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How Do Supranational Regulators Keep Companies in Line? An Analysis of the Enforcement Styles of EU Agencies

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Abstract

National governments have increasingly transferred enforcement powers to EU agencies that monitor and penalize non-compliance by private actors. How do EU agencies apply enforcement competences in practice? Based on the Eurolegalism thesis, pressures for deeper integration have led to the emergence of a more adversarial enforcement style in Europe. Consequently, supranational regulators are expected to employ formal and coercive enforcement instruments. Conversely, studies of EU enforcement suggest that EU agencies may be reluctant to antagonize national governments by prosecuting private actors. In this study, we analyze the enforcement practices of supranational agencies with direct enforcement powers: the EU Aviation Safety Agency (EASA), European Securities and Markets Authority (ESMA) and European Medicines Agency (EMA). We find that EU agencies apply a legalistic approach, but they vary in coerciveness of enforcement. Whereas EU agencies tend to apply more coercive measures against non-conform products, they are generally not adversarial toward non-compliant organizations.

Keywords: EU agencies; enforcement; supervision; Eurolegalism; regulation

Introduction

There is an ongoing debate on whether deeper European integration resulted in a stringent enforcement style in the European Union (EU). Tendencies toward detailed and prescriptive EU regulation have pressured national regulators to adopt increasingly formal, transparent, and judicially enforceable regulatory approaches. Consequently, the EU has allegedly 'undermined informal national styles of regulation based on closed, insider networks' (Kelemen, 2008, p. 33). Instead, national regulators are expected to adopt a more formal and adversarial approach to enforcement, also known as Eurolegalism. A recent study has found evidence of more stringent and detailed public enforcement in two EU member states (Bastings *et al*., 2017). However, it is unclear whether EU supranational enforcement practices also reflect a more adversarial style. This is a significant gap in our knowledge because member states have gradually transferred extensive enforcement powers to supranational institutions that monitor and address private actors' noncompliance with EU policies.

In this study, we examine the supranational enforcement practices of EU agencies. In recent years, the EU set up agencies to support national authorities' enforcement through coordination and training (Versluis and Tarr, 2013). However, EU regulation is often independently applied by these EU-level actors themselves (Scholten and Scholten, 2017; van Rijsbergen and Scholten, 2017), emblematic of an increasingly direct EU administration (Egeberg and Trondal, 2017). In addition, some EU agencies may impose sanctions (market restrictions and financial penalties) on private actors who failed to comply with

EU regulation (Chamon and Wirtz, 2017; Coman-Kund *et al*., 2017; Van Rijsbergen and Foster, 2017). It is an open question, however, how EU agencies use formal competences in practice.

Our study presents a first assessment of how EU agencies have de facto taken up their role as direct enforcers. Whereas EU agencies' practices depend on the formal competences conferred on them by EU legislators, practical implementation is often decoupled from formal structures (Zhelyazkova *et al*., 2018). Furthermore, we apply the Eurolegalism thesis in relation to supranational enforcement practices. Based on this thesis, EU agencies with formal enforcement competences are expected to adopt stringent measures against lawbreaking private actors. On the other hand, EU enforcement is more politicized than its national variant. (Kelemen, 2006; Majone, 2000). Member state authorities may resist supranational enforcement as they maintain control over EU policymaking and implementation (Christensen and Nielsen, 2010; Kelemen, 2002). Supranational institutions allegedly have weaker enforcement competences than national regulatory agencies and use formal instruments as a last resort (Stephan, 2009; Tallberg, 2002). EU supranational enforcement may therefore not be so stringent as the Eurolegalism thesis implies.

To test these competing arguments, we analyze the enforcement practices of three EU agencies: the European Union Aviation Safety Agency (EASA), the European Medicines Agency (EMA) and the European Securities and Markets Authority (ESMA). These EU agencies have the most extensive formal enforcement powers because they can impose financial penalties against private entities. Our study is based on an analysis of enforcement decisions and agency documents, along with 15 elite interviews.

Contrary to traditional EU compliance approaches, we find that EU agencies apply a formalistic and coercive approach to supervision but vary in their level of enforcement of noncompliance. While EU agencies are generally reluctant to impose coercive penalties against organizations, they apply more coercive measures in relation to nonconforming products. A notable exception is ESMA, which does impose adversarial sanctions against certain infringements.

We proceed by discussing Eurolegalism's implications for supranational enforcement and contrastingly why an adversarial approach may not prevail in a supranational context. We then conceptualize enforcement practices and explain our methodological approach. We subsequently analyze the enforcement practices of EU agencies. We conclude with the main implications of our findings and avenues for future research.

I. Formal and Strict EU Enforcement Practices?

It is widely debated whether the American aggressive legal enforcement style is taking hold in Europe and supplanting established national and supranational styles (Kagan, 2003; Kelemen, 2006; van Waarden, 2009). Deeply embedded judicial and legal practices in the United States have led to the emergence of 'adversarial legalism', where policy implementation and dispute resolution practices are characterized by 'lawyer-dominated litigation' (Kagan, 2003, p. 3). US federal legislators rely on ex-ante and ex-post mechanisms to control executive bodies (Epstein and O'Halloran, 1999; Huber and Shipan, 2002). In the US context, adversarial legalism is reflected in the delegation of powers to executive agencies engaged in rule-making and adjudication procedures prescribed by the Administrative Procedure Act and in accordance with their founding acts.

For example, the Environmental Protection Agency (EPA), a federal executive, is empowered to revise air quality standards and establish the requisite level of protection against adverse effects of air pollutants, leading to uniform environmental standards. The American regulatory style contrasts with European traditions, which tend to be more cooperative, and less reliant on lawyers and courts (Kelemen, 2006, p. 103). However, Kelemen (2006) argues that national enforcement styles in Europe have converged around what he calls 'Eurolegalism', resembling the American adversarial approach to enforcement. This new style combines two dimensions of regulatory enforcement: (1) enhanced formalism in the interactions between regulators and regulated entities and (2) coercive, even punitive enforcement measures against noncompliance.

Kelemen provides several explanations for the emergence of Eurolegalism (Kelemen, 2006). First, European integration requires formal, transparent, and legalistic regulatory approaches to create a level playing field. European rules therefore empower private actors to seek redress through national and European courts whenever their EU rights have been violated. Second, the increasing fragmentation of power at the EU level has increased the uncertainty about the formal competences of a growing number of supranational bodies with different formal competences. The proliferation of supranational actors and agencification of the EU causes agency problems as EU legislative bodies have difficulty controlling executive agents' delegated authority. Legislators therefore 'stack the deck' ex-ante by drafting strict and detailed EU rules that limit bureaucratic discretion, leading to detailed laws with strict deadlines and requirements (Franchino, 2004, 2007; Kelemen, 2004). Stricter EU requirements have encouraged an adversarial, judicialized approach to enforcement in the EU member states. Several studies have found evidence for the increased emphasis on litigation in Germany and the Netherlands (Rehder, 2009; van Waarden and Hildebrand, 2009). Furthermore, recent research shows that national regulators have responded to EU integration pressures by converging toward a more formal and stringent enforcement style (Bastings *et al*., 2017; Wieringa and Havinga, 2021). These studies conceptualize Eurolegalism based on two dimensions of enforcement styles: coercion and formalism. Like national regulators, EU agencies with direct enforcement powers face pressures to follow detailed and transparent enforcement procedures that limit their freedom to engage in informal negotiations with regulated entities. Thus, following the Eurolegalism thesis, one would expect that EU agencies have adopted a legalistically formal and a coercive, even aggressive approach to enforcement toward private actors.

II. Is Supranational Enforcement less Adversarial?

Others are skeptical that common, transparent European rules translate into a more adversarial approach toward enforcement. Prevailing distinctive features of national regulatory regimes are expected to impede adversarial legalism in Europe (van Waarden, 2009). Furthermore, EU integration does not affect member states evenly and national regulators customize EU rules to fit national preferences and capacities (Thomann and Zhelyazkova, 2017). As member states remain responsible for the enforcement of many EU rules, persistent national institutional differences could inhibit convergence (van Waarden, 2009). Adversarial legalism is thus unlikely to take firm root in Europe at the national level.

There are reasons to expect that supranational institutions also refrain from adversarial enforcement practices. It is acknowledged that regulators apply responsive strategies, where enforcement is proportionate to the type and level of violations by regulated entities. This research shows that regulators engage with regulated actors and refrain from quickly imposing punitive sanctions (Ayres and Braithwaite, 1992; Gilad, 2009; May and Wood, 2003). In addition, the formal competences of supranational enforcement actors are far from clearly defined. Landmark ECJ rulings such as the Meroni non-delegation doctrine and Greek Maize case (68/88, Commission v Greece) create uncertainty about the actual competences of EU agencies to enforce EU rules autonomously, without the consent of EU legislators. Despite the increasing number of EU regulators, national governments remain responsible for ensuring compliance with EU rules by private regulated entities. Existing research shows that supranational enforcement institutions avoid stirring conflict with national governments. For example, the Commission's responses to noncompliance by national governments resemble a 'management-enforcement ladder' (Jönsson and Tallberg, 1998; Tallberg, 2002). Management implies addressing non-compliance through amicable means, such as problem-solving strategies and dispute-settlement dialogues, without resorting to coercive sanctions. Enforcement, by contrast, refers to deterrence by coercive means including a credible threat of sanctions and referral to the European Court of Justice (ECJ) (Börzel, 2001; Börzel *et al*., 2012; Hofmann and Panke, 2005; Tallberg, 2002). The Commission and member state governments share an interest in avoiding reputation-damaging and resource-consuming litigation and seek last-minute compromise in bilateral negotiations (Börzel, 2001; Pollack, 2003). Furthermore, in recent years, the Commission has increasingly withdrawn from the legal approach to enforcement (Hofmann, 2018). Instead, the Commission relies on decentralized private enforcement and litigation (Hartlapp, 2009). This management-dominated approach also applies to supranational enforcement toward private actors. In the area of EU competition policy, leniency programmes and dispute-settlement procedures have been designed to reduce fines imposed on private companies (Stephan, 2009).

Supranational enforcement toward private actors likely resembles the Commission's approach to member states as it is faced with similarly politicized supranational competences. Member-state governments have maintained influence over the supranational enforcement decisions of EU agencies through national representation on their management boards (Christensen and Nielsen, 2010; Kelemen, 2002). Therefore, it is questionable to what extent EU agencies are fully independent of member states' control. National governments do not always accept decisions for stringent restrictions on crucial national industries (Hall, 2019) and EU agencies might be reluctant to aggravate relations with the EU member-state representatives presiding in the management board. Based on these arguments, EU agencies with direct enforcement powers are unlikely to employ adversarial legalism toward private actors.

III. Assessing (Supranational) Enforcement Practices

Empirical research on regulation often analyzes enforcement practices by reducing it to one or multiple dimensions. To establish whether EU agencies employ adversarial legalism toward private actors, the commonly used dimensions coercion and formalism

(de Boer, 2019; Kelemen, 2012; May and Winter, 2011; McAllister, 2010) are particularly useful. Coercion pertains to the responses of regulators to observed law violations. Coercive enforcement entails quickly issuing threats and imposing unilateral penalties instead of arriving at mutually beneficial solutions. This dimensions therefore pertain to the adversarial nature of enforcement practices. This dimension is closely aligned with the 'hierarchical dimension' of adversarial legalism, where an authoritative organization enforces compliance with prescribed norms and standards (Kagan, 2003). Whereas fines and 'naming and shaming' practices are punitive and are meant to deter noncompliance, denying market access to nonconforming products aims to solve safety issues without the intention (but nonetheless with the possible outcome) of punishing a regulated entity. The level of coercion therefore illustrates whether the adversarial, punitive penalties that would result from Eurolegalism (Kelemen, 2006) are used by EU agencies.

The second dimension, formalism, reflects whether regulators apply formal procedures in their interactions with regulated entities. Kagan (2003) refers to it as 'legal formality' and it pertains to the legalistic component of the Eurolegalism thesis. Formal enforcement entails practices that strictly follow the letter of the law. The Eurolegalism thesis poses that formalizing enforcement is done to limit discretion and subsequently solve agency problems. At the institutional level, this dimension therefore pertains to inspectors' discretion to monitor and prosecute noncompliance. Limits to discretion of inspectors can come from procedures imposed by political principals, but also from EU agencies themselves establishing strict guidelines that formalize the inspectors' approach.

When analyzing formalism and coercion of enforcement, scholars identified ideal types of enforcement styles (May and Winter, 2000) spanning from accommodative (low levels of coercion and formalism) to legalistic (high levels of coercion and formalism). However, regulators combine coercion and formalism to varying degrees in their daily practices.

Case Selection

To determine whether EU agencies have adopted adversarial legalism, we evaluate the enforcement practices of three EU agencies. We selected EASA, EMA and ESMA because these have a diverse set of enforcement instruments. They are the only agencies which have a role in fining private actors (Scholten, 2017). Consequently, these agencies represent a most likely case for the Eurolegalism thesis, as they have adversarial enforcement measures at their disposal.[1] Furthermore, they regulate highly salient sectors; aviation, pharmaceuticals, and financial markets. This may make them opt for more adversarial enforcement to satisfy public safety concerns compared to other agencies.

There are notable differences between the three agencies' competences, specifically when it comes to the object they regulate (organizations and/or products) and the enforcement instruments at their disposal (see also Online Appendix I).

EASA is the only case that supervises and enforces requirements for both products and organizations. Companies that design aircraft, aircraft parts, or modifications require

[1]We disregard enforcement activities toward companies from outside the EU. For EMA, we focus on its human medicine enforcement rather than veterinary medicine.

approval from EASA to operate in the European market (Regulation 2018/1139). Additionally, EASA issues certificates for specific aviation products and supervises their safety. To apply for and hold a product approval, a company needs a valid organizational approval. EASA's strongest enforcement instrument is revoking organizational approvals and certificates. It can also pursue companies for financial penalties but needs the European Commission to formally impose them.

ESMA, on the other hand, only deals with organizational supervision and enforcement. Among other things, ESMA is tasked with the registration and supervision of credit rating agencies (CRA) and trade repositories (TR) and enforces compliance with regulatory requirements (Regulation 1060/2009, Regulation 648/2012). ESMA may revoke an organization's registration as an enforcement measure or may independently decide to issue a financial penalty and/or publish a public notice.

EMA only deals with product supervision and enforcement. The Committee for Medical Products for Human Use (CHMP) issues opinions to the European Commission on whether the benefits of pharmaceutical products outweigh their risks. The European Commission then decides whether products are approved. Reassessment opinions on previously approved medicines are initiated by the Pharmacovigilance Risk Assessment Committee (PRAC) and pass through the CHMP before being sent to the European Commission for formal approval. EMA relies on national regulators to supervise manufacturers. A medicine manufacturer, however, must have the relevant certification to apply for an EMA market authorization for their products, and to continue to market them.

Operationalizing Enforcement Style

Table 1 shows our operationalization of the coercion and formalism dimensions. The measurement is informed by previous research (de Boer, 2019; Kelemen, 2012; May and Winter, 2000; McAllister, 2010) and includes broad indicators to allow for

Table 1: Overview of Operationalization

Dimension	*Activity*	*Indicator*
Coercion	Supervision	Highly intensive proactive monitoring and inspection of compliance rather than relying on complaints from stakeholders
		Requiring regulated entities to submit information with adverse consequences for not doing so
	Enforcement	Imposing stringent sanctions with high costs for regulated entities rather than focusing on clarification and persuasion (see Table 2 and Online Appendix I for additional operationalization)
		Quickly resorting to sanctions rather than escalating as a last resort
Formalism	Supervision	Broad rather than targeted and flexible supervision
		Following formal supervision procedures rather than informal discussion and negotiation
	Enforcement	Consistent rather than ad hoc sanctioning
		Following formal enforcement procedures rather than informal discussion and negotiation

Table 2: Level of Coercion Ranking of Enforcement Instruments

Enforcement instrument	*Level of coercion*
Revoking organizational approval	High
Revoking product approval	
Naming and shaming	
Imposing financial penalties	
Altering product approval	
Imposing periodic penalty payments	
Requiring mitigation	
Educating regulated entities	Low

considering context-specific enforcement practices. Our analysis also recognizes that practices may differ for supervision and enforcement (Liu *et al*., 2018). We conceptualize enforcement as activities by a regulator to mitigate noncompliance with (legal) rules, including formal sanctions such as fines and authorization revocations as well as bilateral measures such as pointing toward ways a company might deal with an infringement.[2] Supervision refers to activities by a regulator to detect noncompliance including monitoring compliance and investigating an alleged violation (Scholten, 2017), but excluding any instance of dealing with observed non-compliant behavior. This distinction is important to consider because decision-making about enforcement and supervision is often done by different departments within an agency (Liu *et al*., 2018), which could result in different pratctices. In addition, EU agencies do not have the same competencies to sanction and inspect, likely resulting in different findings for enforcement and supervision dimensions.

Table 2 provides the ranking of the enforcement instruments available to the three agencies based on the stringency of sanctions. Online Appendix I contains a description of how we arrived at this ranking. We use the indicators from Tables 1 and 2 to explore the presence of coercion and formalism in the enforcement practices of the three agencies.

Data and Analysis

We use agency documents, such as enforcement decisions, press releases, annual reports, and webpages to explore the enforcement styles of the agencies. Furthermore, we held semi-structured interviews with 15 high-level EU and national agency officials involved in the supervision and enforcement of the EU agencies, as well as industry representatives from associations and individual firms (see Online Appendix IV). Elite interviews are ideally suited to assess regulatory styles due to the in depth and nuanced data they yield (Bayerlein *et al*., 2021). We also had written exchanges with EASA and EMA about their practices and sent a survey with open questions to aviation companies ($n = 11$). An overview of our data is found in Appendices II to IV.

[2]ESMA uses a different distinction. Enforcement refers only to its infringement procedure, possibly resulting in financial penalties and public notices. What we conceptualize as enforcement happens at both the supervision and enforcement department of ESMA.

IV. Results

The features of the enforcement styles of EASA, ESMA, and EMA are discussed below along the coercion and formalism dimensions for supervision and enforcement separately. Interview data is referred to with an 'R', document data with a 'D'.

Coercion in Supervision

We find evidence for high intensity of supervision for all three agencies. For example, one industry actor indicated about EASA: 'They [EASA] do require companies to keep the agency informed of any changes within the company [...] There is certain personnel at the company that would effectively have to be approved by EASA being a suitable person for that role.' (R6). This is different for EASA's product supervision. For example, once aircraft designs are approved by EASA, they are typically only inspected when safety incidents occur (R6, R13). EASA only monitors organizational approvals proactively.

The same goes for ESMA, which only supervises organizations and not products. As one official indicated, 'we do our own independent market monitoring. And we also […] interact with the entities that we supervise quite regularly.' (R12.1). ESMA monitors compliance through desk-based and onsite inspections (R3, R12.1, R12.2).

EMA similarly employs an intensive system of risk assessments of pharmaceutical products (R7, R8). As an agency official indicated: 'We maintain a list of the products and the manufacturers and the product they are manufacturing and the interval of inspection. And whether there are any requirements for increased inspection. […] That is done on a continuous basis for all products on the market.' (R8). Approved medicines are regularly monitored by a committee composed of member state agency officials, the PRAC, based on a dossier of information and studies issued by the market authorization holder.

Beyond their own investigations, all agencies use information from stakeholders to supervise. Issues with approved aviation products are reported to EASA by airline companies, national regulators or other credible sources (written correspondence with EASA). ESMA officials point to whistleblowers, counterparties, and national regulators as information sources (R12.1, 12.3). Within EMA, the PRAC may act on issues raised by national regulators, patients or medical professional associations or any other source. As one agency official indicated: 'For centrally authorized products we have specialized phone numbers, email addresses, forms and procedures for the reporting of those.' (R8).

All agencies require companies to submit information, which suggests high coercion in supervision. There are, nonetheless, varying consequences for not doing so. An aviation company representative indicated about EASA that 'for all of those [issues reported by users of aircraft], we have to determine within 72 hours whether there is a safety issue in there. And if there is a safety issue, then you have to report that to EASA' (R13, also R6). Importantly, while product approvals are only re-evaluated when incidents are reported, the system of reporting incidents itself is regularly evaluated as part of the organizational approval supervision. If a company systematically withholds information about incidents or does not systematically monitor them, this will be detected through EASA's organizational approval supervision (R6). ESMA also receives information from companies themselves: 'They [registered organizations] are a supervised entity. They have to monitor very closely. On a regular basis, they are sending reports and various

documentation' (R11). ESMA may compel entities to submit information and submit to an investigation or inspection by imposing periodic penalty payments or increasing fines if applicable (Regulation 1060/2009, art. 36b & Annex IV). Although there is no evidence that ESMA uses these instruments in practice, the agency has imposed sanctions on entities that did not have sufficiently robust internal controls to ensure compliance with the regulation (D7, D9). With respect to EMA, approved medicines are regularly monitored the PRAC based on a dossier of information and studies issued by the market authorization holder. When regulated entities do not submit the required information, the medicine is not evaluated for re-approval. This may cause it to disappear from the market (R7, R8).

In sum, the evidence suggests a high level of coercion in the agencies' supervision practices. Whereas EASA's product supervision is reactive, aviation products are, nonetheless, indirectly proactively supervised through EASA's proactive organizational supervision of companies' internal control producers.

Coercion in Enforcement

There are notable differences between the agencies with respect to the coerciveness of their enforcement. Much of this can be attributed to whether they enforce product or organizational requirements.

Revoking organizational approvals, which is the most coercive enforcement instrument available to the agencies, is relatively rare. EASA indicated: 'This [withdrawing organizational approvals] would be typically a measure of last resort in case of serious noncompliance affecting safety.' An aviation industry actor confirmed this dynamic (R6). EASA has revoked only 7 (D1) and suspended 4 (D2) of the 381 (D3) organizational approvals since its existence. ESMA has only withdrawn organizational authorizations that were renounced by the company itself (D10–18) or of companies that have merged (D19, D20). ESMA has never revoked a registration as an enforcement measure (R3, R10, R11), with one respondent indicating: 'I have never considered in my analysis to recommend withdrawing the registration' (R10). As discussed earlier, EMA does not have the ability to revoke organizational approvals.

Much of the measures that agencies use to resolve non-compliance with organizational requirements suggest lower levels of coercion: i.e. requiring mitigation (see Table 2). EASA principally employs corrective action plans that are drawn up by the companies to address concerns from inspections (R2, R6, R13). Inspection findings must be resolved by the company within a specific timeframe, depending on their safety implications (written exchange with EASA). The agency gives suggestions to the companies on how to comply (R6, R13). EASA clarified in a written response that: 'EASA will, in any case, have a regular dialogue with the organization to determine if there are any other solutions available to address the noncompliance, taking into account the circumstance of the case'. ESMA's enforcement approach also includes clarification and persuasion.[3] When the supervision department encounters non-compliance, the compliance officers require the credit-rating agencies to remediate it (R3, also R5, R9, R10 R12.1, R12.2). Issues of noncompliance are generally addressed through bilateral mitigation measures rather than unilateral enforcement where possible. An ESMA official (R11) indicated that ESMA's

[3]See note 2.

supervision approach helps avoid serious noncompliance issues so that the agency does not have to resort to withdrawing registrations. ESMA also uses facilitative and educational enforcement instruments such as roundtable discussions and general communication about good practices (R12.1).

Another coercive instrument of enforcing organizational requirements is issuing financial penalties and publishing public notices about infringements. This is in practice only done by ESMA. EASA and EMA have the option to prosecute companies for financial penalties but have never done so (R1, R2, R6, R7, R8, EASA written correspondence). EMA has once followed an infringement procedure against a company, but no fine was imposed.

ESMA on the other hand issues financial penalties or public notices regarding to specific infringements related to conflicts of interest, public disclosure of information, operational requirements, organizational requirements, and obstruction of supervision.[4] ESMA uses public notices, a 'name and shame' practice, against lawbreaking private actors as a standard measure against these infringements (R5, R10, R11, R12.1). It also imposes financial penalties against negligent or intentional infringements. At the time of writing, ESMA had imposed eight fines on seven different entities, totaling over 8.5 million euros. This is substantial, as ESMA lists only 42 registered credit rating agencies and seven trade repositories (D17, 18).[5] The fine is lowered when a company has taken mitigation measures, but it is issued nonetheless (R11). This emphasizes the punitive adversarial nature of this enforcement practice.

When it comes to revoking or altering *product* approvals, which is only done by EASA and EMA, there is more evidence of coercive enforcement measures. EASA has revoked 19 aircraft type certificates because of various instances of noncompliance. In an additional 15 cases, the agency issued a threat to revoke a type certificate because of payment issues.[6] EASA clarified that: 'Before revoking or suspending a certificate EASA would first inform the certificate holder about the intention to take this action, state the reasons and give the organization the possibility to submit observations before proceeding with the final decision.' Furthermore, EASA issues airworthiness directives to address safety issues with a product. These documents require aircraft operators to resolve nonconformities or conduct an inspection.

Within EMA, the PRAC can recommend three measures to the CHMP against nonconforming pharmaceutical products: variation, suspension or revocation. Variation means changing the conditions of the market authorization, for example adding a side effect or limiting use to a certain group of patients (R1). Additionally, medicines may be (temporarily) suspended from the market, pending an assessment, when there are concerns for patient safety. Market authorizations are fully and permanently revoked when 'the benefit-risk profile is so dangerous for patients that we think it is no longer possible to show that the benefit-risk profile would be positive.' (R1).

In the period between 2015 and 2019, the PRAC recommended adding a variation to 788 approved medicines, revoking four medicines, suspending six and imposing four

[4]See Annex III of Regulation (EU) No 1060/2009 and Annex I of Regulation (EU) No 648/2012 for the full list.
[5]One fine was imposed on a non-registered entity.
[6]See Online Appendix III.

temporary restrictions[7] out of the 4,001 medicines they evaluated. (D23).[8] A recommendation by the PRAC can have naming and shaming effects for the company (R7, R8). One respondent mentioned that 'It will be published that there are a lot of deviations. And that is not good for the market or the shareholders and so on. So, this is probably the strongest stick that you can use.' (R7). This means that EMA's enforcement instruments regarding products could also indirectly affect companies through naming and shaming (R7, R8).

Respondents nonetheless emphasize that these coercive measures should not be seen as adversarial. Enforcement measures on product approvals are (normally) not due to wrongdoing by the company, but due to new scientific insights about the drug (R7, R8) or emerging safety concerns with an aircraft unforeseen at the time of certification. One respondent explained that revoking pharmaceuticals merely reflects new evidence showing that the benefits of a product do not outweigh their risks (R7). Respondents indicated that EASA's airworthiness directives are not seen as punishment: 'There is no fine or other penalty associated with it.' (R6). While EASA regularly revokes and alters product approvals, this is not an adversarial enforcement measure.[9]

In sum, the enforcement instruments employed by EU agencies are generally not adversarial and punitive. While some instruments are coercive because they have the potential to name and shame lawbreaking companies, most instruments aim to mitigate conflicts. Highly coercive measures regarding non-conforming products are commonly imposed, but typically reflect mitigating safety issues rather than adversarial punishment. ESMA nonetheless imposes penalties depending on the type of noncompliance, pointing to a more coercive and adversarial approach to enforcement.

Formalism in Supervision

All three agencies adopt a broad yet targeted and flexible approach to supervision. Both companies and products are regularly inspected but the extent of supervision depends on their assumed risk of non-compliance. Regarding EASA, respondents (R6, R13) indicated that new companies and those with a poor inspection record get more attention than companies with a good record. Nonetheless, all companies with EASA manufacturing approvals are regularly inspected. Similarly, ESMA's supervision covers all registered Trade Repositories and Credit Rating Agencies but the agency has separate inspection timelines for high- and low-risk companies (R3, R12.1). Respondents furthermore indicate that ESMA considers the size of CRAs in their supervision practices (R9, R12.1, R12.2): 'We are also mindful that the regulatory compliance burden on smaller CRAs is disproportionally large. The regulation [...] was drafted very much with the big three credit rating agencies [Moody's, S&P and Fitch] in mind.' (R12.1). EMA evaluates all approved pharmaceutical products on a regular basis, but there are additional checks if a product poses a high risk (R7, R8). While this targeted approach could be seen as

[7]These decisions were made in EMA's referral process. See Online Appendix III.
[8]These are the variations that result from PRAC's periodic safety assessment. EMA also reviews thousands of (non-enforcement) variations of market authorizations applied for by market authorizations holders.
[9]EASA revokes product approvals regularly, if a company ceases activity ($n = 9$) or if a company requests EASA to revoke the approval of a discontinued product ($n = 91$). Of the product approvals, EASA has revoked 19 because of various instances of noncompliance ranging from not paying fees to having registered a product under a false category. In an additional 15 cases, the agency issued a threat to revoke a type certificate because of payment issues.

evidence of low formalism, this differentiation between companies is codified in formal rules and regulation[10] and is therefore highly formalized.

There are further indications of a highly formal approach to supervision of the three agencies. EASA issues many guidelines that provide legally binding requirements to guide EASA's supervision of compliance. One respondent (R13) elaborated that these regulatory rules make EASA much more formal than its predecessor, the intergovernmental Joint Aviation Authorities. Furthermore, EASA commonly communicates desired norms and behavior through newsletters and memoranda (R2, R13). These norms are not legally enforceable (D4, R13), but they are nonetheless argued to shape the supervision approach of the agency (R13). Several aviation companies, however, indicated that EASA inspectors can be inconsistent between cases. For instance, one company indicated, 'What is acceptable for (or even desired by) one EASA specialist in project X, is declared unacceptable by another specialist in project Y'.

ESMA officials furthermore indicated that they follow formally established supervision tools: 'In terms of tools that we use when it comes to investigations, [name R12.1] mentioned that this is more formal in a way. We are using powers that are entrusted directly to us by the regulation.' (R12.2, also R3, R10). However, ESMA often uses a combination of supervision tools, including informal discussions and negotiations (R9, R12.1).

Our analysis furthermore showed that EMA engages in limited informal discussions during supervision. There is frequent interaction with companies, but they take place through formal channels such as inspections, hearings, reports and dossiers (R1, R7, R8).

Supervision of the three agencies can thus be characterized as highly formal. There is some room to differentiate between companies, but this mostly follows formal guidelines and procedures. Nonetheless, there is still room for informal discussion and negotiation and for differences in approach from inspector to inspector.

Formalism in Enforcement

When it comes to making enforcement decisions, the level of formality is generally much lower and is focused on establishing compliance rather than blindly following legal requirements, although ESMA is an important exception.

EASA generally opts for a relatively informal enforcement approach (R2, R6, R13). An example of this is the sporadic use of EASA's formal appeals procedure; five cases throughout its existence (2002-present) (D5). One respondent indicated that formally appealing inspection decisions may harm the relationship built up with the inspector assigned to a company (R13) and another indicated that companies typically start resolving issues regardless of the formal inspection or appeal procedure (R6). This indicates that informal discussion and negotiations have an important role in EASA's enforcement practices. EASA communicates regularly with companies to solve cases of noncompliance. They interact regarding the exact formulation of the inspection finding, as well as the desired way the finding should be addressed (Written correspondence EASA).

[10]EASA relies on EC regulation 2019/897. See D25 for ESMA. Regarding EMA, regulatory officials indicate the abundance of formal legal requirements for (re)applying for a market authorization with different actors involved in the process (two committees with representatives of all member states (CHMP and PRAC) and the European Commission) that formally reapprove products (R1, R7, R8).

ESMA officials indicated that they decide to employ instruments to enhance compliance on a case-by-case basis (R12.1, R12.2). One official clarified that 'what we are focusing on is the outcome. If we see a concern or a problem, we want it to be fixed. And then on a case-by-case basis, we may use one or several tools to achieve that outcome.' (R12.2). Furthermore, ESMA considers issues caused by the complexity of regulation by engaging in informal discussions and employing mitigation plans to achieve compliance where possible (R12.1, R5).

EMA relies on scientific pharmaceutical knowledge beyond formal legal rules to establish its enforcement decisions (R1, R7, R8). This implies that professional judgement – beyond fulfilling legal requirements – is an important aspect in decision-making. One respondent remarked: 'the philosophy is not to catch people. The philosophy is to be reassured for public health that everything is running smoothly' (R7). Another observed, 'it is a scientific committee. We discuss scientific data, and we take our decisions based on medical scientific data' (R1). For example, EMA considers the availability of an alternative medicine when deciding to restrict market access for a certain product (R7, R8). If patients would suffer too much if a medicine is taken off the market without an alternative, a company gets more room to correct issues than if there would be an alternative (R7).

There are nonetheless formal elements in the enforcement practices of the agencies. For EASA, interaction occurs along the lines of formal procedures such as corrective action plans and establishing the exact formulation of an inspection finding in inspection reports.

Regulated entities, generally, describe ESMA's application of written enforcement procedures as rigid and consistent. When comparing it to the European Banking Agency, an industry representative indicated that as the sole supervisor for its sector, ESMA is more eager to demonstrate its formal strengths and powers in enforcement (R3). An ESMA representative similarly indicated that being consistent is important to the agency as it enhances its credibility as a supervisor (R12.1).

With respect to EMA, formal committee procedures are followed in establishing enforcement (R1, R7, R8). PRAC submits recommendations to one of two committees: the Committee for Medical Products for Human Use (CHMP) or the Coordination Group for Mutual Recognition and Decentralized Procedures – human (CMDh), for approval. The CHMP is responsible for medicines with an EU-level market authorization, whereas the CMDh enforces those with a member-state market authorization. The subsequent decision by the CHMP is forwarded to the European Commission, which decides whether to formally adopt it. Companies can (and have), furthermore apply for a formal re-evaluation of the PRAC decision if they disagree with it. These procedures are well documented on EMA's website (D24).

The most formal application of enforcement competences by EU agencies was found in ESMA's infringement procedure. When it encounters infringements regarding conflicts of interest, public disclosure of information, operational requirements, organizational requirements and obstruction of supervision[4], ESMA maintains a highly formalistic enforcement approach. When ESMA's supervision department has 'serious indications' that these infringements have been committed, the agency is legally compelled to initiate a formal procedure (R12, EU Regulation 1060/2009 art 23E). The procedure starts with the appointment of an Independent Investigating Officer (IIO), who assesses the infringement and submits a report with a recommended enforcement instrument to the Board of Supervisors. The latter decides whether and what enforcement instrument is employed.

Throughout the procedure, there are hearings, exchanges of information and the right for the regulated entity to respond. The agency's discretion of whether to impose a fine is limited (R10, R11, R12), as one ESMA official indicates: 'We have regulations that spell out everything clearly, we are bound by them. [...] So, I do not have any leeway.' (R10). In practice, the board of supervisors and the IIO have nonetheless come to different conclusions regarding negligence (see point 54, D21 and D22), which leads to different sanctioning implications within the agency's decision-making process.

In sum, our analysis shows that the agencies' enforcement practices are generally more informal than its supervision practices, especially in the context of product supervision. Nonetheless, there are several formal elements to it and ESMA's application of the infringement procedure is highly formal due to limited discretion.

The findings on each activity are summarized in Online Appendix V.

Discussion and Conclusion

In this study, we analyzed how EU agencies with direct enforcement powers apply their competences in practice. Based on the Eurolegalism thesis, deeper integration and the separation of powers at the EU level have paved the way for a more adversarial approach to supranational enforcement. However, supranational institutions may be reluctant to apply highly stringent measures against lawbreaking private actors because national regulators remain responsible for the implementation of most EU legislation. Our analysis distinguished between dimensions of formalism and coercion, and we applied these to the supervision and enforcement practices of the three EU agencies with furthest reaching enforcement powers: EASA, ESMA and EMA.

We find that all three agencies generally rely on formal and coercive procedures in their supervision practices. The analysis showed high intensity of monitoring product conformity (conducted by EMA and EASA). In the context of organizational supervision, the EU agencies apply targeted and risk-based approach, which is nevertheless enshrined in formal procedures. Contrastingly, we observe a less formal approach in enforcement decisions and more variation in the level of coercion that EU agencies employ when correcting noncompliance by private actors. While EASA and EMA are generally reluctant to impose coercive penalties against private actors, they do not shy away from applying more coercive measures in relation to nonconforming products (for example, revoking market access and withdrawing nonconforming products). Thus, we find support for the Eurolegalism thesis in the supervision practices of EU agencies, but not in their application of corrective measures against non-compliance. Instead, the enforcement style of EU agencies varies depending on the target of enforcement: organizational performance or product conformity. Based on our findings, EU agencies resemble a 'rule-bound' but non-punitive enforcement style in their interactions with specific companies. However, EU agencies seem to rely on more aggressive supervision and enforcement of (some) product irregularities. A clear exception is ESMA, which does not have the ability to withdraw products and imposes stringent financial penalties against regulated organizations. ESMA's more adversarial approach is largely due to the limited discretion of officials to negotiate mutually beneficial solutions with private actors. ESMA's punitive enforcement practices are also due to the context in which ESMA was established, namely as a measure to regulate financial markets more consistently and stringently after the

financial crisis of 2008 (van Rijsbergen and Scholten, 2017). This is different for EMA and EASA, which emerged more organically (Levi-Faur, 2011). Furthermore, the types of norms the agencies deal with differs from safety (EMA & EASA) to transparency and conflict of interest (ESMA). Sectorial differences likely affect regulatory style of EU agencies, which is an issue for future research to investigate.

Paradoxically, although ESMA has extensive formal powers to directly fine noncompliant national organizations, it is limited in its options to take enforcement decisions. This finding is in line with the assumptions behind the Eurolegalism thesis. According to Kelemen (2006), the proliferation and increasing transfer of formal competences to supranational regulators has prompted European legislators to limit the discretion of supranational agencies in order to avoid 'agency drift'. Furthermore, ESMA's lack of discretion could be partially attributed to high levels of legal uncertainty of its formal competences. The EU treaties are unclear about the delegation of enforcement powers to EU agencies and several court cases diminish the powers of EU agencies to take unilateral decisions about enforcement. This pressures EU agencies to strictly follow formal procedures to justify enforcement practices, that would be otherwise reversed. However, limited discretion in formal competences triggers a coercive response to non-compliance only in the case of ESMA. Future research should try to explain the varied EU agencies' responses to their formal competences. This is especially important because divergence in EU agency practices decreases the legitimacy of the EU, as a centralized and uniform enforcement system.

More generally, however, our findings cast doubt on the 'adversarial' nature of supranational enforcement by EU agencies (van Waarden, 2009). This is different from the US enforcement approach, which is more aggressive in terms of high reliance on litigation. It also diverges from recent studies of enforcement in EU member states, which find that national regulatory styles have converged toward both a more coercive and legalistic enforcement style due to European integration (Bastings *et al*., 2017). Conversely, our findings suggest that EU agencies are less punitive in their enforcement practices than their formal competences would allow. This implies that tendencies that EU agencies are increasingly delegated far-reaching, punitive enforcement powers (Scholten, 2017) and that the EU regulatory space will become increasingly centralized (Egeberg and Trondal, 2017), does not necessarily mean that EU enforcement becomes more punitive and adversarial. National regulatory traditions and member state influence, along with politicization of supranational enforcement may prevent this from happening.

Furthermore, the observed differences in enforcement practices between the three agencies have implications for studies of national enforcement styles. In particular, our study suggests that sectorial differences could become more important with the expansion of supranational agencies. Therefore, with a view to the increasing number of supranational enforcement actors, future research should explain differences in the enforcement practices of supranational institutions across varying dimensions of enforcement.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Supporting Information