. These further questions in spite, the framework developed here is a useful starting point for explaining various regimes for enforcement in the EU.

Chapter 3

Enforcing EU policies: why do EU legislators prefer new networks of national authorities and not existing EU agencies?

This chapter is based on: Van Kreij, L. (2022). Enforcing EU policies: why do EU legislators prefer new networks of national authorities and not existing EU agencies?. *Journal of European Public Policy*, *29*(10), 1568–1589. https://doi.org/10.1080/13501763.2022.2125045

Abstract

Networks of national authorities are often mandated to help enforce EU policies, but receive less scholarly attention than EU agencies. This chapter examines two networks in the policy areas of medical devices and aviation incident investigation. These are puzzling cases, as EU agencies existed in similar policy areas: the EMA and the EASA. Why did EU legislators mandate new networks of national authorities, and not existing EU agencies? This chapter argues that the national authorities' experts held a central position in the decision-making process and have considerably influenced the decision not to mandate the EMA and the EASA. This chapter also refines a common assumption about the Commission, and argues that it seems less keen to establish new EU agencies if these already exist in largely similar policy areas. The chapter's case studies rely on 24 interviews and an analysis of primary and secondary documentation.

3.1. Introduction

Among the various organisations involved in enforcement in the EU, EU agencies have received considerable societal and scholarly attention (e.g. Maggetti, 2019; Scholten & Luchtman, 2017; Versluis & Tar, 2013). Formal networks of national authorities, however, have generated much less interest, even though also these networks are commonly mandated by EU legislators for enforcement of EU policies. While networks and agencies can thus serve a similar purpose, little is known about EU legislators' reasons to mandate for networks of national authorities specifically. The reasons EU legislators would prefer a network to an agency for the fulfilment of enforcement tasks therefore remain unclear.

This matter becomes particularly puzzling when one policy area features a network, while a highly similar policy area features an agency – as is the case with policies for medical products and (civil) aviation safety. In the area of aviation safety, the EASA has considerable tasks for the enforcement of aircraft airworthiness rules. At the same time, the EASA has little to do with investigations of aircraft accidents such as airplane crashes or runway collisions: these investigations are carried out by national authorities and coordinated within the ENCASIA (Regulation (EU) 996/2010). A similar picture arises in the area of medical products. Even though the EMA was already responsible for the safety of medicines circulating in the EU since 1995, the enforcement of policies for medical *devices* – products such as hip joints and surgical instruments – has become coordinated by national authorities within a complex network structure (Regulation (EU) 2017/745). This network, and not the EMA, coordinates investigations and responses to potentially harmful medical devices. Why did EU legislators agree on networks for the coordination of enforcement tasks, and why did they not mandate the agencies that already existed in nearby policy fields? Addressing this question helps to illuminate the great variety of organisations involved in the enforcement of EU policy and inform further choices about their (re)design and operation.

The existing academic literature increasingly acknowledges the specificities of EU agencies and EU networks of national authorities (e.g. Vantaggiato, 2019a; Boeger & Corkin, 2017; Blauberger & Rittberger, 2015; Kelemen & Tarrant, 2011). However, the role of EU agencies and formal networks in *enforcement* receives considerably less attention, even though enforcement is crucial for the effectiveness of EU policies and impacts the design of EU organisations (Scholten, 2017; Salvador Iborra et al., 2018). When it comes to enforcement, existing scholarship on the mandating of EU agencies and networks has engaged in relatively little case study research on the decision-making that led to either type of organisation (see however Maggetti, 2019). More such research has the potential to generate a great deal of new knowledge that is crucial for scholarship to develop further.

This chapter examines why new networks of national authorities are established to coordinate EU policy enforcement, even though EU enforcement agencies already exist in highly similar policy domains. By studying the creation of networks in contexts that are already institutionalized, it aims to add to the scholarship on the differentiation between EU agencies and networks of national authorities. The chapter also seeks to provide insight into EU legislative decision-making on the enforcement of EU policies specifically.

Section 3.2 of this chapter builds upon the existing literature to construct a theoretical framework. After discussing the research design and methodology (section 3.3), the chapter proceeds to case studies of EU medical devices regulation (section 3.4) and aviation incident investigation (section 3.5) – two policy areas in which networks of national authorities coordinate EU policy enforcement. These areas have been selected because EU agencies have enforcement functions in very similar policy areas: the EMA in the field of medicines, and the EASA in the field of aviation safety. Given that agencies *were* established in these domains, case studies of medical devices policy enforcement and aviation incident investigation should help to uncover the process(es) that led EU legislators to mandate networks instead of existing EU agencies. Section 3.6 revisits the theoretical framework in light of the case studies and concludes.

3.2. Building a theoretical framework

The literature has developed several perspectives that help to explain why EU legislators establish EU agencies and networks of national authorities. This scholarship, however, largely refrains from employing these perspectives to study the mandating of these institutions *for enforcement specifically*. To fill this gap, this section first sets the scene: what is EU policy enforcement, and what is new about the involvement of EU agencies and networks of national authorities (2.1)? Building upon the existing literature, the chapter then discusses additional theoretical viewpoints for explaining the choice between EU agencies and networks for EU policy enforcement specifically (2.2). More than other government functions, the enforcement of EU policies is strongly connected to the availability of scarce resources, the conventional mandates of national authorities, and the role of expert values and methods.

New institutions for the enforcement of EU policies

The involvement of EU agencies and networks of national authorities in the enforcement of EU policies is relatively new. For several decades, EU policy enforcement – defined here as public action aimed at preventing or responding to emergencies or violations of legal norms by private actors (cf Röben, 2010) – has rather been the domain of the member states. EU involvement in member state enforcement practices was initially limited to the setting of

generic standards, but since the 1980s, EU enforcement standards for member states and their national authorities have become more numerous and detailed in order to foster the actual (and uniform) application of EU policies (De Moor-Van Vugt & Widdershoven, 2015). Moreover, the EU has increasingly created new EU institutions (Scholten, 2017; Scholten & Luchtman, 2017; Luchtman & Vervaele, 2014). Whereas the Commission itself enforces only in a limited number of policy fields, EU agencies and networks of national authorities are increasingly mandated to coordinate the gathering and sharing of case-specific information as well as responses to emergencies or non-compliance. As touched upon in the introduction, however, EU legislators differentiate between these institutions. In some domains, EU legislators agreed on an EU agency and thus mandated one actor to enforce on behalf of the EU in its entirety (e.g. the European Securities and Markets Authority, the European Railway Agency). Yet in other domains they compromised on a network of national authorities, mandating multiple actors to enforce together (e.g. the Consumer Protection Cooperation network, the Forum for Exchange of Information on Enforcement in the area of chemicals). EU agencies and networks thus appear across policy areas, and even in largely similar ones.

Explaining the choice between an EU agency and a network for EU policy enforcement

Existing scholarship on EU agencies and networks increasingly discusses why EU legislators opt for one or the other organisation (e.g. Kelemen & Tarrant, 2015; Mathieu, 2016). This literature is of course also helpful in explaining the choice between agencies and networks for EU policy enforcement. At the same time, however, EU policy enforcement has several distinct characteristics that warrant some theoretical reorientation.

The existing literature has identified resource scarcity and high technological complexity as conditions favourable to the establishment of networks (Vantaggiato, 2019b), and to some extent also to the establishment of EU agencies (Mathieu, 2020). Enforcement, however, seems particularly resource-intensive in comparison to other government functions. There are several reasons. First, all enforcement – the gathering of information about a great number of actors, their actions and the consequences thereof – requires significant operational capacity as well as legal and technical infrastructure. This also involves continuous interaction with target actors – and activity inherent to enforcement in most policy fields (cf Blauberger & Rittberger, 2015). And at a more fundamental level, the repeated application of rules naturally implies higher costs than their drafting (Parisi & Fon, 2009, pp. 12-13). Empirical findings indeed demonstrate that EU organisations with (regulatory) enforcement tasks have larger operational capacities relative to those performing other functions (Salvador Iborra et al., 2018). Although analytically distinct, resource-intensity becomes especially pronounced regarding policies with a high level of technological complexity. These policies already require scarce expert personnel and specialised infrastructure.

This resource-intensity impacts the context within which EU policy enforcement is coordinated. On the one hand, it can drive coordination: the limited resources required for enforcement may not be equally available in every jurisdiction; may be costly to maintain; or can only be acquired after long periods of time – generating a need to access resources elsewhere or to organise enforcement as cost-efficiently as possible (Vantaggiato, 2019b; Vantaggiato, 2019a; Papadopoulos, 2018; Genschel & Jachtenfuchs, 2018). On the other hand, enforcement's resource-intensity can also constrain coordination. Not only may the centralization of enforcement in an EU organisation weigh heavily on the EU budget: once acquired, legal or technical infrastructure and expertise in one (territorial or functional) jurisdiction may well be incompatible with resources in other jurisdictions. Such path dependencies could thus limit possibilities for coordinating the enforcement of EU policies (Thatcher & Coen, 2008, Mathieu, 2016).

Another characteristic of EU policy enforcement is the primary position traditionally accorded to member states' national authorities. Existing scholarship already emphasises the role of national authorities and their networks during reforms that affect their power. Their turf may be particularly threatened by a merger between the network and an institution with concurring authority, such as pre-existing agencies in nearby policy domains. National authorities may then defend their power, and if they do so successfully, separate institutions can continue to exist in parallel (Vantaggiato, 2019a; Thatcher & Coen, 2008). Among the conditions under which national authorities can succeed in influencing legislative decision-makers are their ability to organise themselves, influence political principals, and control resources (Boeger & Corkin, 2017). These conditions are highly relevant for enforcement. As mentioned above, member states and their national authorities have long been the sole actors to be mandated and supported by the EU for enforcing its policies in many policy domains. These mandates, which are often coupled with legal obligations to increase national authorities' independence and capacities, have given national legislatures and authorities ample impetuses to develop infrastructure, staff and expertise (De Moor-Van Vugt & Widdershoven, 2015).

Resources and mandate, once acquired for domestic EU law enforcement, may bring national authorities in a powerful position to influence negotiations on enforcement reforms at the EU political level. Formally, the outcome of the EU legislative process is a compromise between the Commission, the European Parliament and the Council – whereby the former two tend to prefer EU agencies for ideological and power-based reasons while distributional conflict within the Council renders networks more likely (Kelemen & Tarrant, 2011, 2015; Eberlein & Newman, 2008). It is likely, however, that national authorities weigh in heavily on formal legislators' preferences. Given their powerful position in EU policy enforcement, national authorities are among the few to provide the technical and street-level expertise formal legislators need to devise policies. National authorities will already have access in the early informal stages of

legislative decision-making, when the Commission develops policy initiatives and consults stakeholders. As the expert institutions ultimately realizing EU policies, national authorities may then prevent options from being tabled in the European Parliament and the Council in the first place. And once a proposal is negotiated in the Council, national enforcement authorities have privileged access via their national governments, who are likely to let expert professionals provide the technical input on their behalf.

We may therefore expect national authorities to have a pronounced role in the decision-making process on the coordination of EU policy enforcement. As regards their preferences, existing scholarship has already shown that national authorities seek to strengthen and defend their own arrangements in order to secure bureaucratic power (Vantaggiato, 2019a). At the same time, national authorities need not follow only political or institutional rationales. They may well coordinate for functional reasons (Mathieu, 2020; Eberlein & Newman, 2008; cf Bach et al., 2016), for example in order to share resources for more effective and efficient enforcement (see above). In the area of enforcement, however, also epistemic preferences may influence coordination. Assessing the safety or qualities of a product and establishing norm violations can be very much determined by values or methods specific to a community of professionals working within an established legal and technical infrastructure. Such communities may moreover develop a professional culture they believe is most effective for supervising the actors and behaviour in a particular policy domain. Epistemic considerations – which appear salient in complex disciplines such as medical devices and aviation safety (Schot & Schipper, 2011; Löblová, 2018) – can have a strong bearing on European integration in turn (e.g. Cross, 2011). When it comes to the differentiation between networks and agencies, it seems likely that an epistemically homogenous group makes and defends its own arrangements for enforcement coordination. Communities may protect their professional culture because of its perceived appropriateness or purported effectiveness for enforcement in a specific domain. It may therefore become problematic when vesting enforcement tasks into an existing EU agency is incompatible with the epistemic rationales of one or more powerful communities. These communities are likely to push for separate institutions for enforcement coordination.

Summarizing, we identify the following potential reasons why EU legislators mandate networks for the enforcement of EU policies while EU agencies already exist in highly similar policy areas. The need to organise operations more effectively or efficiently is likely to drive the need for enforcement coordination. National authorities are likely to play a powerful role in the process leading up to that decision, given their traditionally key position in the enforcement of EU policies. At the same time, however, existing infrastructure and expertise can also limit the possibilities for centralization. National authorities may resist integration in to an existing institution – such as an agency – on political and institutional grounds, but also epistemic

preferences may prove to be constraining factors. Budgetary considerations may in turn limit the creation of new institutions at a EU level.

3.3. Research design and methodology

In order to investigate the validity of the explanations above, I studied two policy areas in which a network of national authorities was mandated to coordinate enforcement: medical devices and aviation incident investigation. As mentioned, I selected these areas because they constitute two puzzling, or anomalous cases (Beach, 2017; Rohlfing, 2012). 'For a theory-based case selection of anomalous cases, the relevant criterion is whether the empirical analysis produced surprising insights': 'it holds that the choice of cases is (…) based on a case's cross-case scores that deviate from the theoretically expected scores' (Rohlfing, 2012, p. 92). The cases at hand are anomalous because EU legislators *did* mandate agencies in the two otherwise very similar policy areas of aviation safety certification and medicines regulation respectively (see table 3.1 below). Based on the dimensions identified by the existing literature as relevant for the differentiation between agencies and networks (see section 3.2), EU agencies in the areas of medical devices regulation and aviation incident investigation would theoretically have been the most likely outcomes. The establishment of EU networks therefore constitute failed most-likely, and therefore anomalous cases.

More specifically, the literature identified technical complexity as one reason for EU legislators to differentiate between EU agencies and networks of national authorities (Mathieu, 2020; Eberlein & Newman, 2008). The regulation of medical devices, however, appears only slightly less complex than the regulation of medicines (Eurostat, 2018). Nonetheless, an EU agency (the EMA) has been established for medicines regulation, and a network of national authorities was created for medical devices. The domains are also similar with respect to street-level expertise: medical devices as well as medicines policy enforcers need access to and knowledge about regulated actors. Therefore, the need for street-level expertise cannot explain why the enforcement of medical devices policy requires a different form of coordination (cf Blauberger & Rittberger, 2015). Variations in the degree of political conflict are equally indeterminate (cf Kelemen & Tarrant, 2011). If anything, political conflict should be less pronounced in the domain of medical devices as this industry has comparatively fewer national champions (Altenstetter & Permanand, 2007), rendering an agency more likely. The Commission, furthermore, has no existing competences for medical devices policy enforcement that could be threatened by an agency (cf Thatcher, 2011). Comparable forms of coordination, lastly, preceded both the creation of the EMA and of the network structures for medical devices (cf Thatcher & Coen, 2008).

One would also expect similar outcomes in the aviation domains. Aviation incident investigation as well as airworthiness certification revolve around highly complex products (Eurostat, 2018), and both need access to target actors in order to investigate aviation incidents or enforce airworthiness rules. Hence, street-level expertise as well as technological complexity are indeterminate (cf Mathieu, 2020; Eberlein & Newman, 2008; Blauberger & Rittberger, 2015). Again, the potential for political conflict is higher for airworthiness policies, as they those entail structural consequences for manufacturers and operators. Incident investigations are by definition not structural, which increases the likelihood of an agency for incident investigations (cf Kelemen & Tarrant, 2011). Similar to the domain of medical devices, the Commission has no existing competences to defend, and similar forms of coordination predated the EASA in the area of airworthiness policy as well as the ENCASIA in the area of aviation incident investigation (cf Thatcher, 2011; Thatcher & Coen 2008).

Table 3.1. Two puzzling cases of networks, marked in bold.

	Technical complexity	*Street-level expertise*	*Potential for political conflict*	*Commission competence*	*Pre-existing coordination*	*Outcome*
Medicines	High	Required	High	No	Yes	Agency
Medical devices	High	Required	Low	No	Yes	**Network**
Aviation safety certification	High	Required	High	No	Yes	Agency
Aviation incident investigation	High	Required	Low	No	Yes	**Network**

For both cases, I conducted within-case analyses and studied the decision-making processes that led to enforcement networks for medical devices and aviation incident investigation. The case studies draw upon a study of primary and secondary documentation, as well as 24 semi-structured interviews with (former) officials from the Commission (5), member state governments in the Council (2), EU agencies (2), national authorities (9), the industry (3) and independent experts (2). The number of interviews held for each case is nearly equal. Members of the European Parliament have not been interviewed for this chapter because access proved to be difficult. One interviewee from a consumer organisation dropped out.

As puzzling cases have been selected, many scope conditions apply to the conclusions drawn upon them (Rohlfing, 2012, pp. 201-202). One crucial limit to the conclusions I formulate for networks of national authorities is that they can only apply to cases in which 1) an EU agency already existed in a highly similar policy domain. As follows from the above, the conclusions

are furthermore limited to policy areas that are 2) resource-intensive; 3) have a high level of technical complexity; 4) require street-level expertise; where there was 5) no prior Commission competence; in which enforcement 6) was traditionally conducted by national authorities that 7) already had some coordination arrangements in place.

3.4. Case study: the enforcement of EU medical devices policy

The EU recently enacted the Medical Devices Regulation (MDR, Regulation (EU) 2017/745) to regulate the market for products such as wheelchairs, glasses, and surgical lasers. The MDR comprises several network arrangements, two of which were studied for this chapter (articles 44(10) and 89). The first are joint assessment teams, that supervise the companies (notified bodies) certifying most types of devices before they enter the market. The teams consist of Commission and national authority experts, who assess notified bodies regularly and in case of issues. The second network structure is coordinated market surveillance: when there is a shared concern about a serious incident with a medical device and/or a manufacturer's corrective action (FSCA), national authorities 'actively participate in a procedure to coordinate' their assessments of incidents and the manufacturer's FSCA. Compared to the old framework, these arrangements make for a considerably stronger coordination among national authorities. What were the reasons to opt for network structures, while EU legislators could also have agreed on expanding the EMA – the existing EU agency for medicines regulation?

Delegation to the EMA: preferred by the Commission, not by the national authorities

The need for a more efficient use of national resources fuelled increased coordination of post-marketing surveillance and enforcement vis-à-vis notified bodies. Post-marketing surveillance by national authorities, first, varied considerably depending on the availability of adequate expertise (Interview no. 31; Interview no. 15; Interview no. 4; Interview no. 6; Commission, 2008; see also Jarman et al., 2020; Greer & Löblova, 2017). According to the Commission, incongruent enforcement priorities did 'not help fill this gap': national authorities inconsistently shared case-specific information and responded differently to the same problems (Interview no. 6; Commission, 2012b, pp. 14, 16-17; Commission, 2008, pp. 2, 11-12). Lacunae in know-how also existed in the supervision of notified bodies (Interview no. 32; Interview no. 12; Interview no. 18). Even the industry found that there was room for greater uniformity in the supervision of notified bodies (Interview no. 7; EUCOMED, 2008, p. 3; AdvaMed, 2008, pp. 2 and 3; EUROM VI, 2008, p. 10; IG-NB, 2008, p. 2). These issues existed for some time before the start of the formal legislative process, which commenced after the breast implants crisis in 2010.

In 2010, the EMA was already in operation for nearly two decades. Why did EU legislators refrain from vesting medical devices enforcement tasks into this existing EU agency? The Commission's Directorate-General for health sought to involve the EMA and extend its remit to (certain classes of) medical devices, as it had limited ability to acquire sufficient staff and expertise of its own (Interview no. 30; Interview no. 31; Interview no. 32; Interview no. 18; Interview no. 12; Interview no. 7; Commission, 2008). The idea was applauded by the European Parliament as well as by the EMA itself (Interview no. 18; Interview no. 12; European Parliament, 2012). For post-market surveillance specifically, the Commission proposed that the EMA could coordinate vigilance reports and advise the Commission on restrictive measures; for notified bodies, it wanted the EMA to be able to access notified bodies' certification reports and require corrective action when needed (Commission, 2008, pp. 11-12).

National authorities, however, strongly rejected any role for the EMA in medical devices policy. They were powerfully positioned to do so: the resources that *were* available for the enforcement of medical devices policy had been acquired by the member states' national authorities, who had been in the driver's seat for assessing the safety of medical devices for almost two decades (Directive 93/42/EEC) and already developed arrangements for coordination and information-sharing among them (Interview no. 30; Interview no. 15; Interview no. 18; Interview no. 4). In their opposition to the EMA's involvement, many were eager to put forward epistemic differences between the monitoring and evaluation of medical devices and medicines respectively (Interview no. 18; Interview no. 12; Interview no. 22; Interview no. 7; Ministerie van Volksgezondheid, Welzijn en Sport, 2008, pp. 15-16; Agencia española de medicamentos y productos sanitarios, 2008, p. 14; Irish Medicines Board, 2008, pp. 11-12, 18-19; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008, pp. 1-2; Répresentation Permanente de La France auprès de l'Union européenne, 2008, pp. 13-14; EUROM VI, 2008, p. 20; Commission, 2012c, pp. 11-12; EUCOMED, 2008, pp. 2, 18; IG-NB, 2008, pp. 12-13). All interviewed (former) national authority and industry staff indicated that there was a strong fear within the medical devices community of being submerged into a pharmaceutical milieu, if the EMA became competent for medical devices (Interview no. 18; Interview no. 12; Interview no. 22; Interview no. 7; Interview no. 15; Interview no. 30). One national authority summarised the prevailing opinion regarding vigilance:

> *Under the devices regime every vigilance case is investigated […]. This is fundamentally different to that for pharma where reported problems are collected and statistically analysed to spot potential signals from a number of reports. Were the devices system to be changed in such a way that […] reports were collected until a trigger was reached we believe that this would result in a serious and unacceptable reduction in protection for public health and safety* (Medicines & Healthcare Products Regulatory Agency, 2008, p. 14).

The national authorities as well as the industry also objected to the EMA's involvement with notified bodies. They considered supervision of notified bodies a responsibility of their national authorities and not one of the EMA – the systems they already developed among themselves were the way forward (Commission, 2012c; Interview no. 7; Medicines & Healthcare Products Regulatory Agency, 2008; Direzione Generale dei Dispositivi Medici e del Servizio Farmaceutico, 2008; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008; EUCOMED, 2008, p. 17).

A strengthened network rather than a new agency

These objections were a main reason the Commission dropped the option of an extended EMA (Interview no. 30; Interview no. 31; Interview no. 32; European Commission, 2012a, pp. 10-11). Yet expansion of the EMA was not the only option on the table: another one envisaged by the responsible Commission Directorate-General was a new EU agency fully dedicated to medical devices (Interview no. 30). The idea to centralize enforcement vis-à-vis notified bodies in such a new EU body was not unpopular among national authorities, who referred to their existing forum – the Notified Body Operations Group, NBOG – as a basis for further development (e.g., Interview no. 12; Interview no. 15; Medicines & Healthcare Products Regulatory Agency, 2008; Ministerie van Volksgezondheid, Welzijn en Sport, 2008; Irish Medicines Board, 2008; Répresentation Permanente de La France auprès de l'Union européenne, 2008; Bundesministerium für Gesundheit, 2008; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008). The industry, alluding to the NBOG, also expressed support for an EU body that could monitor and ensure harmonised practices by national authorities responsible for notified bodies (EUCOMED, 2008; AdvaMed, 2008; COCIR, EDMA, EHIMA, EUCOMED, EUROMCONTACT, EUROM VI and FIDE, 2008).

The responsible Commission Directorate-General briefly considered a novel agency specifically for medical devices, but would quickly decide not to take the idea further. Higher Commission levels found an expansion of the European bureaucracy through a new EU agency too salient (Interview no. 31; Interview no. 32; Interview no. 30), but the vast resources involved in centralized enforcement also proved to be a limiting factor. Commission staff members also confirmed that a dedicated body would be too costly, particularly in comparison to the EMA's expansion (Interview no. 31; Interview no. 32; Commission, 2012b, p. 65).

Instead, EU legislators resorted to a strengthening of existing arrangements among national authorities, including joint assessment teams for notified bodies and coordinated surveillance for incidents with marketed devices. The Commission reasoned that joint assessment teams could 'probably be implemented relatively quickly since it would build on existing structures and human resources available at national level' (2012b, p. 40). This option was also long advocated and pushed for by national authorities (Interview no. 15; Commission, 2012c; Ministerie van

Volksgezondheid, Welzijn en Sport, 2008; Irish Medicines Board, 2008; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008; Répresentation Permanente de La France auprès de l'Union européenne, 2008; Laegemiddelkontoret, 2008; see also Commission, 2008). In addition, market surveillance was already coordinated within an informal realm: having anticipated future legislation and wanting to function as a central contact point for the Commission (Interview no. 18), the national authorities referred to the forums in which they already convened and jointly evaluated incidents (Interview no. 15; Irish Medicines Board, 2008). The Council would eventually hardly amend the Commission's proposal during the Council negotiations – in which national authorities' experts participated directly (Interview no. 30; Interview no. 6; Interview no. 22).

3.5. Case study: EU aviation incident investigation

The second case study is about coordination in the domain of aviation incident investigation. The EU established the ENCASIA in 2010, which convenes national authorities for the investigation of accidents and serious incidents involving civil aircraft. The network organises the dissemination of case-specific information, peer-reviews and trainings, coordinates the sharing of resources and 'appropriate assistance', and identifies which national safety recommendations are relevant for the entire EU (Regulation (EU) 996/2010). With the creation of the ENCASIA, the EU increased coordination among national incident investigation authorities. Why did EU legislators seek to strengthen coordination in the first place? And why did they not vest additional functions into the EASA – the pre-existing EU agency in the domain of airworthiness certification?

Delegation to the EASA: preferred by the Commission, not the national authorities

National authorities have long been the only actors that were legally and operationally capable of investigating incidents with civil aircraft (for non-judicial purposes). Rules from the International Civil Aviation Organisation (ICAO), as well as rules from the EU, explicitly require aviation accidents to be investigated by national authorities that are independent and that have adequate resources for their operations (Council Directive 94/56/EC; ICAO Annex 13). Furthermore – and also on the basis of ICAO rules and EU rules – it was already commonplace for national authorities to coordinate incidentally: to share the know-how, staff, and tools necessary to conduct investigations, particularly in case of major incidents that become rarer and more complex (Interview no. 14; Interview no. 23; Interview no. 9; Interview no. 1; Interview no. 11).

Nonetheless, access to resources remained insufficiently uniform. Operational capacity and expertise were relatively concentrated: some national authorities had been able to acquire bigger budgets over time, yet others had rather little resources at their disposal (Interview no.

35; Interview no. 2; Commission, 2009b; ECORYS & NLR, 2007; European Parliament, 2010b). Not only the Commission, but also the national authorities themselves recognised a need to pursue a strengthening of coordination beyond the existing arrangements described above (Commission, 2009b, p. 71; Group of Experts, 2006, p. 3).

When reform in the area of accident investigation took place around 2010, the EASA already existed for several years. The Commission was well aware and initially sought to vest incident investigation tasks into the EASA (Interview no. 35; Commission, 2007c). According to its proposal, the Commission would have become competent to appoint a representative from the EASA to partake in investigations alongside national authorities. The Commission reasoned that 'the Community should organise for its representation [at incident investigations] using the available resources from the Agency and the Member States (…) taking into account the need to use existing expertise' (EASA, 2007, p. 11).

As in the case of medical devices, however, the national authorities disagreed strongly with the Commission on the basis of epistemic considerations. Both national certifiers as well as national incident investigation bodies advocated against an expansion of the EASA's role, arguing that incident investigations should remain separated from aircraft certification (Interview no. 5; Interview no. 2; Interview no. 1; Interview no. 14; Interview no. 23; Interview no. 9; Commission, 2009b, pp. 23-25; EASA, 2007, pp. 11-12). As indicated by the broad spectrum of interviewees, conflating them might result in conflicts of interests: a certifier (EASA) may be too lenient when investigating aircraft it once certified itself, or might use investigation information for improper purposes (Interview no. 5; Interview no. 2; Interview no. 1; Interview no. 14; Interview no. 23; Interview no. 9; see also Dempsey, 2010). The separation of these functions is a longstanding convention in aviation policymaking and was already embedded in both international and EU legal frameworks (Stoop & Roed-Larsen, 2009, p. 1472). The EASA itself had already sought to participate in investigations – fuelling national authorities' need to coordinate amongst themselves (Interview no. 23). The Commission eventually ruled out expansion of the EASA as it did not expect this option 'to get the necessary support from the MS authorities' (2009b, pp. 50-51).

A strengthened network rather than a new agency

After the EASA's expansion was off the table, the Commission's Directorate-General for transport entertained the idea of establishing a novel EU agency: a European coordinator for the investigation of aviation accidents (2009a). It reasoned that a European body could enhance uniformity and generate efficiencies compared to (the then) 28 national authorities (Commission 2009b, pp. 49-50; see also ECORYS & NLR, 2007, pp. 61-62), and its proposal would have received support from the European Parliament (2010a) as well as from the industry

(Interview no. 35). The Commission's internal Impact Assessment Board, however, was critical of the proposed new coordinator:

> *The report should in particular clarify the status and administrative structure of the European Coordinator envisaged under [the then preferred, LvK] policy option 4, also against the background of the Commission's standstill policy on agencies. It should clarify the legal basis of the Coordinator, its relation with the Commission, its governance structure, and its link to the National Safety Investigation Authorities (NSIA). […] It should also be clearer about the possible budget implications […].* (Commission, 2009a, p. 2)

The Commission's final proposal no longer involved the creation of a new EU agency (Commission, 2009b). As in the case of medical devices, the responsible Directorate-General dropped this alternative mainly due to the involved political and financial costs. A new European coordinator, a Commission staff member confirmed, was politically infeasible because of a more general wariness with establishing novel EU agencies, but also because of the costs involved (Interview no. 35). A new EU agency would complement, and not supplement, the existing national authorities. This option, therefore, was 'characterised by the highest implementation risks and cost for the Community budget' (Commission, 2009b, p. 6)

Having ruled out both the EASA and a novel agency, the Commission proposed to formalise and strengthen coordination between national authorities (Commission, 2009b, p. 41). Prompted by its earlier ideas to delegate investigation tasks to the EASA, the national authorities already created the Council of European Safety Investigation Authorities and actively presented themselves to the Commission as a viable option for further strengthening (Interview no. 23; see also ENCASIA Annual Report, 2011, Appendix 1, preamble, and article 10). The national authorities as well as an external consultant hence suggested its formalization as 'a positive step towards more co-ordination regarding accident investigation' (ECORYS & NLR, 2007, p. 66). The Commission indeed proceeded in that direction, and thus allowed the national authorities to sustain their structures – after they successfully opposed expansion of the EASA.

3.6. Discussion and conclusion

This chapter aimed to explain why EU legislators mandate networks of national authorities for EU policy enforcement when they could also have attributed these enforcement tasks to agencies that already exist in highly similar policy areas. Using the cases of medical devices and aviation incident investigation, this section revisits the theoretical discussion of section 3.2.

Resource-intensity influences enforcement coordination

As argued in section 3.2, enforcement is an inherently resource-intensive and therefore costly government task. This resource-intensity may lead to a two-sided dynamic in the decision-making process on the coordination of EU policy enforcement. On the one hand, a high dependency on resources – such as infrastructure, staff and know-how – can fuel a need to cut costs and coordinate in order to organize enforcement efficiently and effectively as possible (Vantaggiato, 2019b). Once acquired, on the other hand, these resources may also constrain the possibilities to organize enforcement across jurisdictions. Existing infrastructure and know-how may not be compatible with resources in other domains and thus limit the possibilities to centralize enforcement coordination (Thatcher & Coen, 2008).

The case studies of medical devices policy and aviation incident investigation indeed indicate that this two-sided dynamic influences the choice between EU networks and EU agencies. On the one hand, different levels of operational capacities and know-how among member states fed the perceived need for enforcement coordination. To a large extent, calls for a more uniform level of resources drove reform in the first place. On the other hand, the cases also demonstrate that enforcement's resource-intensity can simultaneously limit the range of available options. Notably the professional culture that had developed within the respective domains of aviation incident investigation and medical devices proved incompatible with those in the areas of airworthiness certification and medicines policy enforcement. These incongruencies consequently limited the possibilities for vesting enforcement tasks for these policies in the respective existing EU agencies. Budgetary considerations, in turn, were a main reason for the Commission to dismiss the creation of *new* agencies fully dedicated to aviation incident investigation and the enforcement of medical devices policy (see below).

National authorities as influential suppliers of resources

The case studies also demonstrate that choice to coordinate enforcement within networks instead of EU agencies was strongly influenced by national enforcement authorities. They can play a significant role in EU decision-making process on agencies and networks, particularly if their consent is necessary for a (new) organisation's access to resources (e.g. Boeger & Corkin, 2017). Both cases provide strong indications that the national authorities were indeed key to the supply thereof. To the extent they were available at all, the expertise and infrastructure for

enforcement were located nationally rather than at the EU level. Moreover, the accumulation of these resources took place in the context of decades-long (EU) mandates to investigate aviation accidents and enforce medical devices policy on a national level. Any expansion of the EASA or the EMA would, to a large degree, have had to draw from the staff and equipment already acquired by the national authorities. Given the locus of these much-needed resources, the national authorities' agreement was highly relevant for any new organisation's creation.

The national authorities indeed seem to have benefitted from this resource-dependency when they opposed the delegation of additional tasks to existing agencies. In the case of medical devices, the national authorities pleaded strongly against the delegation of medical devices enforcement functions to the EMA; and in the case of aviation incident investigation, national authorities were equally reluctant when the Commission proposed to expand the EASA's enforcement tasks. Given their importance as suppliers of expertise and other resources, the opposition of the national enforcement authorities is likely to have influenced the outcome of the institutional reforms in both cases.

In their opposition against an expansion of the EMA and the EASA, the national authorities may have wanted to protect their bureaucratic turf and that of their existing networks (Bach et al., 2016). However, the cases indicate that their opposition was strongly connected to the perception that the values and methodology of airworthiness and medicines policy enforcement was incompatible with the existing expertise and ideas for medical devices enforcement and aviation incident investigation. Epistemic preferences, in other words, have significantly determined the national authorities' opposition towards the expansion of existing EU agencies in the adjacent policy fields. The opposition against the EMA's expansion was based on differences in enforcement methodology: the assessment of the safety of medicines was considered unsuitable for application to medical devices, and integration of medical devices tasks into the EMA would too easily amount to that. Likewise, in the field of aviation incident investigation, the national authorities jointly opposed expansion of the EASA for incident investigation because of the potential conflicts of interest. The fact that these values were broadly shared among national authorities points to the existence and influence of epistemic communities in these respective areas.

The Commission's constraints regarding agency creation

Expansion of the EMA and the EASA being off the table, one might have expected the Commission to pursue the establishment of *new* agencies specifically for medical devices regulation and aviation safety investigations. Such dedicated agencies would have resolved part of the national authorities' objections, and as discussed in section 3.2, the Commission is often assumed to prefer EU agencies to networks of national authorities for ideological and bureaucratic reasons (e.g. Kelemen & Tarrant, 2011). In line with the work of Greer and Löblova

(2017), however, the case studies of medical devices and aviation incident investigation warrant a closer look at that assumption. The Commission, although it indeed sought to attribute enforcement tasks to an *existing* EU agency, was eventually unwilling to support the *enactment of a novel EU agency* instead. The Commission clearly preferred to delegate additional tasks for the enforcement of medical devices policy to the EMA but did not create a novel agency after the EMA's expansion appeared infeasible. Similarly, when it appeared problematic to provide the EASA a substantial role in accident investigation, the responsible Commission Directorates-General did explore the establishment of novel EU agencies, but discarded their ideas given the substantial budgetary and political consequences. In the cases of medical devices and aviation incident investigation, the formalization and strengthening of existing networks turned out to be the Commission's second-best option instead.

Further research

Using the cases of medical devices and aviation incident investigation, this chapter demonstrated how the necessity, nature and locus of scarce resources can impact EU legislators' decision to mandate networks for enforcement, and not expand existing EU agencies. The case study reports thus help to reflect on theory, but they do not allow for generalizable conclusions on formal networks of national authorities and their mandating for the enforcement of EU law in general. Do national authorities with longstanding enforcement mandates play a similar role in other domains as well? And how does the resource-intensity of enforcement affect EU legislative decision-making in other policy areas, and particularly those that do not involve the same technical complexity as the cases studied for this chapter? The questions raised in this contribution are only few among the many others on EU policy enforcement that still remain unanswered.

Chapter 4

How do EU legislators design EU agencies with enforcement tasks? Case studies of the EASA and the EMA

This chapter is based on a paper that is submitted to a journal and is currently under review.

Abstract

EU policies were long enforced according to a well-established institutional model, in which member state governments made legislative, administrative and operational arrangements for realizing the policies made in Brussels. EU legislators, however, are increasingly creating EU agencies to help enforce EU policies. This chapter attempts to explain this puzzling development, and examines how the design of EU enforcement agencies relates to the member state enforcement model. Has that model affected the establishment of EU agencies with enforcement tasks, and if so, how? The chapter relies on case studies of the EASA and the EMA. These cases show that the member state enforcement model has had stabilizing as well as formative effects on the design of EU enforcement agencies. These institutionalist insights add to a discourse which has so far been mostly functional and political in nature.

4.1. Introduction

In the past decades, the EU has witnessed a great increase in the number of EU agencies. For some time the European Centre for the Development of Vocational Training (1975) and the European Foundation for the Improvement of Living and Working Conditions (1975) were the only ones. Subsequent waves of agency creation (Egeberg & Trondal, 2017), however, have now led to over 30 such agencies; the European Environmental Agency (1993), the EASA (2002), and the European Securities and Markets Authority (2011) are just three examples from a large group that continues to grow today. The European Public Prosecutor's Office (2017) and the European Labour Authority (2019) have recently commenced operations, while a novel EU agency for anti-money laundering is in the process of being established (Commission, 2021).

EU agencies, however, are not only remarkable because of their proliferation, but also because of their increasing involvement in the enforcement of EU policies. Increasingly, EU agencies are mandated to help preventing or responding to harmful and non-compliant behaviour using their own investigative and sanctioning powers, or by coordinating the exercise thereof by other institutions (Scholten & Luchtman, 2017). The EASA and the EMA, for example, have such powers to assure the safety actors and goods on the EU internal market for civil aircraft and medicines. These agencies are, among others, involved in conducting business inspections, and in deciding whether to withdraw unsafe civil aircraft and medicines from the market. In the words of Scholten, 'enforcement is moving to Brussels', and EU agencies are central to this development (Scholten, 2017; Scholten & Scholten, 2017).

The growing number of EU enforcement agencies is puzzling given to some key features of the EU. First, the architecture for effectuating EU policies was built on the premise that their implementation and enforcement is ensured, not by EU institutions, but by the member states. For several decades, the enforcement of EU law was a predominantly national affair, the EU being involved only through the setting of generic standards (Mayer, 2005; De Moor-Van Vugt & Widdershoven, 2015). This institutional paradigm, moreover, seems to have been strongly connected to the characterization of enforcement as a core competence of sovereign nation-states (Genschel & Jachtenfuchs, 2018). Also, growth of the EU's bureaucracy has regularly evoked criticism and public outcry (e.g. Hobolt & Brouard, 2011). Why, then, do EU legislators nonetheless centralize EU law enforcement in the form of EU agencies? Why do EU legislators opt for such novel and emblematic EU bureaucracies to perform tasks that used to be strongly connected to the national level? Although the creation of EU agencies has long been the subject of scholarly debate, these and other questions about the enforcement responsibilities of EU agencies specifically have not yet received sufficient attention. Dealing with them, however, is essential to fully understand the growing EU involvement in the enforcement of its policies, and the functioning of the EU more broadly.

This chapter aims to help solving this puzzle by examining the decision-making process that led to the creation of EU agencies with enforcement tasks. The chapter does so in order to explore how existing institutional paradigms on governance and enforcement in the EU may influence such decision-making processes. Has the member state enforcement model affected the establishment and design of EU agencies with enforcement tasks, and if so, how? The chapter proceeds in two stages. First, it builds a theoretical framework that reviews the available literature on the creation of EU (enforcement) agencies, and demonstrates that this literature has so far overlooked fundamental institutional features of policy enforcement in the EU. The framework theorizes the nature and potential effects of such institutional paradigms. The second part of the chapter then dissects the decision-making processes that culminated in the creation of two EU agencies with enforcement tasks: the EMA in the area of medicines regulation and the EASA in the area of aviation safety. Even though these EU agencies were not established as EU enforcement agencies *per se*, and even though their enforcement powers have grown over the past couple of decades, these agencies were the first with a role in EU policy enforcement which they acquired at the time of their establishment. The last section uses the case studies to revisit the institutionalist accounts introduced earlier.

4.2. Theoretical framework

Functional and political explanations for EU agency creation

The creation of EU agencies has generated scholarly interest for more than 20 years. Two types of views dominate the debate on EU agency creation: functional views and political ones. Functionalism, first, is the oldest perspective on EU agency creation, and may still be the main perspective today (Egeberg & Trondal, 2017). According to functionalists, the creation of an EU agency is the result of calculated deliberation among rational EU legislators for whom an EU agency is an efficient or effective way of solving one or more collective action problems. Dehousse (1997), for example, argued that member states may have difficulties in coordinating their decisions, and that EU legislators create agencies to achieve a greater deal of uniformity. Similarly, Krapohl (2004) claimed that vesting powers in an independent EU agency prevents political actors – such as national governments – from prioritizing their own, short-term interests over long-term and joint (EU) policy goals. The second main view on EU agency creation emphasizes political aspects of the creation process, and focuses on the strategic positions, interests and interactions of actors involved. Kelemen and Tarrant (2011), for example, have argued that the Commission and European Parliament prefer EU agencies for ideological as well for bureaucratic reasons. Thatcher (2011) and Mathieu (2016), however, note that the Commission tends to be more hesitant when the establishment of an EU agency

threatens its own bureaucratic power. Following Kelemen and Tarrant (2011), furthermore, the establishment of an EU agency is more likely when there is less conflict among member states about its potential distributive implications.

These functionalist and political views have helped scholars to identify EU legislators' reasons for creating EU *enforcement* agencies. Scholten and Scholten (2017), for example, have argued in this journal that the inconsistent enforcement of a single EU rule may lead to functional pressure for the centralization of enforcement into EU agencies. Uniform and centralized EU rulemaking can thus spill over into centralized EU enforcement. Elsewhere, this author has argued that the choice for EU enforcement agencies may be influenced by the fact that enforcement is a resource-intensive and costly task, which may be a functional and political imperative to centralize this government task into an EU agency (anonymized). Maggetti (2019), lastly, has argued that the non-attribution of enforcement powers to the European energy regulator could be due to the influence of business interests on the decision-making process.

Functional and political types of reasoning, however, are typically less receptive to the institutional context in which the creation of EU agencies takes place. This context, however, is highly relevant when it comes to the enforcement of EU policies. As touched upon above, the creation of EU enforcement agencies is a considerable departure from the member state enforcement model – a model that has, for several decades, been the blueprint of almost all EU policy enforcement arrangements. Within this model, member state governments held crucial positions in several ways, while EU involvement was nearly absent. Similar to arrangements common in international law (Röben 2010), EU regulatory policies were built on the premise that the member states made legislative, administrative and operational arrangements for their enforcement. Save for outlier domains (notably competition policy), national governments realized substantive norms, particularly given the sovereignty of states in organizing and wielding coercive force (Mayer, 2005; De Moor-Van Vugt & Widdershoven, 2015; Genschel & Jachtenfuchs, 2018). The notion of institutional autonomy even gave member states a considerable leeway in making their arrangements. The EU gradually became more involved in enforcement in the course of the 1980s, but even then its role remained largely confined to generic rules and largely excluded operational involvement. The Commission and ECJ did little more than monitoring member states' commitments towards the EU.

How does this well-established institutional model for EU policy enforcement square with the creation of EU enforcement agencies? After all, the establishment of *novel EU actors with a direct and active role* in enforcing EU policies seems at odds with the *nearly exclusive and well-established role of state governments* in arranging the use of coercion vis-à-vis their citizens and businesses. What were the reasons to establish EU agencies with enforcement tasks, even though the member state model was already well-established? To what extent

did functional and political arguments play a role, and how has the existing model of member state enforcement structured the decision to create EU enforcement agencies?

The effects of existing institutional models on the creation of EU enforcement agencies

The puzzling involvement of EU agencies in the direct enforcement of EU policies requires additional exploration of the role that institutional models can play in EU decision-making processes. The literature on institutionalism shows that there are many ways in which pre-existing institutional models may affect the decision-making on new organizations. This chapter explores how institutional models may have *stabilizing effects* on the one hand, and how they may have *formative* effects on the other.

One plausible stabilizing effect of well-established models is through the values embedded within them. Institutions, scholars have argued, may comprise much more than formal rules alone: a broader perspective on institutions acknowledges that they may also harness and purport values, moral frames, and constructions of meaning. And just like formal rules, these values, templates and constructions may influence policy-makers' decision-making (Hall & Taylor, 1996; March & Olsen, 2008). Policy-makers need not just design an organization to enhance policy effectiveness or according to legal requirements, but also because it is socially (or rather institutionally) legitimate to do so. Functional or political motivations may even be subordinate to social or cultural ones. The traditional institutional model for EU policy enforcement, then, may have embodied such moral frames or sets of values – and one could imagine them having exerted pressure on policy-makers to design subsequent enforcement arrangements accordingly. At face value, the tradition of national enforcement of EU and international policies and the strong link between coercive force and national sovereignty may have had such normative effects – effects that could have had an imaginable impact on the creation of EU enforcement agencies.

Existing institutional models may also affect the creation of novel organizations through the actors and interests embedded within them. Those actors may have an interest in either sustaining or changing the existing model – and thereby either have a *stabilizing* or *formative* influence on the creation of new institutions. In this context, the institutionalist literature emphasizes the role of pre-existing bodies at national level, such as national agencies, and the pan-European networks in which they work together (Thatcher, 2011; Boeger & Corkin, 2017). On the one hand, these national authorities and their networks may seek to *stabilize* the creation of a new EU agency. Existing organizations(s) have shown to defend their bureaucratic turf and oppose to a new institution if it threatens to compete with them for authority (Vantaggiato, 2019a). Research has found that powerful EU agencies have only been established in areas where pre-existing national ones did not yet have existing bureaucratic authority (Thatcher,

2011). This point is highly relevant in the context of EU law enforcement, because national agencies have long had key positions in the traditional institutional arrangements for the enforcement of EU law (this author). These organizations, then, may have an interest in retaining their enforcement authority competence and thus seek to stabilize the creation of new EU enforcement agencies. On the other hand, existing national authorities and their networks have also been shown to *stimulate* the creation of EU agencies. The institutionalist literature has shown that EU agencies may also evolve from EU networks of national authorities and inherit their predecessor's characteristics (Thatcher & Coen, 2008). To enhance their own authority, existing (networks of) national (enforcement) authorities may converge into a new agency and actively contribute to shaping it.

One last way in which existing institutional models could influence novel organizations is through the *formative* effects of models that are perceived as appropriate or suitable. Institutional designs, scholars have argued, can proliferate due to their perceived appropriateness or attractiveness (Christensen & Nielsen, 2010; Radaelli, 2000). The phenomenon is referred to as policy transfer (Dolowitz & Marsh, 1996), and particularly under conditions of uncertainty, models may transfer from one or more (geographical or policy) domains into another with varying degrees of precision. Less than for expected utility or benefit, policy-makers may shape an institution according to a particular model because of its perceived success or legitimacy (Dolowitz & Marsh, 1996). (Semi) independent government agencies seem to have been one such institutional model, which may also have affected arrangements for the enforcement of EU policies. Worldwide, agencies have been created as fitting solutions for a wide array of governance problems, including notably the independent regulation of markets at arm's length of the political arena (Levi-Faur & Jordana, 2004; Majone, 1994). In the EU, waves of agency creation also suggest transfer of the agency model: as touched upon in the introduction, EU legislators established seven between 1990 and 1995, and another 17 were created between 2000 and 2005 (Egeberg & Trondal, 2017). The attractiveness of this agency model, then, may also have had formative effects on the creation of EU agencies with enforcement tasks – EU policy-makers might have perceived the agency model as attractive in spite of well-established member state enforcement model. As it were, the creation of EU enforcement agencies may have taken place at the intersection of the agency model on the one hand and the member state enforcement model on the other – whereby the formative effects of the former may have moderated the stabilizing effects of the latter.

4.3. Research design and methodology

To explore whether and how the creation of EU enforcement agencies may have been influenced by existing institutional paradigms on governance and enforcement in the EU, this chapter uses two case studies of the European Medicines Authority (EMA) in the area of medicines regulation, and the European Aviation Safety Agency (EASA) in the area of airworthiness regulation. Case studies are suitable research designs for studying the highly complex decision-making processes that precede the establishment of EU agencies, and to explore the various ways in which the traditional institutional model for the enforcement of EU policies may have affected those processes. The case studies were conducted to explore the decision-making that led to the EMA and the EASA, to map the diversity of factors and actors that influenced their creation, and to further theory on enforcement by EU agencies.

The creation of EU enforcement agencies in the respective areas of EU medicines regulation and EU airworthiness regulation have been selected because they are deviant, passed least-likely cases. The choice for such cases is 'based on a case's cross-case scores that deviate from the theoretically expected scores' (Rohlfing, 2012). As mentioned, the EMA and the EASA were among the first EU agencies with an enforcement role – which is surprising, given the prominence of the member state enforcement model at the time of their creation. The establishment of EU enforcement agencies was therefore theoretically unlikely, but occurred nonetheless. Because the EMA and the EASA were among the first EU enforcement agencies, studying them may furthermore 'reveal more information because they motivate more actors and more basic mechanisms in the situation studied' (Flyvbjerg 2010, pp. 229-230).

The case studies draw from an analysis of primary documentation (formal documents produced in the legislative processes that led up to the EASA and the EMA), secondary documentation (academic literature or news items), and interviews. These sources have first been quick-scanned for their relevant parts, most of which were then iteratively coded using QSR NVivo. Regarding the interviews, the chapter specifically draws from 17 semi-structured interviews with participants from various stakeholder categories. These interviews were structured around a topic list. As demonstrated below, the results from the documentation study and interviews have been triangulated to ensure their validity. On the condition of anonymity and confidentiality, interviews were held with people who've held positions as a senior Commission official (2), a member of European Parliament (1), a senior official at a national ministry or national competent authority (9), a senior position at the EMA or the EASA (7), and/or industry (2). The interviewees from national competent authorities have held those positions in five of the 11 EU member states at the time of the EMA's and the EASA's creation (Belgium, France, Germany, the Netherlands, and Spain). All interviewees were well-informed about the establishment of the EASA and the EMA and/or the initial years of their functioning.

Some interviewees have held positions at multiple organizations. The number of interviews, lastly, is nearly similar for each case.

4.4. Case study: the EMA and the enforcement of EU medicines policy

The EMA was established in 1995, and since its inception, it assesses highly innovative pharmaceuticals including those manufactured through biotechnology (Regulation (EEC) 2309/93). Companies can apply for a license with EU-wide validity, after which the EMA reviews the application and advises the Commission about its issuing. For enforcement, the EMA can advise the Commission to amend, suspend, or withdraw the license. The agency itself has no operational capacity to retrieve information about the safety of medicines on the market (pharmacovigilance) and it does not have dedicated staff for company inspections. However, since its establishment, the EMA coordinates inspections and pharmacovigilance as carried out by the national authorities. The national authorities share relevant information with the agency.

The functional and political need for reforming the EMA's predecessor

Before becoming a constituent part of the EMA, the Committee for Proprietary Medical Products (CPMP) was the only EU body involved in assessing medicines. The CPMP had long been central to the EU agenda of unifying medicines regulation, already in place since 1963 (Vogel, 1998). Several years after its first attempt to come to harmonized substantive rules, the EU sought to achieve single decision-making in 1975 with the establishment of the CPMP. The CPMP initially gave only non-binding reviews to member states, but was gradually strengthened in 1983 and again in 1987. The latter reform allowed the CPMP to review pharmaceutical companies' applications when one member state objected to mutually recognizing a license as issued by another member state. Regarding enforcement, the CPMP exchanged pharmacovigilance information among member states, gave opinions on unwanted side-effects on request, and – in these cases – sought to coordinate national decisions (Council Directive 75/319/EEC; Commission, 1989a; Sauer, 1994).

The CPMP's reforms, however, stopped short of changing the non-binding nature of its assessments, even though member states remained hesitant to mutually recognize each other's licensing decisions. They regularly re-examined applications while licenses had already been granted by other states, evoking criticism from the industry and the Commission (Interview no. 10; Commission, 1989b). In search for the causes thereof, the Commission pointed to "the absence of confidence in the evaluation of the initial authority, the absence of political will to implement mutual recognition in practice, (…) the unwillingness of experts and national

scientific committees to accept outside advice, [and] disguised protectionism" (Commission, 1989b; also Interview no. 10).

The EMA was established in 1995, and its assessments became a prerequisite for a binding EU-wide license from the Commission. The transition from the CPMP and to the EMA was primarily intended to reform initial medicines licensing. Enforcement, however, was much less salient: the Commission was critical of the CPMP's pharmacovigilance arrangements, but according to an official, only consumers and the European Parliament found them problematic (Sauer, 1994; Abraham & Lewis, 2000). Overall, there was little concern about the safety of medicines on the market – the concept of pharmacovigilance, a Commission interviewee noted, was even in the 1990s still relatively underdeveloped (Interview no. 20).

Stabilizing effects of pre-existing institutional models

When it comes to the domain of medicines policy, the member state model for EU policy enforcement has indeed had two constraining effects on the design of the EMA. First, and specifically in the context of inspections, there was a broadly shared inclination to keep things the way they were. Many found it inappropriate to vest any operational inspection apparatus in the EMA. Not only the national authorities, but also the Commission and the European Parliament perceived inspections as a fundamentally national task – which had, shortly before the EMA's establishment, been affirmed with the Pharmaceutical Inspection Convention and EU legislation (Interview no. 20; Interview no. 16). The European Parliament found inspections to be "implementation measures in the strict sense, given which the sole competent authorities are the national authorities," from which "[i]t follows that *there is no case* for replacing national authorities by Community authorities (or 'Community agents') for these functions" (European Parliament, 1991b, p. 98, emphasis added; Interview no. 25). Commentators agreed (Jones, 1989; Gardner, 1996), and also the Commission noted that "[i]n accordance with the general principles laid down in the Community pharmaceutical directives, the primary *responsibility* for the supervision of manufacturers lies with the competent authorities of the Member State in which the manufacturer is established" (Commission, 1990b, p. 33; emphasis added). An involved Commission official explained that inspectors were even perceived as something akin to a police force – which was the domain of member states proper (Interview no. 20).

One reform *did* take place in the context of enforcement. Unlike a CPMP opinion, an EMA advise to suspend, amend, or revoke an existing license could become binding upon Commission affirmation. The attribution of this enforcement power, however, was merely seen as the logical corollary of EMA's licensing functions. For the Commission, the ability to coordinate market access also implied an ability to advise on suspensions, amendments or revocations: "A coordinated approach to the granting of marketing authorization of biotechnology/high-

technology medicinal products necessarily implies the same for suspensions or withdrawals" (Sauer, 1991, p. 463).

The second stabilizing effect of the member state enforcement model is national authorities' reluctance regarding the establishment of the EMA. The agency's creation was more the result of the Commission's staunch commitment to binding decision-making than of broad support from the national authorities within the CPMP (Interview no. 16; Interview no. 24). As mentioned, the EMA would eventually get decision-making authority, but the scope thereof was limited to biotechnology and other highly innovative medicine. This constituted a novel area of scientific expertise in which national authorities had little existing competencies to defend and much expertise to acquire (Interview no. 10; Interview no. 16). The Commission sought to balance the member states' position and its internal market agenda, and therefore proposed to limit the agency's responsibilities "to ensure the progressive establishment of the Agency and a smooth transfer of responsibilities from the Member States to the Community" (Commission, 1990b, p. 19). Also the CPMP's decentralized working arrangements remained untouched: member states would continue to take turns in assessing medicines applications. The Commission thus saw creation of the EMA as a pooling of member states' resources rather than the establishment of "a massive European Drug Administration" – referring to the Food and Drug Administration in the United States (Commission, 1990b, p. 12).

Formative effects of pre-existing institutional models

As discussed in the theoretical framework, pre-existing institutional models may also have formative effects on the creation of new organizations. In the case of medicines policy, the popularity of agencies in other domains has indeed influenced the establishment of the EMA. A Commission official and European Parliament member confirmed that EU legislators were not only inspired by the United States Food and Drug Administration (see above); they also drew upon trends in the member states, whereby medicines assessments were frequently entrusted to semi-independent agencies. This proliferation of medicines agencies across European states took place to increase "the responsiveness of regulators to industrial demands at minimal expense to the state" (Abraham & Lewis, 2000, pp. 77-78), and the Commission considered that member states' reasons establishing semi-independent were also valid for the EU (Commission, 1990b; Interview no. 20). Echoing them, the Commission wished to "ensure that the administrative arrangements which are adopted are sufficiently flexible to allow for the rapid recruitment and redeployment of personnel" (Commission, 1990b, p. 14). "[F]or managerial and budgetary reasons," the assessment and continuing supervision of novel medicines "would be undertaken better within an Independent European Agency for the Evaluation of Medicinal Products rather than within the Commision [sic] itself" (Commission, 1990b, p. 1). Also the choice to make medicines licenses *formally* conditional upon Commission approval reflected

a common design of national authorities: in most member states, government ministers and not national authorities had the final word on medicines approval (Interview no. 20).

4.5. Case study: the EASA and the enforcement of EU airworthiness policy

When EU legislators created the EASA in 2003, the agency acquired enforcement powers in the context of aircraft design companies and aircraft design licenses. The EASA specifically licenses *type-designs*, which are issued when an aircraft design (typically intended for serial production) meets the applicable airworthiness requirements. After initial licensing, the EASA continues to enforce them: it monitors compliance with airworthiness requirements and can therefore investigate design companies and their assets; and it can amend, suspend or revoke licenses if necessary. The agency also conducts standardization inspections of national authorities for (among others) their supervision of production and maintenance organizations. For these tasks, the EASA has a dedicated staff (Regulation 1592/2002).

The functional and political need for reforming the EASA's predecessor

When the EASA was established, it succeeded the Joint Aviation Authorities (JAA). The JAA existed since 1970 and was an informal forum of European national civil aviation authorities seeking to make joint airworthiness policies (JAA, 2000; see also Manuhutu, 2000; Malanik, 1997). The JAA specifically worked on so-called Joint Aviation Requirements: jointly agreed informal rules which were implemented into the national laws of the participating national authorities. Later, by approximately 1990, the JAA also started developing *procedures for joint aircraft licensing* (JAA, 2000; Interview no. 34; Interview no. 8; emphasis added). These specifically covered the inspections part of the licensing process: whereas all national authorities first conducted separate inspections, a JAA team would now conduct only one round of inspections for all JAA members. These joint inspections allowed the industry and member states to cut costs, even though licenses would still be issued nationally (Interview no. 8; Interview no. 5; Commission, 1994).

Yet in spite of these efforts, the JAA was unable to develop a uniform airworthiness framework. Various interviewees confirmed that regulatory differences remained (Interview no. 8; Interview no. 5; Interview no. 11). States did not succeed in committing to joint decision-making and rule implementation, due to different conceptions of airworthiness (Interview no. 8; Interview no. 5) and diverging interests of national airlines, airports, and unions (Pierre and Peters, 2009; Commission, 1997). EU legislators' efforts to overcome these deficits through incorporation into EU law failed too (Commission, 2001c; Malanik, 1997). Several interviewees also indicated there was not enough confidence between national authorities for the mutual recognition of national

licenses for type designs or maintenance organizations – at least not without (standardization) inspections of each other's work (Interview no. 8); Interview no. 34).

In order to overcome these deficits, reform of the JAA – which later culminated into the EASA – started in the first half of the 1990s (Commission, 1994). These reforms focused on rule-making and initial licensing rather than on enforcement; and were motivated by economic rather than by safety concerns. A system for EU-wide licensing by one body was seen as beneficial for both the industry and the EU: it would reduce the European industry's costs and enhance its competitive position, and help realize the Commission's internal market agenda (Commission, 1997; Commission, 2002; Commission, 1996b). Safety concerns may have sped up reform, but had no substantive influence. An accident in 1996 led the European Parliament and the Council to stress the importance of JAA reform (European Parliament, 1996; Commission, 1996a; Malanik, 1997), but these concerns were about the quality of aircraft of *non-JAA countries* (Manuhutu, 2000; Interview no. 3). None of the interviewees recalled any other specific safety incident that determined the substantive transition from JAA to the EASA.

Stabilizing effects of pre-existing institutional models

There was, in other words, both a functional and political need for reform – safety concerns gave it some momentum, but did not determine its course. This also holds true for the EASA's enforcement powers. There was broad agreement that the EASA should have the power to conduct inspections regarding the type certificates it issued for initial market access. As mentioned, the JAA long held joint inspections, which alleviated costs for both manufacturers and national authorities (Interview no. 5). The JAA and Commission sought to continue this function in the novel agency (Commission, 1996b), and received strong support from the member states in the Council (Council, 2001b). Also the agency's ability to inspect national authorities evoked little discussion: it was inherited from the JAA, which already organized inspections to standardize the work of the member states' competent authorities (see above). The Commission thus felt that a continuation of those standardization inspections in the EASA was required to secure the mutual recognition of relevant licenses (Commission, 2000).

The broad agreement on the need for centralized enforcement functions seems to contradict the expectation that the well-established member state enforcement model has affected the centralization of EU policy enforcement. Still, however, the agency's designers seem to have been unsure as to what was appropriate in the context of EU law enforcement. Not only did the Commission model the wording of the EASA's inspection powers on the Commission's own existing powers for competition policy (Council, 2001b); also the Council wanted to find out how such powers were designed in other policy domains. It therefore commissioned a comprehensive inventory of centralized inspection powers in the EU more generally (Council, 2001b; Council, 2001c). A similar dynamic characterizes the EASA's powers for standardization

inspections: although the Commission wanted the EASA to continue the inspections of the member states as they were previously administered by the JAA, it equally attached value to the conventional enforcement model whereby only "[t]he Commission is responsible for monitoring the application of common rules at national level" (Commission, 2000, p. 7). The Council likewise felt uncomfortable to delegate to the EASA an enforcement function that is traditionally performed by the Commission, and changed the agency's competence to reflect a more subordinate position. When reviewing the legal provisions that circumscribed the EASA's powers for standardization inspections, the Council specifically inserted that the 'the Agency shall assist the Commission for the monitoring of the application of this Regulation', and that this is without 'prejudice to the enforcement powers conferred by the Treaty *to the Commission* (Council, 2001b, emphasis added).

Formative effects of pre-existing institutional models

The theoretical framework also presumed that national authorities – who have had key positions within the member state enforcement model – may oppose the establishment of an EU agency if it threatens their existing competencies. The national authorities and the existing JAA were indeed key to the creation of the EASA, but instead of opposing its creation, they generally supported and actively helped to shape it. The national authorities themselves long sought to strengthen the JAA and already since 1992 discussed the JAA's transformation into "a kind of agency" or international organization (Manuhutu, 2000; Interview no. 34). The national authorities even drafted the earliest proposal for JAA reform, which intended formalize the JAA into an international organization and render its airworthiness rules binding upon the member states (Malanik 1997; Commission 1996a; Interview no. 34). At first, the national authorities intended to keep the administration of type certificates at a national level. According to the Commission, however, this would continue to imply high costs for the industry and negatively affect its competitiveness (Commission, 1996a). The Commission thus issued a concurring proposal for a body *with* licensing powers (Malanik, 1997, pp. 123-124; Commission, 1996a). The Commission nonetheless realized the importance of building upon the pre-existing JAA for its staff and expertise (Commission, 1996b, p. 9; George, 1997; Malanik, 1997; Council, 2001a; Interview no. 27), and therefore wrote to the Council that there would also "be advantage in convincing [the] National Aviation Authorities to carry out jointly as many of their executive tasks as possible" (Commission, 1996b). The Council – that already in 1994 called for a consideration of joint airworthiness certification (Commission, 2002) – eventually agreed to the Commission's proposal in 1998, but reiterated that the novel body would have to "draw on expertise available in the aviation regulatory authorities of full members" (Council, 1998).

The theoretical framework also suggested that institutions can serve as powerful examples for decision-makers in other policy domains if they are seen as appropriate solutions. In the case of aviation safety, decision-makers were indeed long receptive to the agency-model as

it proliferated in other policy domains. As mentioned, the JAA and the Commission initially worked on a treaty-based international organization, but establishment of that institution became highly uncertain due to constitutional issues in some states. The agency-model, which had been on the table since the beginning of the reform process, came back in sight. The Commission as well as the European Parliament already voiced their preference for an agency in 1990 (Commission, 1990a; European Parliament, 1991; Commission, 1994) and also the JAA members considered the idea early on (see above). Characterizing discussions within the EU and the JAA, a JAA staff member specifically noted that "[i]t was felt that a body comparable to the US Federal Aviation Administration (FAA) should be created" (Manuhutu, 2000; Interview no. 34). Also the Commission and the Parliament explicitly marked the existing institutions in the United States as a model for European airworthiness policy (Commission, 1992; European Parliament, 1991; Commission, 2006) not least because of its benefits for the manufacturing industry. The Commission therefore urged, "in order not to put the European industry at a disadvantage," that costs be reduced by an efficient bureaucracy that pools expertise, avoids duplication of work, and exposes the industry to a single procedure delivering a license with EU-wide validity (Commission, 1996b, pp. 2-3 and 7-8).

4.6. Discussion and conclusion

The processes leading to the establishment of EU enforcement agencies are highly complex, and driven by mixes of functional, political and institutional imperatives. This chapter focuses on the latter, given the puzzling departure from the member state enforcement model with the creation of EU enforcement agencies. As it turned out, the well-established member state model for EU policy enforcement has indeed affected the creation and design of the EASA and the EMA. The case studies have revealed several effects of the pre-existing EU enforcement model on the creation of EU enforcement agencies.

Stabilizing effects of the member state enforcement model

First, as set out in the theoretical framework, well-established institutions may affect policy-making processes because of the moral frames or values embedded within them. In the context of EU policy enforcement, a long tradition of enforcing EU and international policies on a national level, and conceptual links between national sovereignty and the use of coercive force, could turn out to be morally constraining aspects of the member state enforcement model. The case studies indeed indicate that such considerations impacted and framed the thinking about the creation of the EASA and the EMA. At the very least, moral considerations triggered hesitancy when decision-makers discussed the attribution and design of enforcement powers. The effect is best illustrated by the case of medicines policy, in which the idea of vesting operational inspection capacities in the EMA was rejected by the broad spectrum

of stakeholders. Crucially, this rejection did not stem from legal limitations or obstacles, but from the very belief that existing legal constructs were compelling arguments for denying the new EMA an autonomous inspectorate. The fact that national authorities' role in inspections reflected principles of EU law and had recently been (re)affirmed was not considered as a legal impediment to EMA inspectors, but as a morally persuasive frame for the design of a new medicines agency. Also, had existing legal constructs been limitations in the narrow sense, they could have been overcome by passing new legislation. The fact that even supranational institutions disapproved an EMA inspectorate underscores the moral effects of the member state enforcement model, for these organizations would otherwise have plausible functional, political and institutional interests in centralizing inspections. The member state enforcement model also had a morally stabilizing effect on the establishment of the EASA, even though the *functional necessity* of centralized inspections was undisputed: the EASA's predecessor already performed joint inspections for almost a decade and demonstrated its economic benefits in the context of aircraft licensing. Still, however, the contrast between EU agency inspections and the premise of the member state enforcement model caused uncertainty. As EU legislators moved into relatively uncharted terrain by agreeing to EU agency inspections, they sought to align the design and legal circumscription of the agency's enforcement powers with what had been common in the member state enforcement model.

Institutional effects of the member state enforcement model

A second way in which the member state enforcement model seems to have affected the creation of EU enforcement agencies is through the pre-existing actors that were already engaged in enforcing EU policies. As discussed earlier, research has shown that existing national organizations may (together) seek to influence the creation of new European ones with a competitive claim to authority. Depending on their preferences, national enforcement authorities might then either stabilize or stimulate the establishment of a new EU agency with enforcement tasks. The case studies indeed show that national authorities and the institutions in which they already cooperated have formed a blueprint for the EMA's and the EASA's role in enforcement. In the case of EU medicines policy, pre-existing national authorities turned out to have a stabilizing influence on the creation of the EMA. This effect is best illustrated by the EMA's substantive decision-making scope, which became limited to the area of biotechnology and other highly innovative medicine, because in these areas, national authorities had little authority to lose and much expertise to gain. An operational role by the EMA in company inspections, furthermore, was pre-empted by a recently concluded convention which put national authorities in a position that they weren't willing to give up again soon. In the case of airworthiness policy, however, the national authorities within the JAA were committed to the creation of a stronger European organization. The JAA had demonstrated the benefits of joint company and standardization inspections, which were to be retained in the EASA. The support of national authorities, who had crucial positions within the old member state enforcement

model, stimulated the establishment of the EASA, and provided the new agency a considerable deal of legitimacy.

The effects of the agency model

As discussed in the theoretical framework, existing institutional models may also stimulate the creation of similar other models. When perceived as appropriate or fitting, particular institutional designs may proliferate across policy domains in a more or less consistent way. Both cases indeed indicate that the model of (semi) independent government agencies has had a formative effect on the creation of the EASA and the EMA, while the effects of the agency model moderated the implications of the member state enforcement model. When opting for EU agencies as the final institutional design, policy-makers in both cases consistently referred to existing agencies in other national policy domains, and in one way or another considered the agency model as a guiding point of reference. In the case of the EASA as well as in the case of the EMA, decision-makers were particularly inspired by counterpart (federal) agencies in the United States – the FAA was repeatedly referred to in the case of airworthiness policy, and the FDA in the case of medicines policy. In both cases, EU policy-makers perceived these U.S. agencies as reputable regulators in their respective domains. The cases furthermore demonstrate that the formative effects of the agency model have moderated the effects of the member state enforcement model: although pre-existing enforcement arrangements resonated in their designs and enforcement powers, EU policy-makers have not seen the creation of EU enforcement agencies as necessarily incompatible with the well-established model for EU policy enforcement.

Further research

This chapter thus explored the various ways in which existing institutional paradigms on governance and enforcement in the EU influence the establishment of EU enforcement agencies. As was shown, the member state enforcement model has not only stabilized, but also contributed to forming their creation. The insights from the literature on institutionalism thus shed a helpful additional light on the establishment of EU enforcement agencies, and thereby add to the existing functional and political perspectives. Together, these theoretical perspectives contribute to a more comprehensive explanation of the role that EU agencies have in the enforcement of EU policies. In the words of Jupille, Caporaso and Checkel (2003), the dialogue between rationalist and institutionalist theories of EU agencies need not be competitive, but seem complementary instead.

This chapter thus helped to reconstruct the establishment processes of the EMA and the EASA. I do not, however, claim exhaustiveness, nor any generalizability, on the basis of the case studies conducted for this study. This chapter focussed on two puzzling cases only, and therefore its conclusions cannot be generalized towards other cases. At the same time, the conclusions

drawn here are suitable as theoretical input, to be validated, amended, or rejected through the study of other EU agencies. This chapter is furthermore among the few that studied EU agencies with specific attention for their enforcement functions. Its institutionalist perspective adds to the mainly functional and political contributions on EU enforcement agencies, and in doing so, helps to reflect on the changing nature and functioning of the EU more broadly. As mentioned in the introduction, however, many more agencies have been established in the past decades, and their establishment processes must be fertile objects for analysis. EU agencies in the AFSJ warrant particular attention, for their institutional context is yet again entirely different. Additional case study research into the establishment of other EU enforcement agencies, as well as the expansion of existing ones, is more than welcome.

Chapter 5

The choice for EU agencies or networks of national authorities: Exploring the relevance of regulated industry characteristics

This chapter is based on: Van Kreij, L. (forthcoming 2023). The choice for EU agencies or networks of national authorities: Exploring the relevance of regulated industry characteristics. In M. Scholten (Ed.), Research Handbook on the Enforcement of EU Law. Edward Elgar Publishing.

Abstract

EU agencies and networks of national authorities are two different types of institutions involved in enforcing EU policies. Despite their proliferation, it is not fully understood why EU legislators choose between them. What explains EU legislators' preference? Existing scholarship points at the need for effective engagement with regulated industries as one potential explanation. This chapter further explores that relationship: to what extent can regulated industry characteristics explain the choice for EU agencies or networks of national authorities? The chapter relies on a comparative analysis of four case studies in the areas of public health and aviation, which are based on 37 interviews and archival research. The chapter finds that the choice between institutional designs indeed relates to a regulated industry's degree of concentration. This paper furthermore finds that the distinction between agencies and networks is not always clear-cut, and calls for a focus on the specific tasks they perform.

5.1. Introduction

The role of the EU in the enforcement of its policies has changed considerably over time. During the EU's first four decades, its involvement in enforcement was indirect at most – not EU institutions, but the member states were responsible for enforcing the substantive norms made in 'Brussels'. In addition to the member states, however, two other types of institutions have recently become involved in enforcing EU policies (Scholten, 2017). First, *EU agencies*: of the more than 30 agencies that have been created since the 1990s, at least nine agencies have active roles in EU policy enforcement (Scholten & Luchtman, 2017). The EASA and the European Maritime Safety Agency, for example, enforce civil aviation and maritime safety policies. Second, formal *networks of national authorities* are increasingly involved in the enforcement of EU policies. Prominent examples of such networks are the European Competition Network and the Consumer Protection Cooperation Network.

When setting up the enforcement of EU policies, EU legislators seem to choose between these two institutional designs. After all, some policy areas feature an EU agency for enforcement coordination, while a network of national authorities helps to enforce in another policy domain. Why do EU legislators choose one institutional design and not the other, even if policy areas are otherwise highly similar? The EASA, for example, has enforcement tasks in the area of airworthiness regulation whereas the ENCASIA coordinates accident and incident investigations. Why does the EU attribute enforcement tasks to an EU agency in one policy domain, whereas it relies on a network of national authorities in the other?

A potential explanation for the choice of either institution's involvement in EU policy enforcement could be related to the characteristics of a regulated industry. Enforcement hinges on interaction with corporations: when responding to emergencies or non-compliance, enforcement authorities handle organizations and individuals, objects such as files or products, and on various locations. Enforcers engage with the regulated industries, as well as with the actors negatively affected by non-compliant or harmful behaviour. Yet industries differ in their characteristics: some policies apply to industries with many small and local corporations, whereas other policies apply to small groups of large corporations operating across the EU. Such differences among regulated industries could be relevant for the design of enforcement institutions, including the choice between EU agencies or networks of national authorities.

Existing research shows that various functional, political and institutional factors can explain the creation of networks of national authorities and the creation of EU agencies. Within this growing body of literature, however, the characteristics of regulated industries remain surprisingly understudied: so far only two contributions argue that the nature of the interaction with regulatees is relevant to the creation of EU networks and agencies (Blauberger & Rittberger,

2015; Pierre & Peters, 2009). More in general, explanatory scholarship on EU policy enforcement remains limited (but see Heidbreder, 2017; Maggetti, 2019; Scholten & Scholten, 2017; Scholten, 2017). The existing literature could benefit from more research into the institutions enforcing EU norms vis-à-vis citizens and businesses, to elucidate the variety of reasons that influence their design.

This chapter therefore explores the relation between institutional design of enforcement on the one hand and industry characteristics on the other. It asks: to what extent do differences among regulated industries have an effect on the choice between EU enforcement agencies and networks of national authorities? In order to answer this question, the chapter first theorizes the role of regulated industry characteristics in institutional design. Based on existing literature, the theoretical framework identifies three potential explanations for the choice between EU enforcement agencies and networks of national authorities.

The potential of these explanations is then examined through a comparison of several case studies. This chapter adopts a most-similar design. The analysis thus involves two pairs of most-similar cases: the cases in each pair are similar in many respects, yet differ when it comes to the institution that coordinates enforcement. This set up allows us to flesh out whether institutional design for the enforcement of EU policies is indeed affected by regulated industry characteristics. The two pairs of cases selected for this chapter are EU civil aviation airworthiness policy and incident investigation, and medical devices policy and pharmaceuticals policy. Each of these pairs thus involves a case with an EU agency (pharmaceuticals policy and aviation safety policy) and a case with a network of national authorities (civil aviation incident investigation and medical devices policy). After discussing this research strategy more elaborately in section 5.3, the results of the comparative analysis are presented in section 5.4. Section 5.5 discusses the results and concludes that the nature of a regulated industry may indeed have an effect on the design the institutions tasked with enforcing EU policies.

5.2. Theory on EU agencies, networks and the relevance of regulated industries

Distinguishing EU agencies from networks of national authorities

EU agencies and networks of national authorities have become pervasive features of the EU. As mentioned, legislators have established over 30 agencies at the time of writing. They are created less frequently than before (Egeberg & Trondal, 2017), but existing EU agencies are also regularly expanded to perform additional (enforcement) tasks (Scholten & Luchtman, 2017). Likewise, the number of networks of national authorities is growing: approximately 20 networks are currently involved in enforcing EU policies (Scholten, 2017). EU agencies and networks of national authorities have proliferated to such an extent that they are now central actors in the direct and networked enforcement of EU policies.

EU agencies and networks of national authorities are thus both frequently mandated to perform enforcement tasks. Yet at the same time, they are two very different types of institutions. Each has some inherent abilities and characteristics the other does not. First, only EU agencies can be mandated to draft or issue decisions that are binding upon regulated industries. Networks cannot, as they lack legal personality and are no unitary actor. Second, only EU agencies can have jurisdiction over the EU in its entirety – a network is bound by the jurisdictions of the national authorities deciding to cooperate within it. EU agencies, furthermore, tend to be more independent from national administrations than networks (Thatcher & Coen, 2008). And most importantly: networks and agencies are *treated* as different types of institutions. Given that some policy areas feature agencies while others feature an EU network (see above), EU legislators seem to have good reasons for choosing between them.

Existing explanations for EU agencies and networks

Scholars have suggested various explanations for the creation of EU agencies (see Egeberg & Trondal, 2017 and Chamon, 2016 for overviews) and networks respectively (see Boeger & Corkin, 2017 for a succinct overview). Increasingly, scholars also seek to explain EU legislators' reasons for choosing *between* these two institutions. Such explanations can be brought under three headers and are not mutually exclusive (cf Kelemen & Tarrant, 2011). Functionalist contributions, firstly, emphasize considerations of utility: EU agencies and networks are established to benefit the effectiveness or efficiency of EU policies. This literature specifically suggests that the choice between institutional designs relates to legislators' preference for coordinated policy implementation, credible commitment, or an efficient gathering of expertise in complex policy areas (Eberlein & Newman, 2008; Mathieu, 2016). The politically oriented literature, secondly, rather sees EU agencies or networks as vehicles for political actors to realize their strategic interests. Legislators' institutional preferences would, for example, be determined by national distributive concerns (Kelemen and Tarrant 2011) or by considerations of bureaucratic

control (Vantaggiato, 2019a). And a third way to view EU agencies and networks is through an institutionalist lens. Institutionalists argue that their creation is path-dependent and primarily depends on the nature and shape of pre-existing arrangements. Pre-existing may transfer characteristics to the institutions replacing them, or resist the creation of new competitors (Boeger & Corkin, 2017).

Only two existing contributions discuss how interaction with regulated industries can be relevant for the creation of EU agencies and networks. Pierre and Peters (2009) locate their contribution in the institutionalist debate, but admit that their explanation is 'to some extent' also functionalist (p. 342). They argue that the institutionalization of public organizations 'is closely related to the nature of the environment within which it functions', and they are keen to highlight 'the importance of interaction between the public and private sectors in the process of institutionalization' (p. 342). The authors specifically argue that '[i]f a poorly institutionalized regulatory organization confronts a well-organized and powerful industry, the chances of successful regulation are minimal and the probabilities of regulatory capture are enhanced. Likewise, if a well-institutionalized regulatory structure confronts a poorly organized set of institutions in its environment it may be able to regulate in a command and control sense, but not be able to engage in more productive forms of bargaining with the environment' (p. 342). Such concentration of the environment, according to Pierre and Peters, can thus partly explain the institutionalization of public organizations. While defining institutionalization as 'routinizing informal practices to create greater predictability', they apply their argument to the creation of an EU agency specifically (p. 339). An EU agency, as an instance of a high institutionalization levels, can thus be seen as a response to 'some need for relatively similar levels of institutionalization between regulators and the regulated' (p. 342).

Blauberger and Rittberger (2015, 2017), secondly, rely on a similar (functionalist) argument but seek to explain the creation of a network instead. They argue that EU legislators opt for networks of national authorities to optimize interaction between the EU and 'target actors, such as firms' (2015, p. 370). Networks can deliver 'a high level of local, street-level expertise', comprising knowledge 'on the particular workings of the target actors, as well as access' to them (p. 370). Because of these capacities, networks moreover 'tend to provide functional advantages over alternative regulatory institutions' (p. 370). EU agencies, Blauberger and Rittberger claim, 'tend to have neither the personnel and financial capacities nor the local knowledge to effectively orchestrate the target actors' (p. 370). Networks of national authorities thus seem to 'thrive in policy areas where the EU's regulatory competencies are highly developed, but its operational capacities are particularly weak' (p. 370).

While these are valuable contributions for the scholarly debate on EU agencies and networks that are involved in enforcement, they leave room for further refinement. First, the contributions

do not explicitly address differentiation *between* agencies and networks. Blauberger and Rittberger imply that *only* networks, and not EU agencies, are able to possess knowledge of and access to 'target actors'. EU agencies are quickly written out of the equation, and potentially relevant differences *among* groups of 'target actors' are not discussed. Likewise, Pierre and Peters focus primarily on an EU agency as a form of high institutionalization. While they state that a 'poorly institutionalized regulatory organization' is not successful when confronting 'a well-organized and powerful industry' (Pierre & Peters, 2009, p. 342), it remains unclear whether such an organization is more effective vis-à-vis a more fragmented industry. Both contributions thereby refrain from discussing the choice *between* networks and EU agencies, and the relevance of interaction with *different* regulated industries. Second, both contributions rely on functionalist arguments of policy utility. In doing so, neither contribution accounts for a more political relationship between policy environments and the choice between EU agencies and networks. Other literature, however, shows that political explanations bear fruit when it comes to closely related aspects of institutional design (Kelemen & Tarrant, 2011).

Novel explanations: the relevance of regulated industries

In order to get a more comprehensive understanding of EU legislators' choice between EU agencies and networks for EU policy enforcement, we should thus account for relevant differences between regulated industries and include other non-functional explanations. The paragraphs hereafter discuss two mechanisms – street-level expertise and bureaucratic turf – which may help to better understand the relationship between regulated industries and the choice between EU agencies and networks for EU policy enforcement.

Different types of street-level expertise

As Blauberger and Rittberger and Pierre and Peters have underscored, the need for street-level expertise may be one reason why EU legislators choose a specific institutional design. If engagement with companies is necessary for a policy to work, institutions are likely to be designed in such a way that they can acquire the knowledge and access required for interacting with the industry. In the context of enforcement, the need for street-level expertise is particularly relevant. Enforcement, after all, often comes down to direct engagement with organizations, people and occurrences at specific locations. To effectively monitor behaviour, respond to emergencies and non-compliance, institutions are likely to have access to and knowledge about regulated industries (Blauberger & Rittberger, 2015).

Blauberger and Rittberger (2015) contend that, when street-level expertise is required, EU legislators choose networks of national authorities that 'tend to provide functional advantages over alternative regulatory institutions, such as EU agencies' (p. 370). Pierre and Peters, however, argue similarly regarding EU agencies. Their contributions therefore seem incompatible, but there is nothing preventing either institution from acquiring the right street-level expertise

to enforce EU policies. Rather, networks and EU agencies seem to embody *different types* of street-level expertise that are suitable for different types of regulated industries. Whereas an EU agency can acquire the expertise for effectively engaging with a more concentrated regulated industry, an EU network of national authorities seems more suitable for an industry that is fragmented and consists of many local corporations. An EU agency with direct enforcement powers necessarily performs these functions for the EU as a whole, so for this agency to perform well, the regulated industry cannot be overly large or fragmented. In the latter case, the need for street-level expertise may motivate EU legislators to choose a network of national authorities operating on a more local level.

Bureaucratic turf of national authorities

A second way in which regulated industry characteristics may affect the choice between institutional designs is through the bureaucratic turf of national authorities. As touched upon in section 5.2, current scholarship indicates that existing institutions, for a fear of losing control, may resist the creation of novel ones with competing authority. The picture arises that national authorities specifically are not keen to transfer competences to an EU-level institution (Bach et al., 2016; Thatcher, 2011). They have shown to actively defend their authority during the creation of such institutions, and may be successful when they control scarce resources and have access to formal legislative actors (Boeger & Corkin, 2017). Member states and their national authorities thus tend to prefer networks to EU agencies, as the latter can amount to a considerable loss of authority. A network provides better guarantees for member state actors to retain competences and influence.

National authorities are indeed likely to weigh in on the choice between EU agencies or networks. Their preferences, however, need not be one-directional. Instead, it may be expected that national authorities' preferences are variable and co-evolve with developments taking place in the regulated industry. When there is a strong link between their jurisdiction and the industry they engage with, national authorities may indeed be protective of their existing authority. But when regulated industries no longer operate in their jurisdiction or have gotten a highly international profile, perceptions of responsibility and control may change. Such changes in the industry may therefore affect national authorities' preferences when it comes to the creation of an EU agency with competing authority. Thus, the less a regulatory industry is distinctly linked to individual jurisdictions, the more national authorities may allow enforcement competences to be attributed to an EU agency. Conversely, the more non-compliance or accidents are linked to distinctly local industries, the more national authorities will prefer the coordination of enforcement within a network.

The relation between regulated industries and institutional design

This section has suggested two possible relationships between regulated industry characteristics and the choice between EU agencies or networks of national authorities (see table 1 below). Summarizing, we may expect enforcement by an EU agency when a regulated industry is highly concentrated and internationally active. An EU agency is most effective in interacting with such industries, and national authorities may be more likely to agree with a novel institution in the field. Alternatively, there will be strong preferences for enforcement by an EU network of national authorities when the regulated industry is fragmented, vast and dispersed throughout the EU. For this type of industry, a network of national authorities may be more effective and preferred by national authorities who consider the industry to be strongly connected to their jurisdictions. The above therefore suggests that regulated industry characteristics *have an effect* on the choice for EU agencies or networks of national authorities. This effect should be observable across cases when industry characteristics differ.

Table 5.1. Summary of the theoretical framework, suggesting two possible relationships between regulated industry characteristics and the choice of institutional designs for EU policy enforcement

Regulated industry characteristics	*Relationship*		*Institutional designs*
Regulated industry is international and concentrated	Different types of street-level expertise	Regulated industry requires engagement on a central level for policies to be enforced effectively	Agency
	Bureaucratic competence	The less firms are limited to the national domain, the more national authorities will support the attribution of enforcement competences to an EU agency	
Regulated industry is local and fragmented	Different types of street-level expertise	Regulated industry requires engagement on a local level for policies to be enforced effectively	Network
	Bureaucratic competence	The more firms manifest locally, the more national authorities prefer to keep decision-making on enforcement within a network	

5.3. Research design and methodology

The following sections explore how regulated industries differ across the four cases introduced above, and how this relates to the choice between networks and agencies for EU policy enforcement. In order to explore the relationships between regulated industries on the one hand and the choice between networks and agencies on the other, this study relies on case study research. Case studies are the best means to analyse EU agencies and networks in the dense context of their establishment while eliciting the aspects that are relevant from a theoretical point of view. A quantitative strategy is less suitable, as EU agencies and networks (with some role in the enforcement of EU policies) are not created in large numbers while the processes leading to their creation are highly complex (the problem of 'too few cases/too many variables'). Much in-depth information about the creation EU agencies and networks remains to be gathered.

This chapter specifically relies on a most-similar case study design, which involves a comparison of highly similar cases. These cases have many relevant aspects in common but still display a difference in the outcome of interest. Such a design allows the researcher to engage in a fine-grained comparison of policy domains and determine whether the different outcomes of interest are caused by reasons that had not yet been studied. For this chapter, two pairs of two most-similar cases were selected: the creation of an agency for airworthiness regulation (the EASA) and a network for aviation incident investigation (the ENCASIA); and the creation of an EU medicines agency (the EMA) and several network structures for medical devices regulation (see table 5.2 below).

This selection of case-pairs thus ensures variation in the outcome (agency or network), while controlling for reasons that are already known to influence institutional design. The cases in each pair thus have aspects in common which could otherwise influence the choice between networks and agencies (see section 5.2). These include notably the technical complexity of regulation (Mathieu, 2016), the existence of prior, similarly weak forms of coordination that were replaced by the respective agencies and networks, prior Commission competences (Thatcher, 2011), and policy domain (Wallace & Reh, 2015). Also the potential for distributive conflict cannot explain EU legislators' choice between institutional designs: in the cases where the potential for political conflict is highest and where a network would theoretically be the most likely outcome (Kelemen & Tarrant, 2011), agencies have been created (airworthiness and medicines regulation). In each pair, therefore, many previously identified reasons for the choice between agencies and networks cannot explain why enforcement tasks in are performed by an EU agency in one case, and by a network in another.

Table 5.2. Two pairs of most-similar cases

							Outcome	
	Policy area	*Technical complexity*	*Prior coordination*	*Prior Commission competence*	*Domain*	*Potential political conflict*	*Agency*	*Network*
Case pair 1	Medicines	High	Yes	No	Public health	High	**EMA**	**-**
	Medical devices	High	Yes	No	Public health	Low	**-**	**Network structures**
Case pair 2	Airworthiness certification	High	Yes	No	Transport policy	High	**EASA**	**-**
	Aviation incident investigation	High	Yes	No	Transport policy	Low	**-**	**ENCASIA**

For each case, I conducted within-case analyses and studied the decision-making processes that led to the establishment of the EMA and the network structures for medical devices, and the establishment of the EASA and the ENCASIA. The case studies draw upon a study of primary and secondary documentation, as well as 36 semi-structured interviews with (former) senior staff from the Commission, the Council, EU agencies, national authorities, the industry and independent experts.

5.4. Case pair 1: regulated industries and the enforcement of aviation safety regulation

In the area of (civil) aviation safety, EU legislators chose two different institutional designs for enforcing EU policies. They created an EU agency – the EASA – to certify aircraft types and the organizations designing them, and to conduct relevant inspections. The investigation of civil aviation accidents, however, is not coordinated by an EU agency, but within the ENCASIA.

These cases do not only differ when it comes to the institutions enforcing EU policies; there are also considerable differences among the industries they engage with. The EASA, on the one hand, was established after a period of significant concentration among corporations. At the time of the Joint Aviation Authorities – JAA, the EASA's predecessor – the civil aircraft market globalized and the industry integrated both horizontally and vertically (Golich, 1992). Mergers were also commonplace during the JAA's reform between 1993 and 2003, and took place notably among manufacturers of large commercial aircraft (including the companies later forming Airbus). Just before the EASA's establishment in 2003, the industry was oligopolistic (Kleiner et al., 2002): only six European and United States firms designed and assembled large

civil aircraft, while they operated from a limited number of member states (Esposito & Raffa, 2006, as cited in ECORYS et al., 2009; Schmitt, 2000; Interview no. 8).

In the case of accident investigations, on the other hand, investigators deal with several industries and other actors at the same time. The variety of potentially involved corporations is inherently larger: investigators not only engage with manufacturers, but also with a variety of aircraft operators from all over the world. Most accidents (and investigations), furthermore, are of a relatively small scale. Those with a European or global impact indeed tend to involve big manufacturers and large operators, but accidents of this size are rare. Most of the time, aviation accidents are a primarily local occurrence: they involve mostly non-commercial small aircraft, occur all across Europe, and tend be of geographically limited relevance (Commission, 2009b; ECORYS, 2007; European Parliament, 2010b).

Different types of street-level expertise

The need for street-level expertise helps to understand why EU legislators specifically chose an EU agency to supervise the concentrated aircraft design and manufacturing industry. At the time of the EASA's predecessor, intense interaction between aircraft type designers and regulators was already commonplace. But as the industry concentrated and sought to increase economies of scale, member states and the Commission agreed to further centralize supervision and increase the bundling of access and knowledge. In this context, the JAA developed a single inspection procedure for the certification of large airplanes – which would later be retained by the EASA (JAA, 2000; Interview no. 34; Interview no. 8). Even the composition of inspection teams was adjusted to ensure effective supervision: as a former JAA staff member noted, also 'the complexity of the product (…) and the burden on the Industry [sic]' had an impact on how many national experts were involved (Sulocki & Cartier, 2003, p. 321). In the JAA's footsteps, the EASA would thus become primarily competent for type designs and type design organizations. National authorities, conversely, would remain responsible for the more numerous and locally operating production and maintenance organizations (Interview no. 34; Interview no. 21). According to the Commission, this design balanced 'the need for centralisation and the use of expertise available in the national administrations and the JAAs', and 'preserve the privileged relationships which the national administrations have been able to develop with those concerned' (Commission, 2000, p. 11; Interview no. 21).

The need for street-level expertise also helps to understand why EU legislators opted for a network in the case of aviation accident investigations. Admittedly, much expertise is needed for investigating complex accidents involving large aircraft, not least to be on par with large manufacturers and operators (Commission, 2009b, p. 15; Interview no. 35). And given the extensive use of such aircraft, there is a need to communicate safety recommendations and monitor their implementation on a European level (Commission, 2009b; Group of Experts, 2006;

ECORYS, 2007). As mentioned, however, accidents of such a scale are rare: most of them are small and local, requiring limited capacities at the EU level. Moreover, accident investigations *always* involve operations on a local level. Whether large or small, every accident requires investigators to arrive quickly, gather evidence and record testimonies on site. Given cultural differences and the politically salient nature of an accident, furthermore, material may better be gathered and assessed by the national authority of a state in which the accident occurred – especially when the addressees of safety recommendations include local authorities or national governments (Commission, 2009b; Interview no. 2; Interview no. 23; Interview no. 14; Interview no. 28).

The necessity of street-level expertise on two levels led to some ambivalence in the early stages of the ENCASIA's creation. Along with the national authorities, the Commission expected an EU agency to bring 'significant safety benefits' as it 'would be well placed to issue safety recommendations addressed to entities at the national and Community level as well as industry' (Commission, 2009b, p. 49; ECORYS, 2007). National authorities and the EU agency could even exist in parallel, 'whereby the [national authorities] would be responsible for investigation of smaller but most numerous accidents involving general aviation aircraft' while 'ensuring that investigation[s] can be instigated in a rapid manner' (Commission, 2009b, p. 47; Commission, 2009a). Yet the Commission also worried that this option would 'be hampered by the fact that the [EU agency] would have to operate as an [investigator-in-charge] in 27 different jurisdictions of the EU [member states]', whereby the specificities of the local situation may 'play an important role (…), having in mind the very operational nature of accident investigation' (Commission, 2009b, p. 49). National authorities furthermore feared that an EU agency would lead to a 'loss of local knowledge' (ECORYS, 2007, p. 62; Interview no. 23; Interview no. 2). These considerations, among several others, eventually led the Commission to only include an EU network for accident investigation in its formal legislative proposal (Commission, 2009b; Interview no. 35).

Bureaucratic competence of national authorities

The bureaucratic competence of national authorities also helps to understand why industry characteristics may relate to institutional design. In the case of airworthiness policy, concentration within the industry led national authorities to think more positively about ceding some of their competencies to the EASA. Importantly, the growth (and integration) of the European aircraft industry was strongly encouraged and supported by national governments (Weiss & Amir, 2023; Commission, 1997; Muller, 1995; Schmitt, 2000; Smith, 2001; Interview no. 34). Thus even though centralization into the EASA would lead to a loss of bureaucratic competence for some member states, the resulting efficiencies would also benefit the development of 'their' aircraft manufacturers (Interview no. 27; Interview no. 21). At the same time, two former JAA members noted that member states with smaller industries

did not have much to lose, as the industry was already moving away from their jurisdictions or merged into larger companies (Interview no. 3; Interview no. 34; Interview no. 8; Interview no. 11). The responsibility for (the more numerous) production and maintenance organizations, however, *would* remain a national competence. member states and their national authorities, one national authority official noted, 'didn't want to centralize everything' (Interview no. 21).

Also in the case of accident investigations, the characteristics of the civil aviation industry seem to have influenced national authorities' views on the establishment of the ENCASIA. Importantly, the concentration among aircraft manufacturers and the limited exposure to large and complex accidents had already led national authorities to tighten informal relations. The expertise for such accidents was particularly scarce among authorities in smaller member states and those with historically smaller aviation industries. Hence the smaller national authorities in particular were positive about an EU agency in the context of complex accidents involving large manufacturers and operators (Commission, 2009b; ECORYS, 2007; Interview no. 14; Interview no. 11; Interview no. 28). Yet other national authorities – and specifically those in member states with traditionally larger aviation industries – opposed an EU agency: they continued feeling responsible for large and complex accidents, given the relevance of such investigations for passenger safety and because their existing expertise for such investigations was worth retaining (Interview no. 28). Also, some authorities feared that investigations by a foreign body might undermine the legitimacy of its conclusions. All in all, national authorities found their existing forums sufficiently productive, and there was no consensus on the need for an EU agency, which was merely qualified as 'a good option for the future' (Commission, 2009b, p. 50; ECORYS, 2007; Interview no. 14; Interview no. 23; Interview no. 2; Interview no. 28).

5.5. Case pair 2: regulated industries and the enforcement of medical products regulation

EU legislators have also established two different institutions for enforcement in the area of medical products. In the case of medicines, the EU established an agency (the EMA) to license notably biotechnology pharmaceuticals and to coordinate their supervision while they are on the market. In the case of medical devices, however, the EU did not create an EU agency. By passing the medical devices regulations in 2017, EU legislators established several network structures to help enforce EU medical devices policy.

These cases do not only differ in terms of institutional design; they also differ when it comes to regulated industry characteristics. When EU legislators created the EMA in 1995, the agency was supervising an industry that had only just emerged. The biotechnology sector – the first class of medicine for which EMA authorization was mandatory – did not exist until the early

1980s, when an essentially novel industry was formed by a wave of new, specialized firms. This group of firms, however, was unable to engage in downstream activities such as manufacture and product approval by the regulatory authorities, and would thus gradually tie up with large incumbent companies (Malerba & Orsenigo, 2015; Pisano, 1989). The pharmaceutical industry more generally is said to have a stable 'oligopolistic core' of 10-20 leading firms (Malerba & Orsenigo, 2015; Permanand, 2006), who serve the EU market by a relatively small number (Eurostat, 2016; Orzack et al., 1992).

The medical devices industry is different. In comparison to pharmaceuticals, the group of medical devices corporations is considerably less concentrated. While the turnover of the EU pharmaceuticals manufacturing market of around €284 billion was incurred by around 4,000 companies, the (continental) European medical technology market of €64 billion was served by almost 63,400 companies (2011 figures: Eurostat, 2022). Most of them are small- and medium-sized enterprises with single product lines (Altenstetter, 2003; Commission, 2012a; Commission, 2012d; MedTech Europe, 2014). The industry of so-called notified bodies, who assess and certify certain specific types of medical devices, is more concentrated: in 2012, 78 such bodies were active on the market (Commission, 2012b).

Different types of street-level expertise

Again, the need for street-level expertise for different regulated industries may help to understand the differences in institutional design. For the benefit of medicines policy, existing expertise was centralized within the EMA to better analyse companies' applications for biotechnological and other innovative medicine. The Commission, European Parliament and national officials confirmed that – given the novelty of biotechnology – the required knowledge was scarce at the national levels and was bundled to assess the new biotechnology industry's products more efficiently and effectively (Commission, 1990b; Interview no. 25; Interview no. 20; Interview no. 33). Furthermore, whereas many existing pharmaceutical companies already had satisfactory relations with national authorities, biotech companies did not yet have such engagements (Interview no. 20). For the 'companies with a Community vocation', the Commission wanted to create direct access to a Community-scale market, while it sought to maintain 'local/regional systems for other firms' (Commission, 1990b, p. 10). The need for a right level of access to (and knowledge about) the industry also helps to understand why the EMA only *coordinates* supervision of marketed pharmaceuticals (and lacks the operational capacity to supervise marketed medicines on its own). Manufacturing and distribution inspections, first, inherently involve local, on-site facility surveys (Commission, 2001a). And as a Commission official involved in creating the EMA indicated, the gathering of information about medicines' adverse side effects is better left to the authorities closest to consumers. This lowers the bar for patients and healthcare professionals to report side effects when they experience them (Commission, 1990b; Interview no. 20; Interview no. 16).

The need for a right level of street-level expertise also played a role in the medical devices case. While the creation of a new EU agency was hardly discussed at all, the involvement of the EMA was broadly rejected, and not least because that was considered inappropriate for an industry of mostly small- and medium-sized enterprises (Commission, 2012c). Regarding notified bodies, the industry noted that direct exchanges with national authorities 'would be more helpful than the larger distance to an anonymous centralised body' (EUROM VI, 2008, p. 12). Imposing restrictive measures, they argued, 'is and should remain the task of the Competent Authorities (…) who have more insight into individual cases (…)' (EUROM VI, 2008, p. 20). The Commission and national authorities, more importantly, also recognized a need for effective interaction with the notified body industry: although direct supervision by an EU agency would 'increase the independence of the inspectors', it would also dissolve 'the day-to-day contact between Notified Bodies and "their" competent authorities which enables practical routine questions to be resolved' (Commission, 2012b, p. 39). With a network structure, the Commission noted, 'only the *coordination* of inspections and sanctioning would be transferred to the EU level' (emphasis added), while national authorities 'would maintain the full responsibility for the regular surveillance audits' (Commission, 2012b, p. 40).

Bureaucratic competence of national authorities

The choice between institutional designs may also have been determined by the varying preferences of the national authorities. The fact that the biotech industry was entirely new led national authorities to take a constructive stance about centralizing competencies into a novel EU agency. Whereas they were reluctant to transfer control of the market of more traditional medicine (for which they had long been responsible already), national authorities lacked expertise for biotechnology. As a Commission official noted, it was difficult to find common positions on drugs that were already on the national markets and were regulated differently (Interview no. 20). Instead, the Commission looked into the biotech industry and other new entrants in the market, as expertise for those products was relatively scarce and concerns about their safety were strong (Interview no. 20). National authority staff members have confirmed that biotechnology was the area in which the EMA's authority was beneficial and least threatening to the existing competences of national authorities – a view also shared by the European Parliament (Interview no. 10; Interview no. 16; Interview no. 33; Interview no. 25). The limited scope of the EMA's authority, in the Commission's words, appeared 'necessary in the first instance to ensure the progressive establishment of the Agency and a smooth transfer of responsibilities from the member states to the Community' (Commission, 1990b, p. 19).

In the case of medical devices, conversely, the national authorities were less supportive of centralizing enforcement tasks into an EU agency. The member states' national authorities' perceived responsibility for the direct supervision of medical devices companies and notified bodies was related to the industry's composition. One national authority noted, for example,

that 'because of the heterogeneity among Notified Bodies (size, area of activity), surveillance and notification by member states is to be preferred' (ZLG, 2008, p. 13). Other national officials too connected the amount of work performed at the member state level to industry and market characteristics; several interviewees even noted that some national authorities had specialized expertise for the specific classes of medical devices that were manufactured in their jurisdiction (Interview no. 12; Interview no. 18; Interview no. 6). The Council, more generally, stressed that the presence of so many small companies in the medical technology industry 'must be considered when future legislative and administrative measures are being adopted at European Union level' (Council, 2011, p. 7).

5.6. Discussion and conclusion

To what extent, this paper asks, do differences among regulated industries have an effect on the choice between EU enforcement agencies and networks of national authorities? This last section draws conclusions from the case studies and discusses them in light of the theory reviewed earlier.

The relation between regulated industries and institutional design

Above all, the case studies show that different institutional designs correspond with different regulated industries. EU agencies were established in the two cases with concentrated industries, whereas networks were created for regulated industries that were larger and more fragmented. It appeared that the creation of the EASA and its authority over aircraft designs corresponds with a considerable concentration among design organizations, and that the EMA was created for dealing with a limited number of novel biotech companies. The inverse holds true in the other two cases. In the case of aviation accidents, the variety of potentially involved actors was large, while accidents tend to be of a limited scale. For coordinating their investigation, EU legislators established a network. And a network of national authorities was also created in the case of medical devices, where the regulated industry is comprised mostly of small- and medium-sized enterprises.

This correspondence, however, can be further qualified on the basis of the most-similar research design. As the cases in each pair are highly similar in many ways other than regulated industries (see section 5.3), we can not only speak of covariation, but also of a *relation* between regulated industries and institutional design. The selection of highly similar cases rules out that other features, which normally influence the choice between EU agencies and networks, impacted institutional design in the cases at hand. Explanations so far provided by the literature – such as technological complexity or distributive conflict – cannot explain the different outcomes within each case-pair. In the cases studied for this chapter, therefore, variation among regulated

industries can be credibly linked to differentiation between EU agencies and networks for the enforcement of EU policies.

Street-level expertise for different industries

Two other case study findings corroborate the identified relationship between regulated industries and institutional design. They are findings that demonstrate *how* this relation works by detailing why different industry characteristics contribute to EU legislators choosing one institution over the other. The first is about the necessity of street-level expertise, which connotes the idea that public institutions need knowledge about and access to regulated industries for effective interaction. But as set out in section 5.2., different regulated industries may require different types of street level expertise: relations with small and concentrated industries may best be maintained by an EU agency, while interaction with large and fragmented industries is best facilitated by national authorities cooperating in a network. As the case studies show, this is a credible explanation for the relationship between regulated industries and institutional design. The EMA and the EASA were indeed (partially) created to bundle resources for effective engagement with the limited number of companies on the market. And in the cases of aviation accident investigation and medical devices, decision-makers rather emphasized proximity and local expertise to investigate small-scale accident investigations and liaise with smaller medical devices companies.

This industry-specific conception of street-level expertise thus helps to explain the choice between EU agencies and networks. Yet it may also explain why EU agencies have more direct enforcement authority for some industries and more indirect authority for others. The EASA's authority, first, appeared strongest for the relatively few design organizations that exist in Europe. Supervision of the far more numerous production and maintenance organizations – which appeared to operate more locally and have 'privileged relationships' with national administrations – continued to be a primarily national authority responsibility. The EMA, similarly, has no autonomous operational capacity for gathering information about the safety of medicines on the market: policy-makers concluded that such information was best gathered close to consumers and healthcare professionals. Thereby, industry-specific (or even market-specific) street-level expertise clarifies why one EU agency can have different legal and operational capacities within one policy domain. It warrants a closer look at EU agencies as well as networks of national authorities, and how they are specifically configured to perform enforcement for different markets or industries.

Bureaucratic competence of national authorities

EU decision-makers' choice between agencies and networks for the enforcement of EU policies may also be determined by the bureaucratic competence of national authorities. As discussed, existing research indicates that national authorities regularly oppose the creation of EU agencies

that threaten member state competences, which renders an EU network more likely. But as conjectured in section 5.2., national authorities need not always oppose the establishment of EU agencies. Changes in the nature of an industry may affect national authorities' perceptions of control and responsibility. A concentrating industry becomes less linked to individual jurisdictions, and may lead national authorities to agree on transferring tasks to an EU agency.

The case studies indeed indicate that national authorities' preferences are relevant for the choice between institutional designs, and that they are related to a perceived responsibility over industries located in their member state. In the case of aviation accident investigation, national authorities felt continually responsible for investigating accidents in their country, and they preferred their existing network arrangements to the creation of an EU agency. Similarly, in the medical devices domain, national authorities were unconvinced of the need for an EU agency, pointing to the industry's activities in their respective jurisdictions. The attribution of certain tasks to the EASA, however, got support from the national authorities, which was clearly connected to the internationalization of the industry. member states either had interests in the industry's growth, or there was no industry in their jurisdiction left to supervise. In the case of medicines regulation, the EMA's creation was almost only possible because its remit would be limited to biotechnology and other highly innovative medicine – a new industry over which the member states had little to no existing competences to defend. This latter point is salient: not only concentrated or small industries, but also new or upcoming ones are a favourable condition for the creation of EU agencies.

Further research

This chapter thus argues that a regulated industry's characteristics relate to the design of EU institutions. The need for street-level expertise to enforce EU policies vis-à-vis regulated industries, as well as national authorities' assumed responsibility over them, help to understand the observed relation between regulated industries and the choice between EU agencies and networks of national authorities.

The limited number of cases studied for this paper, however, limit the generalizability of its conclusions and call for further research. Such research could focus on at least the following four points. Most importantly, this paper focussed on internal market domains in which EU agencies and networks interact with a specific and confined set of regulated companies. This begs the question: do industry characteristics also impact institutional designs in other domains of EU law – such as the AFSJ, where groups of supervised entities are less homogenous and delineable? Second, this chapter framed EU agencies and networks of national authorities as two mutually exclusive institutional designs. This need of course not be the case: as I have argued elsewhere (Van Kreij, 2019), both designs can co-exist and share responsibilities within more complex enforcement regimes. Nonetheless, regulated industry characteristics

may still be relevant in such cases. Industries, after all, need not be entirely concentrated or fragmented either. How do regulated industry characteristics influence institutional designs in more complex enforcement regimes? Lastly: the nature of interactions between enforcers and companies may depend on the type of enforcement style that is employed. A command-and-control style, or more digitalized ways of enforcing EU law, imply a more distant relationship than a cooperative enforcement style does. How does this alter the observed relationship between regulated industries and institutional design? Answering these and related questions will be indispensable for a further understanding of the institutions involved in EU governance, and specifically of those involved in enforcing EU policies.

Chapter 6

Conclusions and implications

6.1. Introduction

The aim of this dissertation has been to explain why EU legislators establish EU agencies and networks of national authorities for the enforcement of EU policies, and why they differentiate between these two institutions.

The EU has long been central to devising regulatory policy on the European continent. And to make individuals and organizations abide by EU substantive norms, the EU initially relied on its member states (Adriaanse et al., 2008; De Moor-Van Vugt & Widdershoven, 2015). Since the 1980s, however, the EU is getting more concerned with EU policy enforcement. EU legislators and the ECJ started formulating norms for how member states ought to enforce EU policies (De Moor-Van Vugt & Widdershoven, 2015), and the Commission stepped up its game to ensure that also member states implement EU (enforcement) standards themselves (Börzel, 2003). Yet the EU is also building distinctly new institutions, as EU agencies and EU networks of national authorities are becoming more involved in EU policy enforcement (Scholten, 2017). These institutions are central to this dissertation. EU agencies, first, exist already since the 1970s, but have proliferated in the course of the last thirty years (Egeberg & Trondal, 2017). They tend to operate (semi-)independently from other organizations, and are established for a circumscribed set of tasks in a specific policy domain – which increasingly includes tasks for making individuals and organizations comply with EU rules (Scholten & Luchtman, 2017). EU networks of national authorities, secondly, are also increasingly involved in EU policy enforcement. Such networks are primarily composed of member states' national enforcement authorities, who coordinate their actions – like sharing case-specific information, or taking enforcement action vis-à-vis individuals or organizations within their respective jurisdictions. Formal EU networks of national authorities are a relatively new phenomenon, but many are involved in EU policy enforcement (Scholten, 2017).

The involvement of EU agencies and networks changes the fabric of policy enforcement, both in the EU as well as in the member states. The implications may be far-reaching, as policy enforcement may have a profound impact on the position of individuals and organizations, can be vital for policy effectiveness, and is strongly associated with state authority and sovereignty. This dissertation has sought to explain how the EU enforcement landscape has changed, by asking why EU legislators create EU agencies and networks of national authorities for EU policy enforcement.

6.2. Main conclusions

The aim of this dissertation has been to explain why EU legislators establish EU agencies and networks of national authorities for the enforcement of EU policies, and why they differentiate between these two institutions. As mentioned, EU agencies and networks are increasingly involved in ensuring compliance with EU policies, but the existing literature had not yet fully found out why one or the other type of institution is selected to do this task and under which conditions. In order to help uncover EU legislators' motivations for vesting enforcement tasks in EU agencies and networks of national authorities, I explored the decision-making processes leading to the establishment of these novel layers of institutions for the enforcement of EU policies.

To that end, I first mapped the scholarship that was relevant for answering the central research question (chapter 2). This scholarship was then used to study the establishment of EU enforcement agencies and networks through a comparative case study design. Four cases were selected and subdivided in two pairs, whereby each pair comprises a case of an EU enforcement agency as well as a case of an EU network of national authorities (see table 6.1 below). I have first studied the two cases of networks of national authorities (chapter 3), then the two cases involving EU agencies (chapter 4), and I finally drew a comparative analysis among all four cases (chapter 5). The results of these chapters are discussed directly hereafter.

Table 6.1. The four cases (and units of interest between brackets) studied for this dissertation.

	Case pair 1: Medical products	*Case pair 2: Aviation safety*
Networks	1. EU medical devices policy (two specific network arrangements)	2. EU civil aviation accident and incident investigation (the ENCASIA)
Agencies	3. EU medicines policy (the EMA)	4. EU airworthiness policy (the EASA)

Potential reasons for the establishment of EU enforcement agencies and networks

Chapter 2 of this dissertation was dedicated to mapping existing scientific contributions on EU agency and network creation, and to assessing their relevance in the specific context of EU policy enforcement.

Chapter 2 argued that existing functional perspectives on EU agency and network establishment can also help to explain their involvement in EU policy enforcement. Chapter 2 discussed several of these perspectives – which are functional as they assume that policy-makers create and design institutions for the benefit of policy functionality. One known functional reason for establishing agencies is that they help political actors achieve long-term, diffuse, or joint policy goals. By creating a more or less independent agency with a circumscribed mandate, politicians

ensure that the achievement of such goals isn't thwarted by short-term, tangible and specific interests (e.g. Krapohl, 2004). In the context of EU policy enforcement, this may mean that EU legislators establish EU agencies, and to some extent networks of national authorities, in order to prevent member states from leniently enforcing EU policies vis-à-vis (national) individuals and businesses. A second functional reason for establishing EU agencies and networks is that these institutions can better gather relevant information and coordinate decisions, especially in cross-border crisis situations. In this light, chapter 2 argued that EU legislators may establish EU agencies and networks of national authorities to jointly gather information about cross-border non-compliance and thus deliver a more coordinated enforcement of EU policies (Boin et al., 2014; Dehousse, 1997; Eberlein & Newman, 2008). One last functional perspective that may help to explain the establishment EU enforcement institutions is their ability to facilitate interactions with specific groups of individuals and organizations. Scholars have particularly argued that EU legislators establish EU networks of national authorities when interaction with individuals and organizations is required – as is the case for enforcement. Networks, it is argued, are capable of providing the street-level expertise that the implementation of EU policies requires (Blauberger & Rittberger, 2015).

According to chapter 2, existing political perspectives can also help explain the involvement of EU agencies and networks in EU policy enforcement. Such perspectives have less to do with policy functionality and more with policy-makers' strategic interests. One supposed political reason for the establishment of EU agencies is that they allow supranational EU institutions to increase their control over EU policies (e.g. Kelemen & Tarrant, 2011). As chapter 2 argues, a wish for more control over policy compliance may likewise fuel the establishment of EU agencies with enforcement tasks. Potential for resource efficiencies may be another driver behind EU agency or network creation. Chapter 2 argued that the potential for efficiencies may be high for enforcement, as rule-enforcement – more than rule-making – requires a continuous appropriation of public funds (Genschel & Jachtenfuchs, 2018). At the same time, existing political accounts have also shown that member states hesitate to transfer powers to the EU for a fear of losing bureaucratic turf (e.g. Bach et al., 2016). Chapter 2 noted that the member states have long been responsible for enforcing EU policies, and may therefore particularly fear centralizations of EU policy enforcement. Electoral opposition might also weigh in on the choice between EU agencies and networks for the enforcement of EU policies (Eberlein & Newman, 2008), as well as conflict among member state governments about the structural consequences for national economic entities (Kelemen & Tarrant, 2011).

Chapter 2 also noted that other relevant perspectives are emerging in the literature. One perspective emphasizes that the creation and design of new institutions can be explained with reference to organizations that already existed. The power of prior institutions may explain why new organizations – EU agencies or networks – inherit some specific characteristics (or

not), including a role in the enforcement of EU policies. Chapter 2 argued that the influence of existing national institutions (Thatcher, 2011; Boeger & Corkin, 2017) is highly relevant for the enforcement of EU policies, which has been the domain of member states and national authorities proper (De Moor-Van Vugt & Widdershoven, 2015). Another perspective shows that the attractiveness of specific institutional models may influence institutional design at the EU level: policy-makers may be predisposed towards specific institutional designs that proliferate in other policy domains and have established a good reputation (Radaelli, 2000). Chapter 2 argued that such policy transfers are particularly interesting in the context of enforcement, given that enforcement – which often involves some coercion vis-à-vis individuals and organizations – is traditionally strongly associated with nation-states and their sovereign rights. Such perceptions are likely to hamper, rather than foster, the centralization of EU policy enforcement in EU agencies and networks. Chapter 2 also argued that substantive and constitutional legal norms may have an impact on the involvement of EU agencies and networks in EU policy enforcement: single decision-making by an EU agency or within strong EU networks, for example, presupposes uniform substantive rules; and constitutional norms can limit the range of alternatives available to EU legislators.

Several perspectives discussed in chapter 2 are expanded upon and subjected to further examination in subsequent chapters. Some of the theory discussed in chapter 2, however, is not followed up upon. Due to the selection of cases which took place after finalization of this theoretical chapter, it was no longer possible to study the potential relevance of different competences in the EU treaties and of the degree of substantive norm uniformization for the creation of EU agencies and networks. After all, EU medicinal products and medical devices policies are based on the same treaty competence, while these policy areas exhibit a similar degree of substantive norm harmonization – and the same goes for airworthiness policy and aviation incident investigation. Also, electoral opposition to the integration of enforcement has not been examined further due to insufficient clues in the source material. The inverse has happened as well: subsequent chapters bring in other parts of institutionalist scholarship that had not yet been discussed, given the predominantly rationalist character of the discussion in chapter 2.

The impact of scarce resources on EU enforcement networks

Chapter 3 specified some of the perspectives discussed above and put them to the test by examining the establishment of EU enforcement networks. Chapter 3 specifically asked why EU legislators establish networks of national authorities for EU policy enforcement while EU agencies with enforcement tasks already exist in highly similar policy domains. This was the case for both medical devices and aviation incident investigation policy: EU legislators established EU networks of national authorities while EU agencies already existed in neighbouring policy domains.

The case studies of chapter 3 indicate that four factors influenced the establishment of these enforcement networks. First, chapter 3 argued that a need to increase the availability of scarce resources – such as expertise or infrastructure – fuels the need for enforcement coordination (Vantaggiato, 2019a). As mentioned, enforcement is an inherently resource-intensive task: whereas rules require no extra costs to remain valid once made, the continuous enforcement of these rules requires the continuous appropriation of public funds to recruit staff, gather expertise, and maintain infrastructure (Parisi & Fon, 2009; Genschel & Jachtenfuchs, 2018). The case studies of medical devices policy as well as aviation incident investigation indeed show that a need for a more uniform availability of resources, and expertise in particular, drove the need towards more enforcement coordination. Both the informal predecessors of the enforcement networks in those policy areas, as well as the Commission's initial attempt for centralization into EU agencies, were driven by a perceived necessity for national authorities to access each other's resources.

The case studies in chapter 3 also confirm that existing enforcement organizations at a national level can have a strong bearing on reforms at an EU level (Thatcher, 2011). As hypothesized earlier, national authorities may hold a powerful position in this respect as, prior to increasing EU involvement, most EU policies had been enforced nationally (De Moor-Van Vugt & Widdershoven, 2015). The case studies in the areas of medical devices policy and aviation incident investigation indeed demonstrate that national authorities are likely to have had a strong position throughout the decision-making processes leading to the establishment of EU enforcement networks. This strong position seems again related to the resources needed for EU policy enforcement. After all, to the extent that scarce expertise and infrastructure *was* available, it was at the disposal of the national authorities. They acquired these resources during the decades that they were central to EU policy enforcement tasks. Their resources would give them a strong position in the reform of medical devices policy enforcement and aviation incident investigation, which revolved, to a considerable extent, about improving the uniform access to resources.

The case studies have furthermore shown that the national authorities are likely to have benefitted from that strong position. They advocated against the Commission's plan to expand the EMA and the EASA, and the outcome of the decision-making processes was along the lines of their preferences. Importantly, national authorities' opposition was linked to the professional culture and the expertise that they developed over the course of the years for enforcement in their respective policy domains. The methodology for establishing non-compliance in the domains of medical devices and aviation incident investigation was, for the national authorities, incompatible with the enforcement methods in the domains of EU medicines and airworthiness policy. Such incompatibilities meant that these existing national institutions opposed the

integration of additional enforcement tasks into the EU agencies that already existed and enforced EU policies in adjacent domains.

Chapter 3, lastly, also examined the argument that EU supranational institutions – and notably the Commission – prefer the establishment of EU agencies as opposed to the creation of EU networks (Kelemen & Tarrant, 2011). In this context, chapter 3 specifically indicates that the Commission was not willing to establish novel EU agencies for the enforcement of medical devices and aviation incident investigation policy. It did seek to vest additional enforcement tasks into the existing EMA and EASA, but once these options were off the table, the Commission did not wish to establish new agencies instead. It found that new EU agencies would weigh too heavily on the EU budget and that they might feed a broader public sentiment against further EU integration through novel EU bureaucracies.

The impact of institutional models on EU enforcement agencies

EU agencies are still being established, however, and have also flourished in earlier periods of time. Chapter 4 shifted focus to the establishment of those EU agencies, which were created at a considerable rate between 1990 and 1995 and between 2000 and 2005 (Egeberg & Trondal, 2017). Chapter 4 took a specific perspective on EU agencies with enforcement tasks and asked whether their establishment and design has been influenced by existing institutional paradigms on governance and enforcement in the EU, and if so, how. After all, EU policy enforcement has long been built upon a specific institutional model with a central role for the member states. As touched upon above, institutional models such as these may guide policy-makers in the establishment and design of subsequent institutions (e.g. Groenleer, 2009). The case studies in chapter 4 focused on the EMA and the EASA and indeed show that such models have influenced EU legislators during the design of the EU agencies for the enforcement of EU airworthiness and medicines policies.

The case studies of the EMA (established in 1995) and the EASA (established in 2003) first show that a preference for agencies should be seen against the background of a worldwide move towards the agencification of government functions (Levi-Faur, 2005). In the context of increasing liberalization and privatization, many governments came to rely on private companies and markets to provide goods and services, while controlling these entities through public organizations operating efficiently and independently from government ministries. The case studies of airworthiness and medicines policy indicate that EU policy-makers in these areas were sensitive to the proliferation of agencies both in the United States as well as in the member states of the EU. When discussing (EU) agencies as an institutional design, policy-makers in both cases considered the agency model as a guiding point of reference and consistently referred to existing agencies in national (airworthiness and medicines) domains.

Yet chapter 4 has also argued that the long tradition of enforcing EU and international policies on a national level could have had normatively constraining effects on the creation of EU enforcement agencies. Well-established institutional models such as these may affect policy-making processes because of the moral frames or values embedded within them. Chapter 4 particularly argued that the member state enforcement model may have structured the establishment and design of EU agencies with enforcement tasks because of conceptual links between national sovereignty and the use of coercive force. The case studies of airworthiness and medicines policy indeed indicate that such considerations have influenced the creation of the EASA and the EMA, as normative implications of the member state enforcement model triggered hesitancy when decision-makers considered the attribution and design of enforcement powers. In the case of medicines regulation, policy-makers stressed the inappropriateness of vesting any operational inspection capacity in the EMA. Inspections were broadly considered to be the domain of the member states proper – even by the Commission and the European Parliament, who would otherwise have a plausible interest in centralizing EU policy enforcement. Strong opposition to inspections were absent in the case of airworthiness policy, but also this case indicates some insecurity among policy-makers concerning the role of EU agencies in the enforcement of EU policies. The need for and benefits of centralized inspections were as undisputed, but throughout the legal design of the EASA's enforcement powers, policy-makers sought to align the agency's powers and role in EU policy enforcement with frames that already existed in the EU more broadly.

The relation between institutional design and industry characteristics

Chapter 5 took yet another complementary perspective on the establishment of EU enforcement agencies and networks. This chapter specifically focused on the relevance of regulated industry characteristics. As discussed earlier, existing contributions had already hypothesized that the need for interaction with individuals and organizations makes the establishment of an EU network of national authorities more likely than the creation of an EU agency (Blauberger & Rittberger, 2015, 2017). In chapter 5, I further elaborated this perspective and claimed that different types of interaction with different regulated industries may relate to differentiation among institutions for EU policy enforcement. Chapter 5 specifically examined the extent to which specific differences among regulated industries relate to the choice between an EU agency and network of national authorities for the enforcement of EU policies.

Based on a comparison of all four cases, chapter 5 indeed finds indications for a relation between the characteristics of regulated industries and the choice between EU enforcement agencies and networks. A comparative analysis of all case studies shows that EU legislators opted for an EU agency in the cases where the regulated industry was more international and concentrated, while they opted for an EU network in the cases where the industry was more fragmented and operated locally. The chapter shows that functional as well as political mechanisms can

explain this relationship between regulated industries and institutional design. The functional reason, first, revolves around the functionality of EU policy enforcement. For enforcement to be effective, more fragmented and locally operating industries seem to require interaction on a local level. Interaction with international and concentrated industries, in turn, is best facilitated by enforcement on a more central level. The political reason for the relationship between institutional design and regulated industries revolves around the bureaucratic competence of national authorities. The more industries operate locally, the more national authorities feel responsible and seek to keep decision-making within a network. The more industries operate internationally, the more national authorities seem willing to let go of their responsibilities and transfer them to the more centralized level of an EU agency. Both mechanisms seem to have played a role in decision-making in all four cases.

6.3. Implications for institutionalism and EU legal scholarship

The conclusions of this dissertation have implications for various types of scholarship that relate to institutional design in the EU. As mentioned, this dissertation builds upon two bodies of academic theory: the literature on institutionalism and the legal literature about EU law and governance. The most relevant contributions to these respective bodies of literature will be discussed in turn.

Institutionalism

One way in which this dissertation contributes to the ongoing institutionalist debate is by demonstrating how the characteristics inherent and specific to the enforcement of EU policies have relevance for the creation of EU agencies and networks of national authorities. Whereas previous contributions on these institutions often overlook differences between the various functions they perform (see however Scholten & Scholten, 2017), this dissertation demonstrates that EU policy enforcement has distinct characteristics that may influence the establishment and design of EU agencies and networks of national authorities tasked with ensuring compliance with EU norms.

The first characteristic relevant for institutional design concerns the role of national authorities. Many existing institutionalist contributions on EU agencies and networks put the EU legislative institutions at the center stage of the establishment process. Given their formal role in making EU legislation, research tends to focus on the Commission, the European Parliament, and the highest member state representatives in the Council (see e.g. Kelemen & Tarrant, 2011). This dissertation, however, draws attention to member states' executive levels and to their national regulatory enforcement authorities in particular. Recent institutionalist scholarship has already appreciated the relevance of national authorities in EU politics (e.g. Boeger & Corkin, 2017),

but this dissertation finds that their position is particularly pronounced when it comes to the centralization of policy enforcement in an EU context. The member states' national authorities themselves are likely to have had a strong influence on the design of EU institutions involved in policy enforcement.

Chapters 3, 4 and 5 show that national authorities had a strong position during the establishment of the EASA, the EMA, the ENCASIA, and the network arrangements for EU medical devices policy. Two conditions, which are connected, allowed them to get this role. Prior to the establishment of the mentioned EU agencies and networks, resources for the enforcement of EU policies were mostly present at the national level. No other institution beyond the national authorities seems to have had as much know-how, staff and infrastructure for ensuring compliance. As has already been argued elsewhere, control over such resources is one condition that allows national authorities to influence EU decision-making (Boeger & Corkin, 2017). Specific to enforcement, however, is that the national authorities acquired these resources in the context of their existing mandates for EU policy enforcement. In the decades prior to the establishment of the EU agencies and networks that were studied for this dissertation, EU policies were enforced purely at national level. This mandate incentivized national authorities to acquire an array of important resources, and would later allow them to get a solid position for influencing enforcement reforms and their outcome.

The second aspect characterizing the reform of EU enforcement institutions concerns the distinct set of actor preferences. Previous research focuses, to a great extent, on functional and political goals that actors pursue when establishing EU agencies or EU networks of national authorities (e.g. Blauberger & Rittberger, 2015), although they recognize that these goals are shaped by institutional contexts in which these actors are situated (Vantaggiato, 2019a). This dissertation, and notably chapters 3 and 5, has revealed additional and novel types of interests that policy-makers pursue when designing EU enforcement institutions. Chapter 3, first, underscores the relevance of (what could be described) as cultures of enforcement that have developed within epistemic communities of enforcing authorities. I demonstrated how expertise and professional methodologies for the enforcement of EU medical devices and incident investigation policies conflicted with those within the EMA and the EASA. This, chapter 3 shows, has led policy-makers to rule out attributing enforcement powers to these existing EU agencies in closely related policy fields. This finding indicates that communities of enforcers develop professional cultures of their own, and that these cultures and their mutual compatibility may influence their preferences during the reform of EU enforcement institutions. Chapter 5, second, demonstrates that policy-makers' preferences for EU agencies and networks of national authorities are also likely to be influenced by the industries in which enforcers ensure compliance. The nature and composition of those industries seem to influence the preferences of the national authorities in particular.

The findings of this dissertation also show that rationales for the establishment of EU agencies and networks were often mixed – contrary to existing research that tends to focus on one type of rationale alone. For example, Kelemen and Tarrant (2011) have exclusively discussed the political reasons for EU legislators to opt for EU agencies or networks, while Blauberger & Rittberger (2017) limit themselves to discussing functional reasons. In line with Mathieu (2016) and Vantaggiato (2019a), the findings of this dissertation paint a more nuanced picture. Not only are decisions influenced by other rationales than functional, political or institutional ones (see above) – this research also demonstrate that these different types of rationales are interrelated. Chapter 3, first, shows that the epistemic rationales underlying national authorities' preferences did not only have a cultural component, but also a functional one. In the case of medical devices, for example, the professional values and methodologies were not only incompatible with those in the domain of medicines policy; regulators of medical devices also believed that substituting their enforcement culture with the medicines policy logic, would deteriorate the safety of medical devices, and thereby the functionality of medical devices policy enforcement more broadly. Chapter 5, second, shows that national authorities' preferences for EU networks or EU agencies need not be either functional or political, but can be both at the same time. As that chapter demonstrates, national authorities' preferences are related to the characteristics of regulated industries: the more international and concentrated an industry, the more prone they are to transferring powers to an EU agency. As it turned out, national authorities' preferences in this context had both a functional as well as a political component. Functionally, different industries may need different types of interaction for enforcement to be effective, and politically, different industries may lead to different perceptions of authority and responsibility.

An important empirical contribution to the institutionalist literature was the Commission's standstill policy on the establishment of novel EU agencies. As discussed, previous work had already indicated that the pace at which new EU agencies are created is in decline (Egeberg & Trondal, 2017), and that the Commission was indeed reluctant to table proposals for new such institutions in specific policy fields (Greer & Löblova, 2017). This dissertation confirms these earlier findings as it shows that the Commission upheld a deliberate standstill policy across policy areas and for a longer period of several years. Chapter 3 demonstrates that the Commission services – in the areas of medical devices and aviation incident investigation – did not wish to table a proposal for the establishment of novel EU agencies and pushed for the expansion of existing agencies instead. The Commission followed this policy at the time when the EU networks for medical devices policy and civil aviation incident investigation were being established. These findings imply that, even though the Commission is hesitant to create *new* EU agencies for specific policy domains for the time being, it is not necessarily wary of EU agency governance per se.

I believe this empirical contribution to the institutionalist debate is relevant for three reasons. First, this finding may help to explain why the proliferation of EU agencies seems to be slowing down (see Egeberg & Trondal, 2017). After all, the diffusion of the EU agency model will inevitably slow down if the Commission is less inclined to table proposals for new EU agencies in the first place. Second, this insight also provides a new insight into the Commission's thinking. Existing contributions have argued that the Commission discards novel EU agencies if it fears that its own competencies may be lost by doing so (Mathieu, 2016; Thatcher, 2011). This reasoning, however, did not apply in the cases of medical devices and aviation incident investigation. The Commission indeed refrained from establishing novel EU agencies in these cases, but a supposed loss of Commission competences cannot explain its refusal to establish new agencies, as it didn't have competencies for medical devices policy enforcement and aviation incident investigations to begin with. Instead, the case studies presented in chapter 3 indicated that the Commission considered new EU agencies as cost-inefficient compared to the expansion of existing ones, and that the Commission may have wanted to pre-empt public outcry against novel EU bureaucracies (Greer & Löblova, 2017). As a consequence, third, research on EU agencies should shift focus from the creation of new institutions to the expansion of existing ones. As the case studies of medical devices and aviation incident investigation have shown, the Commission's standstill policy on EU agencies did not prevent it from seeking to expand the EU agencies already out there. Future agencification in the EU may therefore take place through the expansion of existing agencies' competences rather than the establishment of new ones. Research on this topic should therefore take this into account.

Literature on EU law

This dissertation's findings also have implications for the literature on EU law. One assumption generally underlying the legal literature on the EU is that the creation of EU institutions is the exclusive result of decision-making by the formal EU legislative institutions. According to EU law, the Commission formally proposes the establishment of a particular EU organization, after which the European Parliament and the Council of Ministers agree on whether or not to create that organization – a division of labor which ought to benefit institutional balance and democratic legitimacy. This dissertation qualifies this legal assumption in two important ways. First, and in line with the political sciences literature on EU politics more generally (e.g. Lelieveldt & Princen, 2015), this dissertation shows that important decisions and compromises are made already in the early informal stages of the decision-making process – before any legislative proposals are drafted or submitted to the institutions formally qualifying as the EU's legislator. Chapter 3 shows, for example, that the options of EU agencies for medical devices and incident investigation were already being discussed – and discarded – long before the Commission submitted its proposals to the other legislative institutions. Second, this dissertation demonstrates that national authorities' civil servants are likely to have had a considerable impact on enforcement reforms. These officials, however, are not elected and

have no political responsibility themselves – even though EU legislation is legally seen as the result of a democratic process in which the member states (in the Council) are represented by the ministerial levels who can commit the member state in question (article 16 TEU). This dissertation's findings, in sum, contrast with the strictly legal circumscription of the EU legislative process. While the influence of particular interests and informal decision-making in the early stages of policy-making is not surprising per se, the legal literature does not yet seem to fully apprehend the relevance of early informal decision-making for the outcome of the legislative process.

This dissertation also underscores the relevance of informal norms for decision-making in the EU. Within the legal literature, there is a natural inclination to focus on written and binding rules that originate from authoritative sources; particularly the creation of institutions and attribution of powers is seen as conditional upon higher norms of a constitutional nature. Whereas the literature on EU law has already contested the relevance of higher EU-norms for the creation of EU agencies (e.g. Van Cleynenbreugel, 2014), this dissertation demonstrates that norms of an informal nature and outside the legal hierarchy can have an impact that is much more profound (see also Senden, 2004; Georgieva, 2021). As this dissertation shows, informal norms have been the basis for opposition against expanding existing EU agencies in the policy domains of medicines and airworthiness policy. Chapter 3 showed that national authorities advocated against expending these institutions because of methodologies and values they adhered to for enforcing EU medical devices policy and investigating civil aviation incidents. These rules were not so much laid down in legal sources, but as mentioned, were a part of the prevailing culture among professionals working in the respective policy domains. Additionally, the Commission's informal standstill policy is likely to have prevented the establishment of new EU agencies in those policy domains. Informal norms, lastly, have also influenced the establishment of the EU medicines and airworthiness agencies. As mentioned, these EU agencies were established partly because was agency creation was seen as normal in regulatory governance more broadly (Levi-Faur & Jordana, 2004; Majone, 1994). Conventions in the context of policy enforcement, lastly, have equally influenced the role of such agencies in the enforcement of EU policies.

Another implication of this dissertation for the legal literature on EU law and policy concerns the relation between coordination – through EU agencies and networks – and the concept of mutual trust. In the existing literature, mutual trust tends to be discussed only in relation to systems of mutual recognition, whereby the existence of some trust among member states is seen as a precondition for the functioning of mutual recognition systems (Cambien, 2017; Barnard, 2022). Substituting mutual recognition for coordination through networks and EU agencies, then, may imply that there was insufficient mutual trust to come to collective decisions through mutual recognition. The findings of this dissertation, however, indicate that mutual trust and coordination through EU agencies and networks rather go hand in hand. First,

the case studies have shown that confidence among national authorities can be a precondition for networks and EU agencies to be established in the first place. As demonstrated, coordination through EU agencies and networks was – to some extent – a function of national authorities' willingness to pool operational and decision-making capacities and substitute individual for collective action. Without some confidence in joint decision-making and its comparative advantages, the likelihood of national authorities willing to coordinate would have been rather slim. Second, networks of national authorities and EU agencies can also foster mutual trust in ways it was otherwise lacking. Chapter 4 indicated that mutual recognition systems in the area of airworthiness and medicinal products were malfunctioning: mutual trust among national authorities was insufficient to guarantee the mutual acceptance of inspection results. The EASA and the EMA were established to overcome these deficits, and even though decisions are now indeed made centrally and for the EU at once, they have fostered the confidence among national authorities to work together and make single decisions.

6.4. Implications for practice

This dissertation's central research question was to uncover the reasons why EU legislators establish EU agencies and networks of national authorities for the enforcement of EU policies. The main aim behind this research question was theoretical: to gather information about the establishment of EU enforcement agencies and networks, and to use those insights for a reflection on existing theory. The findings of this dissertation also have some practical relevance nonetheless.

First, this dissertation's insights may benefit future institutional design processes. The preceding chapters have identified some conditions under which EU legislators design institutions for the enforcement of EU policies, and the preferences they had throughout the establishment process. The case studies may not demonstrate the extent to which the created institutions fulfill the objectives EU policymakers wanted them to fulfill, but they do reveal part of why policy-makers did what they did – which may useful knowledge for institutional design in the future. Chapter 5, for example, showed that there may be a relationship between different characteristics of regulated industries and EU legislators' choice between institutional designs. The identification of this relationship may motivate EU legislators to take these and other industry characteristics into account more purposively and explicitly when designing novel institutions, which may benefit the success of future policy reforms. Chapter 4, furthermore, demonstrated that EU policy-makers align institutional designs with model institutions in other policy domains because they are perceived as fitting or appropriate. These findings demonstrate that transferring institutional models that proliferate elsewhere may increase the legitimacy, and thereby the likelihood of realizing proposed policy options.

Also, this dissertation's insights might feed into, or help start, a discussion about national authorities' position in the EU legislative process. National authorities have long been – and likely still are – crucial to the effectuation of many EU policies, and can therefore be crucial to making enforcement *reforms* effective as well. First, this dissertation has shown that national authorities were mandated to enforce EU policies for decades, which has led to the accumulation of substantial expertise and infrastructure at the national level as well as productive relations between authorities and regulated industries. And because they possessed the assets that were not easily accessible otherwise, it may be very relevant to include national authorities in the policy-making process. A different but related reason to embed national authorities' preferences in the reform process is that their concerns and preferences may revolve around substantive issues that are crucial for policy effectiveness. Taking these concerns into account – or not – may substantially affect the outcome of proposed policy reforms, and thereby the functionality and legitimacy of policy more broadly. It is particularly relevant to distinguish 'power' preferences from substantive preferences about policy and enforcement. National authorities, as well as other actors, may seemingly operate in their self-interest, but this purported drive for self-preservation need not be an end in itself, nor need it be the only thing that motivates their opposition to policy reforms. As this dissertation shows, national authorities whose competence is at stake may have valid substantive reasons for advocating against policy reforms, and their concerns should not be mistaken for a mere wish to preserve authority or bureaucratic turf. In the case of aviation incident investigation, for example, national authorities strongly objected to the integration of additional incident investigation tasks in the EASA. Their opposition, however, was closely related to a fear for conflicts of interest that could have hampered both the effectiveness of aviation incident investigations and of airworthiness certification. For example, investigations into aviation incidents may be hampered when joined by the organization that certified the defunct aircraft itself. Likewise, it may not preferable for incident investigation conclusions to feed into the airworthiness certification process. Thus, national authorities' opposition against reforms, even though these may affect their power, need not be couched in the superficial need for self-preservation. They can viably be explained with reference to legitimate concerns about the effectiveness of policies and their enforcement.

Another way in which this dissertation may contribute to improving the EU legislative process is through its insight that the establishment of EU institutions cannot only be explained rationally, but that also non-rationalist mechanisms and institutional conditions are relevant. These insights could be feed into the way EU legislators motivate their decisions and proposals. EU legislators, and the Commission in particular, make great efforts to motivate their policy preferences: in the past decades, the size of explanatory memoranda accompanying legislative proposals have grown considerably, and the EU also more frequently publishes the impact assessments that are the basis for these explanatory memoranda. Those documents, however, tend to paint a rather rationalist picture of the decision-making process. They carefully measure

the extent of policy problems, calculate the costs and benefits of policy options, and use objective standards and benchmarks to make choices between them. While this dissertation confirms that rationalist reasoning may explain why EU legislators reach decisions, it also shows that non-rationalist mechanisms play a considerable role. Chapter 4, for example, showed that the choice for EU agencies in the areas of medicines and airworthiness regulation was partly determined by the popularity of the agency-model in European states and in other parts of the world. And chapter 3 shows that the establishment of EU networks was partly determined by the Commission's perception that creating another EU agency would be very unpopular instead. Such arguments, however, usually do not feature in the Commission's preparatory documents, even though articulating non-rationalist arguments alongside rationalist ones could have distinct advantages. First, it could be a way to be more transparent about the complexity of policy-making processes. There are solid arguments to be as transparent as possible about EU legislative decision-making, and as this dissertation shows, such decision-making consists of more than rationalist arguments. Second, acknowledging the relevance of less rationalist arguments in the decision-making process can also serve to increase the legitimacy of policy outcomes. More-encompassing explanatory memoranda and impact assessments can demonstrate that EU legislators are also sensitive to the values and perceptions that live in society, even though these are less tangible.

6.5. Limitations and avenues for future research

The conclusions drawn in this chapter, as well as the limitations and caveats of this dissertation more broadly, help to point out avenues for future research. The first limitation of the conclusions drawn in this dissertation is their limited generalizability towards other cases. This means that there are very few cases – if any – for which this dissertation's conclusions are likely to hold true. Many scope conditions apply to the conclusions drawn above, and the likelihood of other cases being able to meet them is low. This is not only because of the low number of policy areas in which EU legislators have created networks and EU agencies for the enforcement of EU policies (see chapter 1), but also because these policies and policy areas tend to have specific and distinct dynamics that may affect the creation and design of organizations in those areas (see chapter 2). Several important scope conditions have been discussed in chapters 3 and 5, and they require careful consideration if one seeks to examine the relevance of this dissertation's conclusions for other cases.

One other limitation (and scope condition) of this dissertation is its focus on the *creation* of new EU agencies and networks *in specific periods of time*. Later expansions of existing EU institutions, however, might become a more relevant research focus in the future. This dissertation, for example, focused on the EASA and the EMA at the time of their establishment, but their

mandates and role in EU policy enforcement have changed considerably in the years thereafter. These respective agencies, for example, can now also request the issuing of financial penalties against companies (the EMA since 2004 and the EASA since 2008). These and other interesting changes have not been analyzed here, but this dissertation indicates that such modifications – and most likely, expansions – of existing EU agencies' mandates may become more prevalent than the establishment of novel ones. Salient in this regard is the Commission's presumed standstill policy on EU agencies: when it proved problematic to vest additional competences for medical devices and aviation incident investigation in the EASA and the EMA, the Commission did not pursue the alternative of establishing new agencies. Several new EU agencies have been created in recent years (see section 4.1.), but the speed of EU agency proliferation has declined in comparison to earlier periods of time (Egeberg & Trondal, 2017). Future research on EU agencies may want to follow suit and broaden attention from the establishment of new organizations to the expansion of existing ones.

This dissertation, third, has focused on reasons why EU legislators *differentiate between* EU agencies and networks of national authorities. And even though EU agencies and networks have also been studied in isolation, a considerable part of this dissertation conceptualizes the creation of these respective institutions as a choice between two different alternatives. In reality, however, EU legislators need not treat these institutional designs as two mutually exclusive options. As chapter 2 already acknowledged, both EU agencies as well as networks can co-exist and perform complementary enforcement functions within one policy domain. This does not mean that the analytical distinction between EU agencies and networks is an overly simplistic view of reality. As shown, there are cases in which EU legislators treat them as alternatives, and these cases are worthwhile studying. Nonetheless, it could be worthwhile for future research to focus on the complementary exercise of enforcement functions by different institutions. The legal literature on EU policy enforcement has already shown how some EU agencies and national authorities simultaneously perform enforcement tasks, and to what issues this can lead. The theory on institutionalism, in turn, has already acknowledged that the creation of one institution does not necessarily lead to the abolishment of another (Thatcher, 2011; Vantaggiato, 2019a). Future research, however, could also benefit from mapping the axes along which tasks are divided between multiple complementary institutions, and exploring the reasons behind such divisions.

This dissertation has also been limited to studying institutions with a role in the enforcement of EU policies. As mentioned in the introduction, EU institutions that perform enforcement functions for the benefit of national policy goals are outside the scope of this dissertation. This means that the conclusions drawn here are not *a priori* relevant for studying EU enforcement institutions that help achieving national policy goals – including, for example, EU agencies in the AFSJ, such as Eurojust or the European Union Agency for Law Enforcement Cooperation

(Europol). Even though it concerns EU institutions with a considerable role in enforcement, the roles of EU legislative actors in the AFSJ have traditionally been very different from those in the internal market domains that were the subject of this dissertation. Furthermore, enforcement in the AFSJ tends to be closely related to the criminal laws of the member states. This means that not only the position, but also the preferences of decision-making actors may be construed differently than in internal market domains. Future research on institutionalism could benefit from studying the establishment of EU enforcement agencies and EU networks in the AFSJ, and particularly from distinguishing between EU legislators' rationales for these institutions and institutions in the domain of the internal market.

6.6. Closing remarks

In the beginning of this dissertation I referred to the ideas of David Howarth. He argued that there are strong resemblances between the work of lawyers and the work of professional engineers: both groups of professionals build, revise and fix systems, and both groups of professionals work to make these systems best serve people and their needs. Now where does this dissertation leave the engineers that build our systems for the enforcement of EU policies? Its aim, after all, was not to produce normative insights about how such systems should be altered or improved. Its findings, however, seem an important prerequisite for doing so: in order to change our enforcement systems, they ought to be understood in the first place. This dissertation has shown how some of today's significant enforcement systems have come to be, and how EU and national engineers went about in devising them.

Appendices

References

Dutch summary | Nederlandstalige samenvatting

Acknowledgements | Dankwoord

About the author

Appendices

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A. Literature

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ICAO Annex 13 Aircraft Accident and Incident Investigation

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Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency

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Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Council Directive 94/56/EC of 21 November 1994 establishing the fundamental principles governing the investigation of civil aviation accidents and incidents

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Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC

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Dutch summary | Nederlandstalige samenvatting

In dit proefschrift onderzoek ik instituties van de Europese Unie (EU) die bijdragen aan de handhaving van EU-beleid. Twee typen instituties staan in het onderzoek centraal: EU-netwerken, bestaande uit autoriteiten van de lidstaten die samenwerken bij de handhaving van EU-beleid; en EU-agentschappen, die als min of meer zelfstandige organisaties aan die handhaving bijdragen. Deze netwerken en agentschappen komen voor op allerlei beleidsterreinen, maar voor mijn onderzoek heb ik me tot vier specifieke terreinen beperkt: het beleidsterrein van medische hulpmiddelenregulering, dat van ongevalsonderzoek in de luchtvaart, het beleidsterrein van medicijnregulering, en het beleid ten aanzien van de luchtwaardigheid van luchtvaartuigen. Op deze vier beleidsterreinen is de EU nadrukkelijk aanwezig, maar zijn er belangrijke verschillen als het gaat om de instituties die bijdragen aan de handhaving: op de eerste twee beleidsterreinen zijn er EU-netwerken die bijdragen aan de handhaving, terwijl er op de laatste twee beleidsterreinen handhavingstaken zijn toebedeeld aan EU-agentschappen.

De centrale vraag bij mijn onderzoek was dan ook: waarom richten EU-wetgevers agentschappen en netwerken van nationale autoriteiten op voor de handhaving van EU-beleid, en waarom differentiëren ze tussen deze twee typen instanties?

EU-netwerken en de rol van professionele cultuur

Na een verkennende inventarisatie van de bestaande wetenschappelijke literatuur bestudeerde ik eerst de oprichting van twee netwerken die bijdragen aan de handhaving van het EU-beleid inzake medische hulpmiddelen en luchtvaartongevalsonderzoek. Ik heb deze terreinen gekozen omdat er voorafgaand aan de totstandkoming van deze EU-netwerken al EU-*agentschappen* bestonden op twee andere, zeer vergelijkbare beleidsterreinen: die van medicijnbeleid en luchtwaardigheidsbeleid. Dat roept de vraag op waarom handhavingstaken voor het beleid inzake medische hulpmiddelen niet zijn toebedeeld aan het reeds bestaande EU-medicijnagentschap, en waarom handhavingstaken voor luchtvaartongevalsonderzoek niet zijn toebedeeld aan het al opgerichte EU-agentschap voor luchtvaartuigluchtwaardigheid. Waarom hebben EU-wetgevers nieuwe netwerken van nationale autoriteiten opgericht terwijl er op zeer vergelijkbare beleidsterreinen al EU-agentschappen waren?

Voordat de genoemde netwerken werden opgericht verkende de Europese Commissie inderdaad eerst of de handhaving van medische hulpmiddelenbeleid en luchtvaartongevalsonderzoek mede kon worden toebedeeld aan de genoemde (en dus reeds bestaande) EU-agentschappen voor medicijnbeleid en luchtwaardigheidsbeleid. Ook voor de Europese Commissie waren er evidente overeenkomsten tussen luchtvaartongevalsonderzoek en luchtwaardigheidsbeleid enerzijds, en tussen medicijnbeleid en medische hulpmiddelenregulering anderzijds. Toch is

deze toebedeling uiteindelijk niet tot stand gekomen, en uit mijn onderzoek blijkt dat weerstand van de nationale autoriteiten uit de lidstaten dat mede heeft voorkomen. Deze autoriteiten hebben weliswaar geen formele rol bij de oprichting van EU-netwerken en EU-agentschappen, maar kunnen toch van grote invloed zijn op de Europese besluitvorming. Verrassend was dat de nationale autoriteiten met name tegen toebedeling hebben gepleit omdat dat indruiste tegen de professionele cultuur die eigen is aan medische hulpmiddelenregulering en aan luchtvaartongevalsonderzoek. Zo blijkt de methodiek voor de handhaving van medische hulpmiddelenbeleid op belangrijke aspecten te verschillen van de handhavingsmethodiek van medicijnbeleid, en uit vrees dat de handhaving van medische hulpmiddelenbeleid onder druk kwam te staan door toebedeling aan het EU-agentschap voor medicijnen, hebben de nationale autoriteiten tegen die toebedeling weerstand geboden. Een soortgelijke dynamiek deed zich voor op het terrein van luchtvaartongevalsonderzoek.

Omdat toebedeling van handhavingstaken aan de bestaande EU-agentschappen op vergelijkbare beleidsterreinen zoveel weerstand opriep, onderzocht de Europese Commissie ook de mogelijke oprichting van aparte agentschappen voor medische hulpmiddelenbeleid en ongevalsonderzoek. Maar ook zulke nieuwe EU-agentschappen bleken niet haalbaar: EU-wetgevers vreesden dat dat anti-Europese sentimenten in de samenleving kunnen voeden, en het was bovendien kostbaar ten opzichte van toebedeling aan bestaande agentschappen. Het alternatief dat overbleef was om bestaande samenwerkingsverbanden tussen nationale autoriteiten te formaliseren en te intensiveren. En zodoende heeft de EU-wetgever ervoor gekozen om handhaving op het gebied van medische hulpmiddelenbeleid en ongevalsonderzoek in de luchtvaart mede toe te bedelen aan netwerken van nationale autoriteiten.

EU-agentschappen en de rol van het lidstaatmodel

Na bestudering van de EU-netwerken richtte mijn onderzoek zich op de twee genoemde EU-agentschappen: het EU-agentschap voor medicijnregulering en het EU-agentschap voor de luchtwaardigheid van luchtvaartuigen. EU-agentschappen met handhavingstaken zijn bijzondere instituties omdat vrijwel al het EU-beleid lange tijd gestoeld was op een model waarin de lidstaten – en hun nationale autoriteiten – voor de handhaving zorgdroegen. Mede ingegeven door soevereiniteitsoverwegingen was het aan de lidstaten om dwang jegens burgers en bedrijven in te regelen en toe te passen, waarbij ze bovendien beschikten over een ruime mate van autonomie. De oprichting van EU-agentschappen die (min of meer) zelfstandig aan handhaving bijdragen zijn een significante verandering ten opzichte van dat model, hetgeen de vraag oproept of dat model bij de totstandkoming van die agentschappen überhaupt een rol heeft gespeeld. Heeft het lidstaatmodel invloed gehad op de oprichting van EU-agentschappen met handhavingstaken, en zo ja, hoe?

Uit mijn onderzoek blijkt dat het lidstaatmodel inderdaad een effect had op de oprichting van de EU-agentschappen voor medicijnregulering en luchtwaardigheidsregulering. Tijdens mijn onderzoek heb ik drie verschillende effecten kunnen ontwaren. Op de eerste plaats gingen er morele effecten uit van het lidstaatmodel. Tijdens de oprichting van het EU-agentschap voor medicijnregulering hebben alle actoren zich bijvoorbeeld onomwonden uitgesproken tegen de aanstelling van EU-ambtenaren die de bevoegdheid zouden hebben om bedrijven te inspecteren. Hoewel dat juridisch gezien niet onmogelijk was, vond men dat het verrichten van inspecties en het aanstellen van inspecteurs een verantwoordelijkheid van de lidstaten was, waarbij men verwees naar de manier waarop de handhaving van EU-beleid tot dan toe gebruikelijk was (het lidstaatmodel). Een soortgelijke dynamiek deed zich ook weer voor op het terrein van luchtwaardigheidsregulering.

Op de tweede plaats kwam er vanwege het lidstaatmodel een bijzonder gewicht toe aan de voorkeuren van bestaande instituties die het EU-beleid al decennialang op nationaal niveau hadden gehandhaafd. In de loop der jaren hadden de nationale handhavingsautoriteiten veel gezag en (schaarse) kennis vergaard, waardoor hun voorkeur van grote invloed kon zijn op de oprichting van een EU-agentschap. In het geval van luchtwaardigheidsregulering stonden de nationale autoriteiten positief tegenover een EU-agentschap en droegen zij actief bij aan de oprichting ervan. Maar dat was anders in het geval van medicijnbeleid, waarbij het EU-agentschap uiteindelijk geen bevoegdheden kreeg op de (deel)gebieden waarop de nationale autoriteiten al competent waren.

En op de derde plaats waren er belangrijke institutionele ontwikkelingen op nationaal niveau waarvoor ook beleidsmakers op EU-niveau gevoelig waren. Toen de EU-agentschappen voor medicijnregulering en luchtwaardigheid werden opgericht vond er wereldwijd een grote omslag plaats in de manier waarop landen hun overheidsapparaten inrichtten. Steeds vaker werden overheidstaken op afstand van de politiek geplaatst en toebedeeld aan min of meer onafhankelijke overheidsinstanties. En waar die institutionele veranderingen zich voordeden in de lidstaten, werden ze in meer of mindere mate overgenomen op EU-niveau. Zowel bij de oprichting van het medicijnagentschap als bij de oprichting van het luchtwaardigheidsagentschap lieten beleidsmakers in de EU zich inspireren door de vele agentschappen die elders in Europa en in de wereld werden opgericht. Het kopiëren van institutionele modellen kan bijdragen aan de legitimiteit ervan.

EU-agentschappen, EU-netwerken, en de samenstelling van industrieën

Het laatste deel van mijn onderzoek richt zich specifiek op de onder toezicht staande industrieën. Om beleid te kunnen handhaven interacteren instituties met de industrieën waarop zij toezicht houden, en eerder onderzoek gaf al aanleiding om te denken dat de samenstelling van zulke industrieën van invloed kan zijn op de oprichting van een EU-agentschap of de keuze voor een EU-netwerk van nationale autoriteiten. In dit deel van mijn onderzoek stond de vraag centraal: wordt de keuze om handhavingstaken toe te bedelen aan een EU-agentschap of een EU-netwerk beïnvloed door verschillen tussen onder toezicht staande industrieën?

Mijn onderzoek identificeert inderdaad een verband tussen de keuze voor een EU-handhavingsagentschap of een EU-netwerk enerzijds, en de mate van industriële concentratie anderzijds. Zo blijkt dat de onder toezicht staande industrieën gefragmenteerd zijn en lokaal opereren op de twee beleidsterreinen waar EU-netwerken bijdragen aan de handhaving (medische hulpmiddelen en luchtvaartongevalsonderzoek), en is de industrie juist geconcentreerd op de beleidsterreinen waar handhavingstaken zijn toebedeeld aan EU-agentschappen (medicijnen en luchtwaardigheid van luchtvaartuigen).

In mijn onderzoek identificeer ik twee redenen voor dit verband. Het eerste verband heeft te maken met de effectiviteit van de handhaving. EU-agentschappen hebben een EU-wijd mandaat, waardoor zij effectiever kunnen handhaven ten aanzien een klein aantal grote ondernemingen die in de hele EU actief zijn. Het mandaat van EU-netwerken is er daarentegen op toegerust om te kunnen handhaven ten aanzien van een groot aantal ondernemingen die primair lokaal actief zijn. En het tweede verband heeft opnieuw te maken met de voorkeuren van nationale autoriteiten. Waar industrieën gefragmenteerd en lokaal actief zijn lijken nationale autoriteiten handhaving dichterbij te willen houden in de vorm van een EU-netwerk, terwijl zij bereid zijn om verantwoordelijkheden af te staan aan een EU-agentschap wanneer de industrie geconcentreerd is en EU-wijd opereert.

Acknowledgements | Dankwoord

Een proefschrift schrijf je weliswaar zelf maar gelukkig nooit helemaal alleen, en daarom wil ik graag iedereen bedanken die aan mijn onderzoek en onderwijs van de afgelopen tijd heeft bijgedragen.

Allereerst wil ik het bestuur van het Utrecht Centre for Regulation and Enforcement in Europe (RENFORCE) en het bestuur van het departement Bestuurs- en Organisatiewetenschap (USBO) bedanken, omdat zij mijn onderzoekstraject mogelijk hebben gemaakt. Daarnaast bedank ik ook graag de RENFORCE- en USBO-onderzoekers met wie ik op enig moment inhoudelijk van gedachten heb kunnen wisselen. Mijn bijzondere dank gaat daarbij uit naar Koen Bovend'Eerdt, Michael Hübner, Ton van den Brink, Sebastiaan Princen, Linda Senden, Sybe de Vries, John Vervaele, Nathan Meershoek, Joske Graat, Iro Karagianni, Michiel Luchtman, Colin Scott, Machiel van der Heijden – jullie hebben mijn gedachten, presentaties en stukken met grote regelmaat voorzien van de verrassende, kritische blik die ze goed konden gebruiken.

Daarnaast wil ik ook graag de leden van het Jean Monnet Network on EU law Enforcement (EULEN) bedanken, alsook de deelnemers aan de workshop 'European Administrative Networks. Exploring and explaining the establishment, functioning, impact and accountability of administrative networks in European Union (EU) implementation and enforcement'. Ik bedank in het bijzonder Kelly Blount, David Fernandez Rojo, Ellen Mastenbroek, Dorte Sindbjerg Martinsen, Martino Maggetti, Kutsal Yesilkagit, en Francesca Pia Vantaggiato. Veel dank voor de fijne samenwerking en voor de vele waardevolle inzichten die ik daaraan heb overgehouden.

Verder gaat mijn dank ook uit naar alle medewerkers van de afdeling Internationaal en Europees Recht en de afdeling Staatsrecht, Bestuursrecht en Rechtstheorie. Ik heb genoten van het onderwijs dat ik samen met jullie mocht verzorgen en leerde daar bovendien ook ontzettend veel van. Ik wil Pauline Phoa, Willem Janssen, Hanneke van Eijken, Olia Kanevskaia, Lukas van den Berge en Lisette ten Haaf heel erg bedanken voor hun uitstekende coördinatie en begeleiding; en natuurlijk bedank ik ook graag alle andere docenten met wie ik dat onderwijs gaf.

Voor mij zijn bovendien Angélique Neisingh, Saïd El Yahiaoui, Miranda Walraven, Natasja Costeris, Judith Rippen, Helena Skolozdra, Inge Terwan, en Titia Kloos van grote waarde geweest. Jullie hebben me natuurlijk geholpen bij alle organisatorische, administratieve en praktische kanten van het onderzoek en onderwijs, maar wat jullie eigenlijk doen is nog veel belangrijker dan dat: ik bedank jullie vooral voor de warme tijd die ik bij het departement Rechtsgeleerdheid heb gehad, en waaraan jullie zo veel hebben bijgedragen.

En dan bedank ik ook graag degenen met wie ik op de Newtonlaan mijn werkkamer deelde, en met wie ik het lief en leed van de afgelopen jaren heb kunnen delen. Elmar Schmidt, Joske Graat, Lyndsey Thomsin, Kaan Özkonak, Danaï Georgula, Marize Verhagen, Viktorija Morozovaite en Gabriël van Roosmalen – bedankt voor al het plezier dat we samen hebben beleefd.

Als laatste wil ik enkele personen graag afzonderlijk noemen. Anna Gerbrandy, jij was niet alleen degene die mij tot de academische wereld toeliet; dankzij jou heb ik die wereld ook leren begrijpen. Die belangrijke inzichten hebben mij veel gebracht en ik wil je dan ook graag bedanken voor alle steun die je me in de voorbije jaren gaf. Baine Kerr en Merel Keijzer – jullie sterke karakters en briljante humor verrijken mijn leven op vele manieren. Bedankt voor de afgelopen jaren en voor de unieke vriendschap die daaruit is voortgekomen. En als laatste mijn onwijs grote dank aan mijn copromotor Mira Scholten en promotor Judith van Erp. Jullie scherpe feedback, jullie geduld (dat ik regelmatig op de proef stelde), en bovenal jullie energie en optimisme hebben mij telkens weer vooruitgebracht. Ik ben er nog altijd ontzettend blij mee dat jullie dit project met mij aandurfden, en zal altijd dankbaar blijven voor alles wat jullie me in de voorbije jaren hebben geleerd.

About the author

Laurens van Kreij was born in 1994 in Oss, the Netherlands. After graduating from secondary school in 2012, he went on to study at the Utrecht University School of Law. In 2015 he obtained his Bachelor of Laws degree, after which he was enrolled in the Legal Research Master programme at that same university. Having completed this masters programme, he went on to conduct his PhD research EU policy enforcement through EU agencies and networks of national authorities, while simultaneously teaching courses in European law and legal theory. He currently works as a policy advisor at the Dutch Ministry of Infrastructure and Water Management.

Appendix 1. Archival records (non-confidential only)

Case study 1. EU medical devices policy (two specific network arrangements)

Date	*Title*	*Author*	*Reference number*
23/07/1991	Commission proposal	European Commission	COM(1991) 287 FINAL
29/01/1992	Opinion of the European Economic and Social Committee	European Economic and Social Committee	92/C 79/01
26/02/1992	EP Committee opinion on 1st reading	European Parliament	N/A
15/04/1992	EP Committee report on 1st reading	European Parliament	A3/1992/178
13/05/1992	EP Opinion on 1st reading	European Parliament	92/C 150/03
28/07/1992	Commission amended proposal	European Commission	COM(1992) 356 final
17/12/1992	Agreement on Council common position	Council of the European Union	C3-0105/93
17/12/1992	Agreement on Council common position	Council of the European Union	N/A
08/02/1993	Adoption of Council common position	Council of the European Union	4327 / 1 /93 + ADD 1 [document inaccessible online]
05/03/1993	Transmission to EP of declaration on common position	European Parliament	SEC/1993/362/ FINAL [document inaccessible online]
21/04/1993	EP position on 2nd reading	European Parliament	93/C 150/03
01/06/1993	Commission amended proposal	European Commission	COM(1993) 241 FINAL
02/07/2003	COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT on medical devices	European Commission	COM(2003) 386 final
25/10/2005	COMMUNICATION OF THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS	European Commission	COM(2005) 535 final
22/12/2005	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives	European Commission	COM(2005) 681 final
22/12/2005	Impact Assessment for MDCG.208	European Commission	SEC(2005) 1742
06/05/2008	European Commission Recast of the Medical Devices Directives Public Consultation	European Commission	N/A
06/05/2008	NL Response to Recast of the Medical Devices Directives Public Consultation	Department of Pharmaceutical Affairs and Medical Technology, Dutch Ministry of Health, Welfare and Sport	N/A

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
06/05/2008	SE Response to Recast of the Medical Devices Directives Public Consultation	Medical Products Agency (Sweden)	N/A
06/05/2008	Italian Response to Recast of the Medical Devices Directives Public Consultation	Government of Italy	N/A
06/05/2008	Irish Response to Recast of the Medical Devices Directives Public Consultation	Irish Medicines Board	N/A
06/05/2008	German NCA Response to Recast of the Medical Devices Directives Public Consultation	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten	N/A
06/05/2008	German Government Response to Recast of the Medical Devices Directives Public Consultation	Bundesministerium für Gesundheit	N/A
06/05/2008	French Response to Recast of the Medical Devices Directives Public Consultation	Représentation permanente de la France auprès de l'Union européenne	N/A
06/05/2008	Danish Response to Recast of the Medical Devices Directives Public Consultation	Danish Ministry of Health and Prevention	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Joint Medical Device Industry Contribution	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Eucomed	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Dental Trade Alliance	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Dental Trade Alliance	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Diagned	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	EDMA	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Irish Medical Devices association	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	EUROM VI	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Spectaris	N/A
06/05/2008	Industry Interest Group Response to Recast of the Medical Devices Directives Public Consultation	EuroGentest	N/A

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
06/05/2008	German Notified Bodies Interest Group Response to Recast of the Medical Devices Directives Public Consultation	IG-NB	N/A
06/05/2008	Consumer Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Medicines in Europe Forum, HAI Europe, ISDB, EAHP	N/A
06/05/2008	Consumer Interest Group Response to Recast of the Medical Devices Directives Public Consultation	Ordre national des chirurgiens-dentistes	N/A
30/06/2008	Background paper	European Commission	[unknown]
05/12/2008	Summary of the Commission public consultation on the recast of the general regulatory framework for medical devices	European Commission	N/A
23/01/2010	Commission "Exploratory Process on the Future of the Medical Device Sector	European Commission	N/A
31/03/2010	ANNEXES to the Annexes to the COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Community work programme 2010.	European Commission	COM(2010) 135 final
23/02/2011	Summary of the Commission public consultation on specific aspects related to in vitro diagnostic medical devices and the revision of Directive 98/79/EC	European Commission	N/A
23/05/2011	Cardiologist Group Calls For Centralized Device Oversight In Europe	Medtech Insight	N/A
08/07/2011	Council conclusions on innovation in the medical device sector	Council of the European Union	2011/C 202/03
23/09/2011	Draft Opinion of the Impact Assessment Board	European Commission	[unknown]
01/02/2012	Analysis of the PIP Breast implants case in the light of the envisaged revision of the EU regulatory framework for medical devices	European Commission	N/A
14/06/2012	European Parliament resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP	European Parliament	N/A
24/09/2012	Europe Device Reg Reform Proposal: More Scrutiny Of Notified Bodies Expected	Medtech Insight	N/A
26/09/2012	Commission legislative proposal	European Commission	COM(2012) 542 final
26/09/2012	Commission impact assessment Part I (systemic/horizontal impact assessment)	European Commission	SWD(2012) 273 final Part I

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
26/09/2012	Commission summary impact assessment	European Commission	SWD(2012) 274 final
26/09/2012	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals	European Commission	COM(2012) 540 final
26/09/2012	Commission press release	European Commission	IP/12/1011
26/09/2012	Commission explanatory memorandum	European Commission	COM(2012) 541 final
26/09/2012	Commission impact assessment Part IV	European Commission	SWD(2012) 273 final Part IV
26/09/2012	Commission impact assessment Part II (MD impact assessment)	European Commission	SWD(2012) 273 final Part II
26/09/2012	Commission impact assessment Part III (IVD impact assessment)	European Commission	SWD(2012) 273 final Part III
01/10/2012	EU Device Reform Proposal Adds More Government Scrutiny, But No FDA-Like Review Body	Medtech Insight	N/A
10/10/2012	MINUTES of the 2017th meeting of the Commission held in Brussels	European Commission	PV(2012) 2017 final
29/10/2012	Surprise Inspections, And More, Coming Soon To The EU	Medtech Insight	N/A
06/12/2012	Debate in Council	Council of the European Union	N/A
08/02/2013	Opinion of the European Data Protection Supervisor on the Commission proposals for a regulation on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and regulation (EC) No 1223/2009 and a regulation on in vitro diagnostic medical devices	European Data Protection Supervisor	2013/C 358/07
08/02/2013	EP (IMCO) Committee opinion	European Parliament	PE507.987
14/02/2013	Opinion of the European Economic and Social Committee	European Economic and Social Committee	2013/C 133/10
12/04/2013	EP Committee draft report	European Parliament	PE507.972
22/04/2013	Pre-Market Authorization And Other Sweeping Proposals Unveiled In EU Parliament	Medtech Insight	N/A
29/04/2013	EU Parliament's Public Health Committee Debates Device Reform Proposal	Medtech Insight	N/A
14/05/2013	EP Committee tabled amendments	European Parliament	PE510.741
14/05/2013	EP Committee tabled amendments	European Parliament	PE510.765
14/05/2013	EP Committee tabled amendments	European Parliament	PE510.766
14/05/2013	EP Committee tabled amendments	European Parliament	PE510.767
21/05/2013	EP Committee tabled amendments	European Parliament	PE510.851

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
20/06/2013	EP (EMPL) Committee opinion	European Parliament	PE506.249
25/09/2013	(Vote in committee, 1st reading/single reading)	European Parliament	N/A
09/10/2013	Committee report tabled for plenary, 1st reading/single reading	European Parliament	A7-0324/2013
22/10/2013	Results of vote in Parliament	European Parliament	N/A
22/10/2013	Debate in Parliament	European Parliament	N/A
22/10/2013	Decision by Parliament, 1st reading/ single reading	European Parliament	T7-0428/2013
26/11/2013	Council presidency progress report on the examination of proposals on medical devices	Council of the European Union	16609/13
26/11/2013	Council exchange of views on the examination of proposals on medical devices	Council of the European Union	16610/13
11/12/2013	Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices. DE/SE/BE/IT/UK and NL delegations	Council of the European Union	DS 2046/13
27/01/2014	Debate in Council	Council of the European Union	17583/13
28/01/2014	Debate in Council	Council of the European Union	17583/13 ADD 1
31/01/2014	Debate in Council	Council of the European Union	17583/13 ADD 1 REV 1
05/02/2014	Debate in Council	Council of the European Union	17583/13 COR 1
06/02/2014	Debate in Council	Council of the European Union	17583/13 ADD 1 REV 1 COR1
06/02/2014	Debate in Council	Council of the European Union	17583/1/13 REV 1
06/02/2014	Debate in Council	Council of the European Union	17583/13 ADD 1 REV 2
26/02/2014	Debate in Council	Council of the European Union	17583/1/13 REV 1 COR 1
26/02/2014	Debate in Council	Council of the European Union	17583/13 ADD 1 REV 2 COR 1
02/04/2014	Decision by Parliament, 1st reading/ single reading	European Parliament	T7-0266/2014
15/05/2014	Council presidency progress report on Chapter VIII	Council of the European Union	9094/1/14 REV 1
16/05/2014	Council presidency progress report on Chapter IV	Council of the European Union	9773/14
28/05/2014	Council presidency progress report on Chapter VII	Council of the European Union	10146/14
12/06/2014	Council presidency progress report on the examination of proposals on medical devices	Council of the European Union	10855/14
07/07/2014	Debate in Council (press message)	Council of the European Union	11122/14
16/07/2014	Debate in Council	Council of the European Union	11195/14
16/07/2014	Debate in Council	Council of the European Union	11195/14 ADD 1
12/11/2014	Unofficial room-document regarding Articles 63 and 66	Council of the European Union	MDEV-64

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
25/11/2014	Council presidency progress report on the examination of proposals on medical devices	Council of the European Union	15881/14
26/11/2014	Council presidency progress report on the examination of proposals on medical devices	Council of the European Union	16116/14
01/12/2014	Debate in Council (press message)	Council of the European Union	16269/14
05/12/2014	Debate in Council	Council of the European Union	16258/14 ADD 1
17/12/2014	Debate in Council	Council of the European Union	16258/1/14 REV 1
18/12/2014	Debate in Council	Council of the European Union	16258/1/14 ADD 1 COR 1
01/01/2015	The European Medical Technology Industry – in figures (2014)	MedTech Europe	N/A
30/03/2015	Working party revisions Chapter VIII	Council of the European Union	8276/15 LIMITE PHARM 18 SAN 126 MI 260 COMPET 166 CODEC 589
14/04/2015	Working party revisions Chapter VII	Council of the European Union	7714/15 LIMITE PHARM 15 SAN 96 MI 208 COMPET 141 CODEC 451
11/06/2015	Presidency proposal of 11 June 2015 for a regulation on medical devices	Council of the European Union	9769/15 PHARM 26 SAN 176 MI 391 COMPET 304 CODEC 858
19/06/2015	Debate in Council (press message)	Council of the European Union	472/15
05/10/2015	Debate in Council	Council of the European Union	12488/15
05/10/2015	Debate in Council (press message)	Council of the European Union	12670/15
04/12/2015	Debate in Council	Council of the European Union	14215/15
01/02/2016	Europe Readies For Big Changes In Device Post-Market Surveillance	Medtech Insight	N/A
31/05/2016	Debate in Council	Council of the European Union	9261/16
31/05/2016	Debate in Council	Council of the European Union	9262/16
31/05/2016	Debate in Council	Council of the European Union	9263/16
15/06/2016	Debate in Council	Council of the European Union	9364/3/16 REV 3
16/06/2016	Debate in Council	Council of the European Union	9490/16
27/06/2016	Debate in Council	Council of the European Union	10617/16
08/07/2016	Debate in Council	Council of the European Union	11004/16
08/08/2016	Debate in Council	Council of the European Union	10617/1/16 REV 1
09/08/2016	Debate in Council	Council of the European Union	11662/16
31/08/2016	Debate in Council	Council of the European Union	11662/16 COR 1
01/09/2016	Debate in Council	Council of the European Union	11661/16
12/09/2016	Debate in Council	Council of the European Union	11661/16 REV 1
14/09/2016	Debate in Council	Council of the European Union	11661/16 REV 1 ADD 1
16/09/2016	Debate in Council	Council of the European Union	11661/16 REV 2
20/09/2016	Debate in Council	Council of the European Union	N/A

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
24/09/2016	Debate in Council	Council of the European Union	11661/16 REV 2 ADD 1
16/11/2016	Debate in Council	Council of the European Union	5207/16
01/01/2017	The European Medical Technology Industry – in figures (2016)	MedTech Europe	N/A
22/02/2017	Position of the Council at first reading	Council of the European Union	10728/16 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977
22/02/2017	Draft statement of the Council's Reasons	Council of the European Union	10728/16 ADD 1 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977
24/02/2017	Debate in Council	Council of the European Union	6592/17
27/02/2017	Council statement on its position	Council of the European Union	10728/16 COR 2
27/02/2017	Council statement on its position	Council of the European Union	10728/16 REV 1
27/02/2017	Council statement on its position	Council of the European Union	6592/1/17 REV 1 CODEC 252 PHARM 5 SAN 70 MI 149 COMPET 137
28/02/2017	Council statement on its position	Council of the European Union	10728/16 REV 2
28/02/2017	Council statement on its position	Council of the European Union	6592/1/17 REV 1 ADD 1 CODEC 252 PHARM 5 SAN 70 MI 149 COMPET 137
06/03/2017	Position of the Council at first reading	Council of the European Union	10728/3/16 REV 3 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977
07/03/2017	Statement of the Council's Reasons	Council of the European Union	10728/4/16 REV 4
07/03/2017	Statement of the Council's Reasons	Council of the European Union	10728/4/16 REV 4 ADD 1
08/03/2017	Position of the Council at first reading	Council of the European Union	10728/4/16 REV 4 PHARM 43 SAN 284 MI 478 COMPET 402 CODEC 977 PARLNAT 369
09/03/2017	Commission communication on the position of the Council on the adoption of a Regulation of the European Parliament and of the Council on medical devices	European Commission	COM(2017) 129 final
10/03/2017	Commission communication to the EP on the position of the Council at first reading	European Commission	7192/17

Case study 1. EU medical devices policy (two specific network arrangements) (continued)

Date	*Title*	*Author*	*Reference number*
15/03/2017	EP Committee draft report	European Parliament	PE601.098
16/03/2017	(EP Committee referral announced in Parliament, 2nd reading)	N/A	N/A
17/03/2017	Commission communication to the EP on the position of the Council at first reading	European Commission	7192/17 REV COR 1
21/03/2017	Vote in committee, 2nd reading	European Parliament	N/A
23/03/2017	Committee recommendation tabled for plenary, 2nd reading	European Parliament	A8-0068/2017
04/04/2017	Debate in EP	European Parliament	CRE 04/04/2017 - 12
05/04/2017	Act adopted by Council	Council of the European Union	7972/17
05/04/2017	Decision by EP, 2nd reading	European Parliament	T8-0107/2017
05/04/2017	Decision by EP, 2nd reading (summary)	European Parliament	T8-0107/2017 (summary)
28/02/2018	Meeting of the Medical Device Coordination Group Brussels, 28 November 2017	Medical Device Coordination Group	N/A
25/09/2018	TERMS OF REFERENCE OF THE MDCG WORKING GROUP ON MARKET SURVEILLANCE	Medical Device Coordination Group	N/A
25/09/2018	TERMS OF REFERENCE OF THE MDCG WORKING GROUP WORKING GROUP ON POST-MARKET SURVEILLANCE AND VIGILANCE (PMSV)	Medical Device Coordination Group	N/A
[unknown]	EP report on 2nd reading	European Parliament	A3-0088/1993

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA)

Date	*Title*	*Author*	*Reference number*
01/04/1994	The European Aerospace Industry Trading Position and Figures 1994	European Commission	III/4001/94-EN
12/09/2001	White paper European transport policy for 2010: time to decide	European Commission	COM(2001) 370 final
01/07/2002	STAR 21: Strategic Aerospace Review for the 21st century	High-Level European Advisory Group on Aerospace	inapplicable
11/06/2003	Commission Decision of 11 June 2003 setting up a group of experts to advise the Commission on a strategy for dealing with accidents in the transport sector	European Commission	2003/425/EC
01/07/2003	ANALYSIS OF THE EUROPEAN AIR TRANSPORT INDUSTRY 2001	European Commission	inapplicable
13/10/2003	A coherent framework for aerospace – a response to the STAR 21 report.	European Commission	COM(2003) 600 final
01/01/2004	Strategic Alliances and Internationalisation in the Aircraft Manufacturing Industry	Ecorys	inapplicable
22/06/2006	COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT Keep Europe moving - Sustainable mobility for our continent Mid-term review of the European Commission's 2001 Transport White Paper	European Commission	COM(2006) 314 final
01/07/2006	Manufacture of aerospace equipment in the European Union	Eurostat	inapplicable
03/07/2006	FINAL REPORT OF THE GROUP OF EXPERTS TO ADVISE THE COMMISSION ON A STRATEGY TO DEAL WITH ACCIDENTS IN THE TRANSPORT SECTOR	Group of Experts to advise the Commission on a strategy to deal with accidents in the transport sector	inapplicable
19/07/2006	ECAC CODE OF CONDUCT ON CO-OPERATION IN THE FIELD OF CIVIL AVIATION ACCIDENT / INCIDENT INVESTIGATION	ECAC	inapplicable
27/10/2006	ANNUAL SAFETY REVIEW 2005	EASA	inapplicable
20/03/2007	Summary of the replies received by the Commission following the public consultation through the web concerning a possible revision of Directive 94/56/EC establishing the fundamental principles governing the investigation of civil aviation accidents and incidents and of Directive 2003/42/EC on occurrence reporting in civil aviation	European Commission	inapplicable
13/06/2007	MINUTES OF THE MEETING OF THE EASA MANAGEMENT BOARD HELD ON 13 JUNE 2007 AND SUMMARY OF DECISIONS TAKEN (MB NO. 03/2007), Summary of decisions	EASA	MB NO. 03/2007
13/06/2007	European Commission, Agenda Item 14: Accident Investigations, EASA MB 03/ 2007, WP 14 Accident Investigations (June 13, 2007)	European Commission	ASA MB 03/ 2007, WP 14 Accident Investigations

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA) (continued)

Date	*Title*	*Author*	*Reference number*
20/07/2007	Impact Assessment on the modification of Directives 94/56/EC and 2003/42/EC (Framework Contract for Ex-ante evaluations and Impact Assessments, TREN/A1/46-2005), Final Report	ECORYS Nederland BV and National Aerospace Laboratory NLR	inapplicable
02/12/2008	Analyses of the European air transport market Annual Report 2007	German Aerospace Center	inapplicable
30/06/2009	Opinion of the Impact Assessment Board on the Impact Assessment on the Commission's proposal on better efficiency in the investigation and prevention of civil aciation accidents and incidents	European Commission	Ref. Ares(2009(150236
26/08/2009	Opinion of the Impact Assessment Board on the Impact Assessment on: Commission's proposal on better efficiency in the investigation and prevention of civil aviation accidents and incidents	European Commission	
01/10/2009	Presentation of the Commission's proposal	European Commission	inapplicable
01/10/2009	Citizens' summary Investigation of civil aviation accidents – proposed EU law	European Commission	WEB-2009-01290-00-00-EN
29/10/2009	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on investigation and prevention of accidents and incidents in civil aviation	European Commission	COM(2009) 611 final
29/10/2009	COMMISSION STAFF WORKING DOCUMENT accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on investigation and prevention of accidents and incidents in civil aviation SUMMARY IMPACT ASSESSMENT	European Commission	SEC(2009) 1478 final
29/10/2009	COMMISSION STAFF WORKING DOCUMENT accompanying the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on investigation and prevention of accidents and incidents in civil aviation IMPACT ASSESSMENT	European Commission	SEC(2009) 1477 final
29/10/2009	Flying safer: Commission proposes new rules for better investigation of civil aviation accidents	European Commission	IP/09/1612
05/11/2009	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on investigation and prevention of accidents and incidents in civil aviation	Council	15469/09
18/12/2009	FWC Sector Competitiveness Studies - Competitiveness of the EU Aerospace Industry with focus on: Aeronautics Industry	Ecorys, CESifo, IDEA Consult, Bauhaus Luftfahrt, DECISION Etudes & Conseil	inapplicable
14/01/2010	WORKING DOCUMENT From : General Secretariat To : Delegations	Council	16775/09
29/01/2010	WORKING DOCUMENT From : General Secretariat To : Delegations	Council	5778/10

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA) (continued)

Date	*Title*	*Author*	*Reference number*
17/02/2010	WORKING DOCUMENT From : General Secretariat To : Delegations	Council	6035/10
25/02/2010	WORKING DOCUMENT From : General Secretariat To : Delegations	Council	6793/10
02/03/2010	WORKING DOCUMENT From : General Secretariat To : Delegations	Council	6793/1/10
04/03/2010	REPORT From : Working Party on Aviation To : COREPER General approach	Council	6835/10
08/03/2010	PROVISIONAL AGENDA for: 3001st MEETING OF THE COUNCIL OF THE EUROPEAN UNION (TRANSPORT, TELECOMMUNICATIONS AND ENERGY)	Council	6986/10 OJ CONS 14 TRANS 47 TELECOM 20 ENER 57
08/03/2010	REPORT From : COREPER To : Council General Approach	Council	7085/10
09/03/2010	Corrigendum to Report 7085/10	Council	7085/10 COR 1
10/03/2010	Addendum to report 7085/10	Council	7085/10 ADD 1
11/03/2010	Revised corrigendum report	Council	7085/10 COR 1 REV 1
12/03/2010	ADDENDUM to DRAFT MINUTES of the 3001st meeting of the Council of the European Union (TRANSPORT, TELECOMMUNICATIONS and ENERGY), held in Brussels on 11 and 12 March 2010 (published 20-12-2010)	Council	7402/10 ADD 1 PV/CONS 14 TRANS 68 TELECOM 26 ENER 69
12/03/2010	PRESS RELEASE 3001st Council meeting Transport, Telecommunications and Energy Brussels, 11-12 March 2010	Council	7332/10 (Presse 55)
12/03/2010	OUTCOME OF PROCEEDINGS From : Council General Secretariat To : Delegations	Council	7442/10
15/04/2010	***I DRAFT REPORT on the proposal for a regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation (COM(2009)0611 – C7-0259/2009 – 2009/0170(COD))	European Parliament	PE439.970
10/05/2010	AMENDMENTS 68 - 170 Draft report Christine De Veyrac (PE439.970v2-00) on the proposal for a regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation (repealing Directive 94/56/EC)	European Parliament	PE441.211
21/05/2010	Opinion of the European Data Protection Supervisor on the proposal for a Regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation	European Data Protection Supervisor	2010/C 132/01

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA) (continued)

Date	*Title*	*Author*	*Reference number*
27/05/2010	Opinion of the European Economic and Social Committee on the 'Proposal for a regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation' of 27-5-2010 (published 21-1-2011_	European Economic and Social Committee	2011/C 21/11
17/06/2010	REPORT From: Working Party on Aviation To: COREPER Preparation for the next informal trilogue	Council	10862/10
23/06/2010	Outcome of the informal trilogue	Council	11287/10
24/06/2010	Corrigendum to 11287/10	Council	11287/10 COR 1
29/06/2010	Analysis of the final compromise text with a view to agreement	Council	11445/10
12/08/2010	***I REPORT on the proposal for a regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation (COM(2009)0611 – C7-0259/2009 – 2009/0170(COD))	European Parliament	A7-0195/2010
01/09/2010	OCCURRENCE REPORTING AND ACCIDENT/ INCIDENT INVESTIGATION IN EU CIVIL AVIATION. Study	European Parliament	inapplicable
20/09/2010	17. Investigation and prevention of accidents and incidents in civil aviation (debate)	European Parliament	CRE 20/09/2010 - 17
21/09/2010	Expanations of vote	European Parliament	PV 21/09/2010 - 5.3
21/09/2010	(Commission position on EP amendments on 1st reading	European Commission	inapplicable
24/09/2010	Outcome of the European Parliament's first reading	European Parliament	13746/10
01/10/2010	Outcome of the European Parliament's first reading	Council	PE-CONS 36/10
04/10/2010	Procedural document	Council	14224/10
08/10/2010	CORRIGENDUM 1 to LIST OF "A" ITEMS for: 3035th meeting of the COUNCIL OF THE EUROPEAN UNION (Competitiveness - Internal Market, Industry, Research and Space)	Council	14523/10 COR 1 PTS A 78
08/10/2010	LIST OF "A" ITEMS for: 3035th meeting of the COUNCIL OF THE EUROPEAN UNION (Competitiveness – Internal Market, Industry and Research)	Council	14523/10 PTS A 78
12/10/2010	DRAFT MINUTES Subject 3035thmeeting of the Council of the European Union (COMPETITIVENESS (Internal Market/Industry/ Research))held inLuxembourgon 11and 12October2010 (published 12-11-2010)	Council	14773/10 LIMITE PV/CONS 50 COMPET 286 RECH 325

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA) (continued)

Date	*Title*	*Author*	*Reference number*
12/10/2010	ADDENDUM TO DRAFT MINUTES Subject: 3035th meeting of the Council of the European Union (COMPETITIVENESS (Internal Market/ Industry/Research)) held in Luxembourg on 11 and ADDENDUM TO DRAFT MINUTES Subject: 3035th meeting of the Council of the European Union COMPETITIVENESS (Internal Market/ Industry/Research)) held in Luxembourg on 11 and 12 October 2010 (published 12-11-2010)	Council	14773/10 ADD 1 PV/CONS 50 COMPET 286 RECH 325
12/10/2010	PRESS RELEASE 3035th Council meeting	Council	14426/1/10 REV 1 PRESSE 263 PR CO 23
12/10/2010	Voting Result of the Council	Council	14882/10
13/10/2010	Commission response to text adopted in plenary	European Commission	SP(2010)7193
20/10/2010	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE INVESTIGATION AND PREVENTION OF ACCIDENTS AND INCIDENTS IN CIVIL AVIATION AND REPEALING DIRECTIVE 94/56/EC	Council	PE-CONS 36/2/10
29/10/2010	French version	Council	15574/10
29/10/2010	Slovenian version	Council	15574/10
01/01/2011	2011 work program	ENCASIA	inapplicable
19/01/2011	Rules of Procedure for the European Network of Civil Aviation Safety Investigation Authorities (ENCASIA)	ENCASIA	inapplicable
24/06/2011	Public Consultation on a possible revision of Directive 2003/42/EC on occurrence reporting in civil aviation and of its implementing rules	European Commission	inapplicable
11/09/2011	Summary report of the contributions received to the online public consultation on a possible revision of Directive 2003/42/EC on occurrence reporting in civil aviation and its implementing rules	European Commission	inapplicable
06/12/2011	State of Global Aviation Safety (2011)	ICAO	inapplicable
01/01/2012	Annual report 2011	ENCASIA	inapplicable
06/06/2013	COMMISSION STAFF WORKING DOCUMENT Fitness Check - Internal Aviation Market Report on the suitability of economic regulation of the European air transport market and of selected ancillary services	European Commission	inapplicable
19/09/2013	Polish version	Council	13488/13
07/11/2014	German version	Council	13623/14
05/08/2016	Hungarian version	Council	9360/16
14/07/2017	Romanian version	Council	10954/17
29/08/2018	Support study to the evaluation of Regulation (EU) No 996/2010 on the Investigation and Prevention of Accidents and Incidents in Civil Aviation Final Report	European Commission	inapplicable

Case study 2. EU civil aviation accident and incident investigation (the ENCASIA) (continued)

Date	*Title*	*Author*	*Reference number*
08/12/2020	A Statistical Analysis of Commercial Aviation Accidents 1958-2019	Airbus	inapplicable
10/02/2021	Study on the economic developments of the EU Air Transport Market FINAL REPORT	European Commission	inapplicable

Case study 3. EU medicines policy (the EMA)

Date	*Title*	*Author*	*Reference number*
01/01/1988	Contributions for a Future Marketing Administration System	Committee for Proprietary Medicinal Products	III/3785/88
22/03/1988	Report on the Activities of the Committee for Proprietary Medicinal Products	European Commission	COM (88) 143 final
01/01/1989	Compilation of Comments Received on Outstanding White Paper Proposals for Completion of the Internal Market in the Pharmaceutical Sector	European Commission	III/8293/89EN
01/01/1989	Responses to consultation documents (among which at least the consultation document 'Memorandum on the Future System for the Authorization of Medlclnal Products In the European Community")	European Commission	III/8265/89 and Fedesa 29.9.89
01/04/1989	Memorandum on the future system for the authorization of medicinal products in the European Community, April 1989. In: International Medicines Regulations : a Forward Look to 1992 (by Walker and Griffin)	European Commission	N/A
01/09/1989	Report on pharmacovigilance in the European Community	European Commission	III/3577/89
01/12/1989	Future system for the authorisation of medicinal products with the European Community. A discussion document	European Commission	III/8267/89 Revision 2
14/11/1990	Explanatory Memorandum on the Future System for the Free Movement of Medical Products in the European Community	European Commission	COM(90) 283 final
31/12/1990	Proposal for a Council Regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products	European Commission	COM(90) 283 final
15/02/1991	REPORT FROM THE COMMISSION TO THE COUNCIL ON THE ACTIVITIES OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS	European Commission	COM(91) 39 final
28/05/1991	Report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy	European Parliament	A3-0148/91

Case study 3. EU medicines policy (the EMA) (continued)

Date	*Title*	*Author*	*Reference number*
12/06/1991	Legislative resolution embodying the opinion of the European Parliament on a Commission proposal for a Council regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products	European Parliament	OJ C 183, 15.7.1991, p. 145
14/10/1991	Opinion of the European Economic and Social Committee	European Economic and Social Committee	OJ C 269, 14.10.1991, p. 84
31/10/1991	Explanatory Memorandum AND amended proposal: Future system for the free movement of medicinal products in the European Community	European Commission	COM(91) 382 final
01/01/1993	Background report: The European Medicines Evaluation Agency	European Commission	ISEC/B33/93
12/05/1993	Report ON THE OPERATION OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS IN 1991 AND 1992	European Commission	SEC(93)771
26/05/1993	Legislative resolution embodying the opinion of the European Parliament on the Council proposal for a regulation laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products	European Parliament	OJ C 176, 28.6.1993, p. 118
01/01/1994	Regulatory perspectives at European level	European Commission	N/A
02/03/1994	ON THE OUTLINES OF AN INDUSTRIAL POLICY FOR THE PHARMACEUTICAL SECTOR IN THE EUROPEAN COMMUNITY	European Commission	COM(93) 718 final
02/03/1994	Unknown	European Commission	COM(93)718
15/01/1996	First General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1995	EMA	EMA/MB/065/95
01/06/1996	RAPID ALERT SYSTEM (RAS) IN PHARMACOVIGILANCE	European Commission	N/A
23/02/1999	Tasks of the European Agency for the Evaluation of Medicinal Products (EMEA)	Council of the European Union	ST 6227 1999 INIT
19/04/2000	Working Party on Control of Medicines and Inspections Revision of Compilation of Community procedures on administrative collaboration and harmonisation of inspections	European Commission	N/A
10/07/2000	Pharmaceuticals in the European Union	European Commission	N/A
07/11/2000	Evaluation of the operation of Community procedures for the authorisation of medicinal products	European Commission	N/A
22/01/2001	Review of pharmaceutical legislation	European Commission	N/A

Case study 3. EU medicines policy (the EMA) (continued)

Date	*Title*	*Author*	*Reference number*
01/05/2001	REVISED COMPILATION OF COMMUNITY PROCEDURES ON ADMINISTRATIVE COLLABORATION AND HARMONISATION OF INSPECTIONS	European Commission	N/A
18/07/2001	Reform of EU Pharmaceutical Legislation	European Commission	N/A
23/10/2001	Report on the operation of the authorisation procedures for medicinal products adopted and available in all languages of the European Community	European Commission	COM(2001) 606 final
26/11/2001	Proposal and explanatory memorandum	European Commission	COM(2001) 404 final
20/12/2001	Outcome of proceedings from Working Party	Council of the European Union	15445/01
21/01/2002	Outcome of proceedings from Working Party	Council of the European Union	5219/02
19/02/2002	Outcome of proceedings from Working Party	Council of the European Union	6021/02
28/02/2002	Outcome of proceedings from Working Party	Council of the European Union	6585/02
05/03/2002	Working document : modifications of Regulation (EEC) n°2309/93 (European medicines evaluation Agency)	European Commission	N/A
05/03/2002	Working document : modifications of the pharmaceutical legislation related to human medicinal products	European Commission	N/A
15/03/2002	Outcome of proceedings from Working Party	Council of the European Union	7000/02
09/04/2002	Outcome of proceedings from Working Party	Council of the European Union	7346/02
25/04/2002	Outcome of proceedings from Working Party	Council of the European Union	8122/02
22/05/2002	Contribution of legal service to proceedings of Working Party	Council of the European Union	9111/02
05/06/2002	Report from working party to COREPER	Council of the European Union	8962/02
18/06/2002	COREPER to Council	Council of the European Union	10058/02
26/06/2002	Press release of the 2440th Council (HEALTH)	Council of the European Union	C/02/182
04/07/2002	Contribution of legal service to proceedings of Working Party	Council of the European Union	10645/02
15/07/2002	Draft minutes of the 2440th Council (HEALTH)	Council of the European Union	ST/10411/2002
18/09/2002	Opinion of the Economic and Social Committee	European Economic and Social Committee	2003/C 61/01
26/09/2002	Note from the General Secretariat	Council of the European Union	12332/02

Case study 3. EU medicines policy (the EMA) (continued)

Date	*Title*	*Author*	*Reference number*
09/10/2002	REPORT on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use	European Parliament	A5-0340/2002
29/10/2002	Joint note COM EP COUNCIL	Council of the European Union	13241/02
12/03/2003	Outcome of proceedings from Working Party	Council of the European Union	7084/03
21/03/2003	Outcome of proceedings from Working Party	Council of the European Union	7580/03
03/04/2003	Amended proposal	European Commission	COM(2003) 163 final
07/04/2003	Outcome of proceedings from Working Party	Council of the European Union	8105/03
29/04/2003	Outcome of proceedings from Working Party	Council of the European Union	8700/03
12/05/2003	Report from working party to COREPER	Council of the European Union	8966/03
19/05/2003	Note to COREPER	Council of the European Union	9466/03
21/05/2003	Report to COREPER	Council of the European Union	9469/03
26/05/2003	Note to COREPER	Council of the European Union	9602/03
27/05/2003	Note to COUNCIL	Council of the European Union	9680/03
02/06/2003	Note from Slovakia to delegations	Council of the European Union	10034/03
02/06/2003	Note from Slovenia to delegations	Council of the European Union	10033/03
02/06/2003	Note from Poland to delegations	Council of the European Union	10032/03
02/06/2003	Note from Hungary to delegations	Council of the European Union	10031/03
02/06/2003	Note from Lithuania to delegations	Council of the European Union	10030/03
02/06/2003	Note from Latvia to delegations	Council of the European Union	10029/03
02/06/2003	Note from Estonia to delegations	Council of the European Union	10028/03
02/06/2003	Note from Czech Republic to delegations	Council of the European Union	10027/03
02/06/2003	Note from Malta to delegations	Council of the European Union	10091/03
02/06/2003	Note from Cyprus to delegations	Council of the European Union	10131/03
12/06/2003	Note to delegations	Council of the European Union	10450/03

Case study 3. EU medicines policy (the EMA) (continued)

Date	*Title*	*Author*	*Reference number*
27/06/2003	Agreement on Council common position	Council of the European Union	9994/03
30/06/2003	Outcome of proceedings	Council of the European Union	11001/03
08/09/2003	Statement of the Council's reasons	Council of the European Union	10950/3/03
29/09/2003	Adoption of Council common position	Council of the European Union	2003/C 297 E/02
07/10/2003	Commission declaration on Common position	European Commission	SEC/2003/1082/ FINAL
25/11/2003	VOLUME 9 - PHARMACOVIGILANCE Medicinal Products for Human use and Veterinary Medicinal Products	European Commission	N/A
02/12/2003	RECOMMENDATION FOR SECOND READING	European Parliament	A5-0446/2003
17/02/2004	Opinion of the Commission on the European Parliament's amendments	European Commission	COM(2004) 124 final
10/03/2004	Council approval of EP second amendments	Council of the European Union	7181/04
24/03/2004	Addendum to draft minutes	Council of the European Union	7255/04 ADD 1
03/10/2014	Compilation of Community Procedures on Inspections and Exchange of Information	European Commission	N/A

Case study 4. EU airworthiness policy (the EASA)

Date	*Title*	*Author*	*Reference number*
11/09/1990	ARRANGEMENTS CONCERNING THE DEVELOPMENT, THE ACCEPTANCE AND THE IMPLEMENTATION OF JOINT AVIATION REQUIREMENTS (Cyprus Arrangements)	JAA	N/A
27/09/1990	Proposal for a COUNCIL DIRECTIVE on the harmonization of technical requirements and procedures applicable to civil aircraft	European Commission	COM(90) 442 final
30/05/1991	Report of the Committee on Transport and Tourism on the Commission proposal for a Council directive on the harmonization of technical requirements and procedures applicable to civil aircraft	European Parliament	C3-0367/90
29/04/1992	The European Aircraft Industry: First assessment and possible Community actions	European Commission	COM(92) 164 final
18/04/1994	Council Conclusion on the SITUATION OF EUROPEAN AIR TRANSPORT	European Council	6295/94 (Presse 71 - G
01/06/1994	COMMUNICATION FROM THE COMMISSION THE WAY FORWARD FOR CIVIL AVIATION IN EUROPE	European Commission	COM (94) 218 final
01/06/1994	Study to analyse the most efficient way to conduct airworthiness certification	European Commission	unknown
01/10/1994	Consultation paper	European Commission	unknown
05/11/1994	Council Resolution of 24 October 1994 on the situation in European civil aviation	European Council	OJ C309
12/06/1996	Defining a Community Aviation Safety Improvement Strategy	European Commission	SEC(96) 1083 final
10/12/1996	Recommandation de DECISION DU CONSEIL autorisant la Commission à engager des négociations afin de créer une organisation européenne compétente en matière de sécurité de l'aviation civile	European Commission	SEC (1996) 2152 final
24/09/1997	The European Aerospace Industry Meeting the Global Challenge	European Commission	COM (97) 466 final
16/07/1998	Council Decision of 16 July 1998 authorizing the Commission to initiate negotiations with a view to concluding an agreement establishing a European Aviation Safety Authority	Council of the European Union	unknown
20/05/1999	THE EUROPEAN AIRLINE INDUSTRY: FROM SINGLE MARKET TO WORLD-WIDE CHALLENGES	European Commission	COM (1999) 182 final
01/06/1999	Joint Aviation Authorities Administrative and Guidance Material Section Three: Certification	JAA	unknown
21/03/2000	In view of the discussions within the Council on the creation of the European Aviation Safety Authority in the Community framework	European Commission	COM (2000) 144 final
01/04/2000	Consultation paper	European Commission	unknown
26/06/2000	2279th Council meeting	Council of the European Union	9547/00 (Presse 224)

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
04/12/2000	Explanatory memorandum to proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency	European Commission	COM (2000) 595 final
04/12/2000	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency	European Commission	COM (2000) 595 final
11/12/2000	furore over EASA's proposed fees hike	Council of the European Union	ST 14325 2000 INIT
13/12/2000	Report of Coreper to Council	Council of the European Union	ST 14613 2000 INIT
20/12/2000	2324th Council meeting TRANSPORT Brussels, 20 and 21 December 2000	Council of the European Union	200014004/00 Presse 470
16/03/2001	Outcome of Proceedings from Working Party	Council of the European Union	ST 7244 2001 INIT
16/03/2001	Report of the AVIATION working party to Coreper/ Council	Council of the European Union	ST 7148 2001 INIT
26/03/2001	Report of Coreper to Council	Council of the European Union	ST 7375 2001 INIT
29/03/2001	Inventory of provisions in Community legislation concerning inspections by the Commission in Member States	Council of the European Union	ST 7312 2001 INIT
31/05/2001	Opinion of the Economic and Social Committee on the 'Proposal for a Regulation of the European Parliament and of the Council on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency'	European Economic and Social Committee	2001/C 221/05
13/06/2001	Transition aspects from JAA to EASA	Council of the European Union	ST 9889 2001 INIT
15/06/2001	Report from Council Secretariat General Montreal Convention on Air Carrier liability:Amendment to Reg. 2027/97 = Common position	Council of the European Union	ST 9890 2001 INIT
15/06/2001	Working party to Coreper/Council Draft Regulation establishing common rules in the field of civil aviation safety and setting up of a European Aviation Safety Authority (EASA) = Preliminary orientation of the Council	Council of the European Union	ST 9749 2001 INIT
19/06/2001	Report from Council Secretariat General Montreal Convention on Air Carrier liability:Amendment to Reg. 2027/97 = Common position	Council of the European Union	ST 9890 2001 COR 1
20/06/2001	2340th Council Meeting on 4/5 april	Council of the European Union	7820/01
22/06/2001	Report from Coreper to Council on Montreal Convention on Air Carrier liability : Amendment to Reg. 2027/97 = Common position	Council of the European Union	ST 10273 2001

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
22/06/2001	Report from Coreper to Council on Draft Regulation establishing common rules in the field of civil aviation safety and creating a European Aviation Safety Authority (EASA) = Orientation Debate	Council of the European Union	ST 10257 2001
22/06/2001	Draft Regulation establishing common rules in the field of civil aviation safety and creating a European Aviation Safety Agency (EASA) = Orientation Debate	Council of the European Union	ST 10257 2001 COR 1
28/06/2001	2364th Council meeting TRANSPORT/ TELECOMMUNICATIONS Luxembourg, 27/28 June 2001	Council of the European Union	ST 10235 2001 (Presse 257)
13/07/2001	REPORT on the proposal for a European Parliament and Council regulation on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency	European Parliament	A5-0279/2001
24/07/2001	OUTCOME OF PROCEEDINGS from Working Party to delegations	Council of the European Union	ST 11539 2001
05/09/2001	European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency (COM(2000) 595 — C5-0663/2000 — 2000/0246(COD))	European Parliament	C5-0663/2000
17/09/2001	Draft report from Working Party to Coreper Draft regulation	Council of the European Union	ST 11907 2001 INIT
03/12/2001	Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	Council of the European Union	ST 13382 2001
06/12/2001	2374th meeting of the Council (TRANSPORT/ TELECOMMUNICATIONS) held in Luxembourg on 15 and 16 October 2001	Council of the European Union	ST 12896 2001
12/12/2001	Position commune arrêtée par le Conseil en vue de l'adoption du règlement du Parlement européen et du Conseil concernant des règles communes dans le domaine de l'aviation civile et instituant une Agence européenne de la sécurité aérienne	Council of the European Union	ST 13382 2001 ADD 1
12/12/2001	Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	Council of the European Union	ST 13382 1 2001 ADD 1 REV 1
19/12/2001	Common Position (EC) No 17/2002 of 19 December 2001 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	Council of the European Union	2002/C 58 E/05

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
20/12/2001	Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	Council of the European Union	ST 13382 1 2001 REV 1
20/12/2001	Position commune arrêtée par le Conseil en vue de l'adoption du règlement du Parlement européen et du Conseil concernant des règles communes dans le domaine de l'aviation civile et instituant une Agence européenne de la sécurité aérienne	Council of the European Union	ST 13382 1 2001 REV 1 ADD 1
11/01/2002	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a Regulation of the European Parliament and of the Council on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency	European Commission	SEC (2002) 23
21/03/2002	RECOMMENDATION FOR SECOND READING on the Council common position for adopting a European Parliament and Council regulation on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	European Parliament	A5-0093/2002
07/05/2002	OPINION OF THE COMMISSION pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency	European Commission	COM(2002) 241 final
18/06/2002	(approval by the Council of the EP amendments at 2nd reading)	Council of the European Union	ST 8757 2002
15/07/2002	(signature by Council and Parliament)	European Council and European Parliament	N/A
30/03/2004	EASA 2003 Report of activity	EASA	MB 02/2004
15/11/2005	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	European Commission	COM(2005) 579 final
24/11/2005	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (presented by the Commission)	Council of the European Union	ST 14903 2005 INIT

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
25/11/2005	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (presented by the Commission)	Council of the European Union	ST 14903 2005 COR 1
20/02/2006	Wijziging van de Wet luchtvaart ter uitvoeringvan een viertal verordeningen van de Europese Unie op het terrein van luchtvaartuigen en de verzekering daarvan, passagiersrechten en beperking aansprakelijkheid van de luchthavencoördinator	Staatssecretaris van Verkeer en Waterstaat	30456, nr. 3
30/05/2006	Outcome of discussions in Working Party	Council of the European Union	ST 9102 2006 INIT
31/05/2006	Progress report	Council of the European Union	ST 9499 2006 INIT
14/06/2006	European Aviation Safety Agency 2005 Activity Report	EASA	07-2006
03/07/2006	Outcome of discussions in Working Party	Council of the European Union	ST 10670 2006 INIT
18/07/2006	Outcome of discussions in Working Party	Council of the European Union	ST 11561 2006 INIT
08/08/2006	Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency COM(2005) 579 final	European Economic and Social Committee	C 185/19
08/09/2006	Outcome of discussions in Working Party	Council of the European Union	ST 12196 2006 INIT
20/09/2006	Clean text with inclusion of Presidency suggestions	Council of the European Union	ST 13023 2006 INIT
20/09/2006	Outcome of discussions in Working Party	Council of the European Union	ST-12962-2006-INIT
20/10/2006	Outcome of discussions in Working Party	Council of the European Union	ST 14140 2006 INIT
20/10/2006	Outcome of discussions in Working Party	Council of the European Union	ST-13838-2006-INIT
08/11/2006	Outcome of discussions in Working Party	Council of the European Union	ST-14662-2006-INIT
14/11/2006	Outcome of discussions in Working Party	Council of the European Union	ST-15241-2006-INIT
24/11/2006	General approach	Council of the European Union	ST-15308-2006-INIT
27/11/2006	General approach	Council of the European Union	ST-15308-2006-COR-1
30/11/2006	General approach	Council of the European Union	ST-15901-2006-INIT
08/12/2006	General approach	Council of the European Union	ST-15901-2006-COR-1-REV-1

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
12/12/2006	2772nd Council Meeting Transport, Telecommunications and Energy Brussels, 11-12 December 2006	Council of the European Union	15900/06 (Presse 343)
13/12/2006	General approach	Council of the European Union	ST-16271-2006-INIT
31/01/2007	REPORT on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	European Parliament	A6-0023/2007
19/03/2007	Outcome of the European Parliament's first reading	European Parliament	C6-0403/2006
20/04/2007	Consideration of the results of the first reading of the European Parliament; preparation of informal contacts with the Parliament	Council of the European Union	ST-8236-2007-INIT
25/04/2007	Consideration of the results of the first reading of the European Parliament; preparation of informal contacts with the Parliament	Council of the European Union	ST-8236-2007-COR-1
26/04/2007	Outcome of Coreper of 25 April 2007	Council of the European Union	ST-8931-2007-INIT
21/05/2007	Political Agreement	Council of the European Union	ST-9547-2007-INIT
22/05/2007	Political Agreement	Council of the European Union	ST-9547-2007-COR-1
29/05/2007	Political Agreement	Council of the European Union	ST-9915-2007-INIT
05/06/2007	Political Agreement	Council of the European Union	ST-9915-2007-ADD-1
08/06/2007	2805th Council meeting Transport, Telecommunications and Energy Luxembourg, 6-8 June 2007	Council of the European Union	10456/07 (Presse 133)
13/09/2007	Information from the Presidency	Council of the European Union	ST-12756-2007-COR-1
25/09/2007	Information from the Presidency	Council of the European Union	ST-12756-2007-COR-2
03/10/2007	Position commune arrêtée par le Conseil en vue de l'adoption du règlement du Parlement européen et du Conseil concernant des règles communes dans le domaine de l'aviation civile et instituant une Agence européenne de la sécurité aérienne, et abrogeant la directive 91/670/CEE du Conseil, le règlement (CE) n° 1592/2002 et la directive 2004/36/CE	Council of the European Union	10537/07 ADD 1
03/10/2007	DRAFT STATEMENT OF THE COUNCIL'S REASONS	Council of the European Union	ST-10537-2007-ADD-1

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
04/10/2007	Common Position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC	Council of the European Union	10537/07
04/10/2007	Common position adopted by the Council	Council of the European Union	ST-10537-2007-INIT
05/10/2007	Common Position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC	Council of the European Union	10537/07 ADD 1 COR 1
05/10/2007	Common position adopted by the Council	Council of the European Union	ST-10537-2007-ADD-1-COR-1
07/10/2007	Adoption of common position and statement of reasons	Council of the European Union	ST-13270-2007-INIT
12/10/2007	List of A Items	Council of the European Union	13708/07
15/10/2007	Common Position adopted by the Council on 15 October 2007 with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC	Council of the European Union	10537/3/07 REV 3
15/10/2007	Common Position adopted by the Council on 15 October 2007 with a view to the adoption of a Regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC	Council of the European Union	10537/3/07 REV 3 ADD 1
15/10/2007	Voting result	Council of the European Union	ST-13910-2007-INIT
15/10/2007	Common position	Council of the European Union	ST-10537-2007-REV-3
15/10/2007	STATEMENT OF THE COUNCIL'S REASONS	Council of the European Union	ST-10537-2007-REV-3-ADD-1

Case study 4. EU airworthiness policy (the EASA) (continued)

Date	*Title*	*Author*	*Reference number*
18/10/2007	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT in accordance with the second paragraph of Article 251(2) of the EC Treaty concerning the common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	European Commission	COM(2007) 631 final
28/11/2007	RECOMMENDATION FOR SECOND READING on the Council common position for adopting a regulation of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC	European Parliament	A6-0482/2007
12/12/2007	POSITION OF THE EUROPEAN PARLIAMENT adopted at second reading on 12 December 2007 with a view to the adoption of Regulation (EC) No .../2008 of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (EP-PE_TC2-COD(2005)0228)	European Parliament	TC2-COD(2005)0228
19/12/2007	COMMISSION OPINION pursuant to Article 251(2), third subparagraph, point (c) of the EC Treaty on the European Parliament's amendments to the Council Common Position regarding the proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	European Commission	COM(2007) 864 final
30/01/2008	(approval by the Council of the EP amendments at 2nd reading)	European Council	ST 5393 2008
20/02/2008	(signature by Council and Parliament)	European Council and European Parliament	N/A
11/04/2012	Wijziging van de Wet luchtvaart in verband met de uitvoering van verordening (EG) nr. 216/2008 van het Europees Parlement en de Raad van 20 februari 2008 tot vaststelling van gemeenschappelijke regels op het gebied van burgerluchtvaart en tot oprichting van een Europees Agentschap voor de veiligheid van de luchtvaart	Staatssecretaris van Infrastructuur en Milieu	33476, nr. 3
23/04/2015	Study on the resources deployed in the area of European aviation safety before and after the creation of EASA	European Commission	N/A

Appendix 2. Participants Information letter

This letter informs you about participation in an interview that is part of an academic research project. That research project seeks to understand why the European Union legislator differentiates between enforcement by EU networks of national authorities on the one hand, and EU agencies on the other. It does so by gathering and analyzing data from interviews with a variety of stakeholders in the policy areas of aviation safety, medical devices and medicines.

You will be interviewed by Laurens van Kreij LLM. He carries out the abovementioned project as part of his PhD research, under the supervision of prof. dr. Judith van Erp, professor of public institutions, and dr. Miroslava Scholten, associate professor of EU law. The study is commissioned by Utrecht University, located in Utrecht, the Netherlands.

You have been contacted for an interview because you fall within the target group for this study: you (may) have any knowledge of the European market for medical devices and/or medicines, and/or (political decision-making) on the current and previous regulation thereof, and/or the establishment and role of the Medical Devices Coordination group or its (in)formal predecessors, and/or the establishment and role of the European Medicines Agency.

Participation consists of taking part in an interview with various open-ended questions (semi-structured interview). You can decide to leave one or more questions unanswered or, at any point in time, decide to stop the interview without stating reasons. You're advised to observe any secrecy obligations resting upon you. The interview is expected to last 1 to 2 hours. You will receive no remuneration.

The interview may be recorded, subject to your consent. As soon as possible after the interview, the recording (and/or any notes taken during the interview) will be stored and encrypted on a Utrecht University location with restricted and secure access. Any recording will be deleted immediately after a pseudonymized transcript has been made. The transcript and/or notes will remain stored on the internal Utrecht University location for 10 years. Personal data will be stored separately from the pseudonymized transcript and will, unless agreed otherwise, be deleted by the end of the project.

When referencing to the interview in research publications, the researcher only refers to those pseudonymized credentials. Pseudonymization involves a reference to the position (and the organization) indicated by you on the consent form.

The full details of the processing of research and personal data are outlined in the Research Data Management Plan for this project. The latest version of the Research Data Management Plan for this project will be provided by the researcher, upon request.

Might you have any questions or wish to obtain further details after the interview has taken place, feel free to use the contact details.

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Appendix 3. Interviews topic list

Case studies 1 (medical devices) and 2 (Aviation incident investigation)

1. Functions of the ENCASIA/the MDCG and other cooperation arrangements in Regulation (EU) 2017/745

- What functions does the ENCASIA/Regulation (EU) 2017/745 perform when it comes to cooperation among national authorities?

Specific probe for medical devices

- Regulation (EU) 2017/745 includes a medical devices coordination group, joint assessment teams to designate and supervise notified bodies, and lastly, it prescribes a procedure for the cooperation of national authorities in the evaluation of incidents with medical devices. What do these arrangements involve, and is this a complete description of the arrangements for cooperation among national authorities?

Specific probe for the ENCASIA

- The ENCASIA seems to facilitate the sharing of resources among member states' investigation bodies, common training and/or common standards for training investigators. To what extent is that a correct and complete description of the ENCASIA's functions?

2. Pre-existing structures

- What structures for cooperation were in place before the establishment of ENCASIA/before the adoption of Regulation (EU) 2017/745? What functions were performed within these arrangements?

Specific probe for medical devices

- National authorities seem to have cooperated within the Medical Devices Expert Group and Notified Body Operations Group. What were the functions of these arrangement, and to what extent were they different from those later performed by the Medical Devices Coordination Group?

Specific probe for the ENCASIA

- National authorities seem to have cooperated within the Council of European Safety Investigation Authorities, the Group of Experts on accident investigation of the European Civil Aviation Conference, and through cooperation provisions in Directive 94/56/EC.

What were the functions of these arrangements, and were they any different from those performed within ENCASIA?

3. Reform of aviation incident investigation policy

- When and how did reform of aviation incident investigation policy/the regulation of medical devices come on EU legislators' agenda in 2008?

- Why did reform of aviation incident investigation/the regulation of medical devices come on their agenda?

- To what extent were the pre-existing cooperation arrangements that we just discussed – including any advantages or disadvantages – related to the decision-making process on reform of aviation incident investigation/the regulation of medical devices came on their agenda?

Specific probes for medical devices

- To what extent have the PIP/metal-on-metal hip joints issues affected the timing or substantive direction of the decision-making process?

- The Commission seems to have identified (potential and/or actual) inconsistencies between national authorities with regard to notified body designation and monitoring, and with regard to vigilance and market surveillance. Why did the Commission believe such inconsistencies existed? What were the risks involved in such inconsistencies? To what extent did the industry, the European Parliament, national governments and competent authorities share this analysis?

- There seems to have been discussion about bringing medical devices within the EMA's remit. Why did the Commission consider this policy option? What were the opinions among member state governments, their national authorities, the European Parliament, and the industry? Opposition seems to have been couched in differences in methodologies for the monitoring and evaluation of medical devices and medicines respectively. To what extent is that correct?

- A novel EU authority for medical devices also seems to have been a subject of debate. What did the Commission, national authorities, governments, and the European Parliament feel for such a novel authority?

Specific probes for the ENCASIA

- Why has the investigation of civil aviation incidents in Europe not been attributed to the already existing EASA?

- There is a case for separating certification tasks from incident investigation tasks. To what extent has that indeed a reason for not vesting incident investigation capabilities in EASA? Were there other reasons, and if so, what were they?

- The Commission also seems to have entertained the idea of establishing a novel EU body for incident investigation: a European Coordinator for incident investigation in the EU. Do you know why the Commission thought of proposing this policy option? Do you also know why the Commission later took the idea of a European Coordinator off its agenda?

- What do you know about the positions of the member states, and/or their national investigation authorities, the European Parliament, and the industry throughout the process of reform?

- The Council seems to have downscaled cooperation provisions compared to Directive 94/56/EC. Which member states might have sought a relaxation of those cooperation provisions, and why?

Case studies 3 (medicinal products) and 4 (airworthiness)

1. Rule-making, certification and enforcement functions of the EASA/EM(E)A and national competent authorities

- What rule-making, certification and enforcement role did the EASA/EM(E)A fulfill since the agency's establishment, and for what types of product categories?

- At the time of establishment, what was the specific role of the EASA/EM(E)A in inspecting and sanctioning businesses? How was the division of work between the agency and the competent national authorities?

- To what extent was the EASA/EM(E)A involved in inspecting the work of national authorities?

2. The JAA/CPMP and its functions

- To what extent did the member states of the European Union perform the functions of the EASA/EM(E)A prior to their establishment?

Specific probes for the JAA

- The JAA seems to have developed and administered procedures for joint inspections (technical findings) among national competent authorities, with the purpose of issuing type certificates on a national level. Why did the JAA have these procedures, and did they work satisfactorily? And why did the JAA not issue type certificates itself?

- To what extent did the JAA also conduct those inspections for establishing (ongoing) compliance and/or airworthiness, after (type) certificates had been issued? And why (not)?

- To what extent was the JAA involved in issuing airworthiness directives, suspensions or withdrawals of (type) certificates? And why (not)?

Specific probes for the CPMP

- The CPMP seems to have been responsible for reducing and preventing discrepancies in the assessment of medicinal products, as conducted by the national competent authorities. Why did the CPMP have this task, and did it work satisfactorily? Why did the CPMP not conduct medicinal products assessments by itself?

- To what extent was the CPMP involved in inspecting businesses or in pharmacovigilance? And why (not)?

- To what extent was the CPMP involved in amending, suspending or withdrawing medicines marketing authorizations? And why (not)?

3. Reform of the JAA/CPMP

- When did reform of the JAA/CPMP come on EU legislators' agenda? Was there any event related to the timing of the JAA's/CPMP's reform?

- What other stakeholders played a role in the reform of the JAA/CPMP beyond the EU legislative institutions? To what extent did the industry/JAA/CPMP, or the national competent authorities within the JAA/CPMP, themselves play such a role?

- What were the preferences of the industry/national competent authorities/JAA/CPMP/EU legislators/other stakeholders in the reform process? Why did these stakeholders envisage such reforms? How relevant were their preferences for the reform process?

- What was your opinion on the reform process? What did you think of the stakeholders' involvement and preferences?

Specific probes for the EASA

- What were the reasons for attributing, to the EASA, the power to issue, suspend and withdraw type certificates, and issue airworthiness directives?

- Why has the power to issue certificates for *individual* aircraft not been attributed to EASA?

- Why did the EASA acquire the capability to inspect businesses?

- Why did the EASA become capable of conducting standardization inspections among national competent authorities?

- Why did EU legislators choose for an EU agency to perform these functions for the regulation of airworthiness?

Specific probes for the EM(E)A

- Why did the EM(E)A become competent to coordinate inspections as carried out by the national authorities? Why did the EM(E)A not become competent to inspect businesses itself?

- How did the EM(E) gather pharmacovigilance information?

- Why did the EM(E)A's opinions about issuing, amending, suspending and withdrawing the required marketing authorizations become conditional upon Commission agreement?

- Why did EU legislators choose for an EU agency to perform these functions for the regulation of biotechnological and other highly innovative medicine?

- Why did the scope of the EM(E)A's decision-making authority not extend to other types of medicine beyond medicine based on biotechnology or other highly innovative techniques?

Appendix 4. List of interviews

Interview no.	*Interview date*	*Interviewee category*
1	18 August 2020	Academia
2	15 September 2020	National authority
3	15 September 2020	National authority
4	16 September 2020	Independent consultant
5	27 October 2020	EU agency; member state ministry
6	28 October 2020	Member state ministry
7	29 October 2020	Industry
8	13 November 2020	EU agency
9	09 December 2020	National authority
10	10 December 2020	EU agency
11	17 December 2020	Industry; national authority
12	06 January 2021	National authority
13	07 January 2021	Industry
14	15 January 2021	National authority
15	26 January 2021	National authority
16	28 January 2021	EU agency; national authority
17	01 February 2021	National authority
18	04 February 2021	National authority
19	04 February 2021	EU agency; national authority
20	11 February 2021	Commission
21	11 February 2021	EU agency; national authority
22	24 February 2021	Member state ministry
23	25 February 2021	National authority
24	04 March 2021	EU agency; national authority
25	05 March 2021	European Parliament
26	09 March 2021	Industry
27	15 March 2021	Commission
28	19 March 2021	National authority
29	25 March 2021	National authority
30	29 March 2021	Commission
31	27 April 2021	Commission
32	27 April 2021	Commission
33	28 May 2021	National authority; member state ministry
34	08 October 2021	EU agency; national authority
35	14 January 2022	Commission
36	26 January 2022	Commission