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

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ABSTRACT

Networks of national authorities are often mandated to help enforce EU policies, but receive less scholarly attention than EU agencies. This article examines two networks in the policy areas of medical devices and aviation incident investigation. These are puzzling cases, as two EU agencies already existed in similar policy areas: the European Medicines Agency (EMA) and the European Aviation Safety Authority (EASA). Why did EU legislators mandate new networks of national authorities, and not existing EU agencies? The article argues that 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. The article 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 article's case studies rely on 24 interviews and an analysis of primary and secondary documentation.

KEYWORDS Agencies; aviation incident investigation; enforcement; European Union; medical devices; networks

Introduction

Among the various organizations involved in enforcement in the European Union (EU), EU agencies have received considerable societal and scholarly attention (e.g., Maggetti, 2019; Scholten & Luchtman, 2017; Versluis & Tarr, 2013). Formal networks of national authorities, however, have generated much less interest, even though 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

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legislators would prefer a network to an agency for the fulfillment 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 European Aviation Safety Agency (EASA) has considerable tasks for the enforcement of aircraft airworthiness rules. At the same time, this EU agency has little to do with investigations of aircraft accidents such as airplane crashes or runway collisions. These investigations are instead carried out by national authorities and coordinated within the European Network for Civil Aviation Safety Investigation Authorities (ENCASIA, Regulation (EU) 996/2010). A similar picture arises in the area of medical products. Even though the European Medicines Agency (EMA) was already responsible for the safety of medicines circulating in the EU since 1995, the enforcement of policies for medical *devices* – e.g., 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 organizations involved in the enforcement of EU policy and informs 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., Blauburger & Rittberger, 2015; Boeger & Corkin, 2017; Kelemen & Tarrant, 2011; Vantaggiato, 2019). 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 organizations (Salvador Iborra et al., 2018; Scholten, 2017). When it comes to enforcement, existing scholarship on the mandating of EU agencies and networks has not often engaged in case study research on the decision-making that led to either type of organization (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 article 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 article also seeks to provide insight into EU legislative decision-making on the enforcement of EU policies specifically.

The section hereafter builds upon the existing literature to construct a theoretical framework. The article then proceeds to case studies of EU medical devices regulation and aviation incident investigation – 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 new networks instead of existing EU agencies. The last section revisits the theoretical framework in light of the case studies and concludes.

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? Building upon the existing literature, the section then discusses additional theoretical viewpoints for explaining the choice between EU agencies and networks for EU policy enforcement specifically. 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 (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 (Jans et al., 2015). Moreover, the EU has increasingly created new EU institutions (Luchtman & Vervaele, 2014; Scholten, 2017; Scholten & Luchtman, 2017). 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).¹ EU agencies and networks thus appear across policy areas, and even in highly 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 organization (e.g., Kelemen and Tarrant, 2011; 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, 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 favorable to the establishment of networks (Vantaggiato, 2018), 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 (see, however, Blauburger & 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 organizations 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 specialized 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 – which generates a need to access resources elsewhere or to organize enforcement as cost-efficiently as possible (Genschel & Jachtenfuchs, 2018; Papadopoulos, 2018; Vantaggiato, 2018, 2019). On the other hand, enforcement's resource-intensity can also constrain coordination. Not only may the centralization of enforcement in an EU organization 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 (Mathieu, 2016; Thatcher & Coen, 2008).

Another characteristic of EU policy enforcement is the primary position traditionally accorded to member states' national authorities. Existing scholarship already emphasizes 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 (Thatcher & Coen, 2008; Vantaggiato, 2019). Among the conditions under which national authorities can succeed in influencing legislative decision-makers are their ability to organize 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 (Jans et al., 2015).

Resources and mandates, that were 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 (Eberlein & Newman, 2008; Kelemen & Tarrant, 2011, 2015). 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 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 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, 2019). At the same time, national authorities need not follow only political or institutional rationales. They may well coordinate for functional reasons (Eberlein & Newman, 2008; Mathieu, 2020; see, however, Bach et al., 2016), e.g., 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 that is most effective for supervising the actors and behavior in a particular policy domain. Epistemic considerations – which appear salient in complex disciplines such as medical devices and aviation safety (Löblová, 2018; Schot & Schipper, 2011) – 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 effectiveness for enforcement in a specific domain. It may therefore be 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 organize 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, in turn, may limit the creation of new institutions at an EU level.

Case studies: medical devices regulation and aviation incident investigation

Case study research design and method

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 civil aviation safety certification and medicines regulation respectively (see Table 1 below). Based on the dimensions identified by the existing literature as relevant for the differentiation between agencies and networks, EU agencies in the areas of medical devices regulation and aviation incident investigation would theoretically have been the most-likely outcomes. The EU networks thus 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 (Eberlein & Newman, 2008; Mathieu, 2020). 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

Table 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

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 (see Blauberger & Rittberger, 2015). Variations in the degree of political conflict are equally indeterminate (see 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, rendering an agency more likely (Altenstetter & Permanand, 2007). The Commission, furthermore, has no existing competences for medical devices policy enforcement that could be threatened by an agency (see Thatcher, 2011). Comparable forms of coordination, lastly, preceded both the creation of the EMA and of the network structures for medical devices (see 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 factors (see Blauberger & Rittberger, 2015; Eberlein & Newman, 2008; Mathieu, 2020). Again, the potential for political conflict is higher for airworthiness policies, as they entail structural consequences for manufacturers and operators. Incident investigations are by definition not structural, which increases the likelihood of an agency for incident investigations (see 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 ENCASIA in the area of aviation incident investigation (see Thatcher, 2011; Thatcher & Coen, 2008).

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) staff from the Commission (5), 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 because access proved to be difficult. One interviewee from a consumer organization dropped out.

As puzzling cases have been selected, many scope conditions apply to the conclusions drawn upon them (Rohlfing, 2012). 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.

Case study 1: coordination for 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 article (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 constitute a considerably stronger form of 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 fueled 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, 27 April 2021; Interview, 26 January 2021; Interview, 16 September 2020; Interview, 28 October 2020; Commission, 2008; see also Jarman et al., 2021; Greer & Löblová, 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 28 October 2020; Commission, 2012a, pp. 14, 16–17; Commission, 2008, pp. 2, 11–12). Lacunae in know-how also existed in the supervision of notified bodies (Interview, 27 April 2021; Interview, 6 January 2021; Interview, 4 February 2021). Even the industry found that there was room for greater uniformity in the supervision of notified bodies (Interview 29 October 2020; 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 the Commission had limited abilities to acquire staff and expertise of its own (Interview, 29 March 2021; Interview, 27 April 2021; Interview, 27 April 2021; Interview, 04 February 2021; Interview, 6 January 2021; Interview, 29 October 2020; Commission, 2008). The idea was applauded by the European Parliament as well as by the EMA itself (Interview, 4 February 2021; Interview, 6 January 2021; 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, 29 March 2021; Interview, 26 January 2021; Interview, 4 February 2021; Interview, 16 September 2020). In their opposition to EMA involvement, many were eager to put forward epistemic differences between the monitoring and evaluation of medical devices and medicines respectively (Interview, 4 February 2021; Interview, 6 January 2021; Interview, 24 February 2021; Interview, 29 October 2020; Agencia española de medicamentos y productos sanitarios, 2008, p. 14; Commission, 2012b, pp. 11–12; EUCOMED, 2008, pp. 2, 18; EUROM VI, 2008, p. 20; IG-NB, 2008, pp. 12–13; Irish Medicines Board, 2008, pp. 11–12, 18–19; Ministerie van Volksgezondheid, Welzijn en Sport, 2008, pp. 15–16; Représentation Permanente de La France auprès de l'Union européenne, 2008, pp. 13–14; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008, pp. 1–2). 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, would the EMA become competent for medical devices (Interview, 4 February 2021; Interview, 6 January 2021; Interview, 24 February 2021; Interview, 29 October 2020; Interview, 26 January

2021; Interview 29 March 2021). One national authority summarized 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, 2012b; Interview, 29 October 2020; Direzione Generale dei Dispositivi Medici e del Servizio Farmaceutico, 2008; EUCOMED, 2008, p. 17; Medicines & Healthcare Products Regulatory Agency, 2008; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 2008).

A strengthened network rather than a new agency

These objections were a main reason for the Commission to drop the option of an extended EMA (Interview 29 March 2021; Interview, 27 April 2021; Interview, 27 April 2021; European Commission, 2012c, 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 29 March 2021). 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, 6 January 2021; Interview, 26 January 2021; Bundesministerium für Gesundheit, 2008; Irish Medicines Board, 2008; Medicines & Healthcare Products Regulatory Agency, 2008; Ministerie van Volksgezondheid, Welzijn en Sport, 2008; Répresentation Permanente de La France auprès de l'Union européenne, 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 harmonized practices by national authorities responsible for notified bodies (AdvaMed, 2008; COCIR, EDMA, EHIMA, EUCOMED, EUROMCONTACT, EUROM VI and FIDE, 2008; EUCOMED, 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, 27 April 2021; Interview, 27 April 2021; Interview, 29 March 2021), but also the vast resources involved in centralized enforcement proved to be a limiting factor. Commission staff confirmed that a dedicated body would be too costly, particularly in comparison to EMA expansion (Interview, 27 April 2021; Interview, 27 April 2021; Commission, 2012a, 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’ (2012a, p. 40). This option was also long advocated and pushed for by national authorities (Interview 29 January 2021; Commission, 2012b; Irish Medicines Board, 2008; Laegemiddelkontoret, 2008; Ministerie van Volksgezondheid, Welzijn en Sport, 2008; Répresentation Permanente de La France auprès de l’Union européenne, 2008; Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, 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, 4 February 2021), the national authorities referred to the forums in which they already convened and jointly evaluated incidents (Interview, 26 January 2021; Irish Medicines Board, 2008). The Council would hardly amend the Commission’s proposal during its negotiations – in which national authorities’ experts participated directly (Interview 29 March 2021; Interview, 28 October 2020; Interview, 24 February 2021).

Case study 2: coordination for EU aviation incident investigation

The second case study is about coordination in the domain of aviation incident investigation. The EU established the European Network of Civil Aviation Safety Investigation Authorities (ENCASIA) in 2010, which convenes national authorities for the investigation of accidents and serious incidents involving civil aircraft. The network organizes 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 EU in its entirety (Regulation 996/2010). With the creation of 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 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 have adequate resources for their operations (Council Directive 94/56/EC; ICAO Annex 13). Furthermore – and also on the basis of ICAO 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, 15 January 2021; Interview, 25 February 2021; Interview, 9 December 2020; Interview, 18 August 2020; Interview, 17 December 2020).

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, 14 January 2022; Interview, 15 September 2020; Commission, 2009b; ECORYS and NLR, 2007; European Parliament, 2010b). Not only the Commission, but also the national authorities themselves recognized a need to strengthen 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 14 January 2022; Commission, 2007). According to its proposal, the Commission would have become competent to appoint a representative from the EASA to participate in investigations alongside national authorities. The Commission reasoned that ‘the Community should organize 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, 27 October 2020; Interview, 15 September 2020; Interview, 18 August 2020; Interview, 15 January 2021; Interview, 25 February 2021; Interview, 9 December 2020; 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, 27 October 2020; Interview, 15 September 2020; Interview, 18 August 2020; Interview, 15 January 2021; Interview, 25 February 2021; Interview, 9 December 2020; 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 and Roed-Larsen, 2009, p. 1472). The EASA itself had already sought to participate in investigations – only fueling national authorities’ need to coordinate amongst themselves (Interview, 25 February 2021). The Commission eventually ruled out EASA expansion 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 EASA 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 and NLR, 2007, pp. 61–62), and its proposal would have received support from the European Parliament (2010a) as well as from the industry (Interview 14 January 2022). 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, *author initials*] 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 of novel EU agencies, but also because of the costs involved (Interview 14 January 2022). 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 formalize 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, 25 February 2021; see also ENCASIA Annual Report, 2011, Appendix 1, preamble, and Article 10). The national authorities as well as an external consultant thus suggested its formalization as ‘a positive step towards more coordination regarding accident investigation’ (ECORYS and 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 EASA expansion.

Discussion and conclusion

This article 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 held earlier’.

Resource-intensity influences enforcement coordination

As argued above, 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, 2018). 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

cultures that developed within the respective domains of aviation incident investigation and medical devices proved incompatible with those of airworthiness certification and medicines policy enforcement. These incompatibilities subsequently limited the possibility to vest enforcement tasks in the 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 the choice to coordinate enforcement within networks instead of EU agencies was strongly influenced by national enforcement authorities. They can play a significant role in the EU decision-making process on agencies and networks, particularly if their consent is necessary for a (new) organization'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 at the national 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, national authorities' agreement was highly relevant for any new organization's creation.

The national authorities seem to have benefited 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 (see p. 8); and in the case of aviation incident investigation, national authorities were equally reluctant when the Commission proposed to expand the EASA's enforcement tasks (p. 13). 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 determined national authorities' opposition vis-à-vis the expansion of existing EU agencies in adjacent policy fields. The opposition against EMA 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 and aviation safety investigation. Such dedicated agencies would have resolved part of the national authorities' objections, and as discussed earlier, 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 Löblová (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 EMA expansion appeared infeasible. Similarly, when it appeared problematic to provide the EASA a substantial role in accident investigation, the responsible Commission services did explore the establishment of novel EU agencies but discarded their ideas given 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 article 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 the 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 article? The questions raised in this contribution are only a few among the many others that continue to remain unanswered.

Note

1. An EU agency is understood here as a permanent body with legal personality by virtue of EU law, operating (semi) autonomously from political actors. An EU network of national authorities is defined as one or more permanent protocols that are laid down in EU law and through which primarily national authorities can cooperate bi- or multilaterally.

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