

Theoretical Framework

Introduction

This project sets out to study the two facets of a ‘technocratic’ ERA: its internal operation and its autonomy from external influence. The main research questions have been outlined before:

How technocratic is the regulatory output of ERAs, and how is this assured?

In the introduction, we already identified two main sub-questions:

1. *How technocratic do ERAs operate internally (and how is this assured)?*
2. *How autonomous are ERAs from external influence (and how is this assured)?*

These questions identify the two main threats to the ‘technocratic operation’ of ERAs. Firstly, they might themselves consider non-scientific arguments in their decision making or apply expert knowledge strategically in order to pursue organizational or other self-interest. Secondly, they might be prone to external influence, potentially falling prey to capture (REF). As ‘network’ actors, both threats are particularly prominent with ERAs: Closely interacting with other scientific and non-scientific actors, ERAs rely on external input to regulate effectively. At the same time, these external actors enjoy direct access to the agencies, providing the precondition to exert influence. This makes ERAs particularly responsive to potential threats to their autonomy. As a consequence to the two threats to technocratic ERAs, the truth table suggests four potential behaviours of ERAs:

The External Dimension	The Internal Dimension		
		<i>Expertise-driven</i>	<i>‘interest-driven’/advocacy actor</i>
	<i>Autonomy</i>	Agencies behave like an epistemic community. They strive to fulfill their mandate (good regulation) by proper use of their expertise and are not ‘captured’ or otherwise influenced by external non-scientific interests.	Interest-driven behavior: agencies are just like another pressure group, but autonomous from others in the policy system under consideration. (‘ERAs are political actors in their own right’ (Moe))
	<i>Lack of autonomy</i>	Agencies act like agents (internal department): they develop their decisions using expertise, so their utility function is different from the one of the principals. But this utility function does not imply ‘output’ but is rather overturned by external influence.	De facto, agencies are not an actor distinct from others: we understand their behavior by looking at the utility function of the actor(s) in the policy system which induce their preferences into the agency.

Towards the end, the study will address a third question:

3. How influential are ERAs in the overall regulatory process?

The answer to this final question allows to evaluate the relevance of ERAs in the EU regulatory decision making. It allows to assess the importance of the answers provided to the main research questions.

This chapter now sets the theoretical/conceptual ground for the empirical analysis. The initial task of the study is to locate the behaviour of ERAs in this typology. A second (and perhaps more challenging) step aims to identify explanations for my findings, on both the internal and the external dimensions. In rough strokes, the framework covers three main areas: I. the internal behavior of ERAs; II. the influence of external actors on the agency output; and III. the role of ERAs in the regulatory system (making them prone to be influenced, but also to influence the regulatory decision making). All three areas are closely intertwined.

In the first empirical part of the dissertation (Chapter III), I model the internal behaviour of ERAs. Here, I make recourse to the concept of epistemic communities. If expertise ranks central in agency operation and if agencies apply this expert knowledge to promote their mandate, then they behave like epistemic communities. If they, to the contrary, use their expertise strategically to pursue organizational or other self-interest, they behave like advocacy actors. To explain the internal behavior of ERAs, I will refer to structural/organizational as well as professional arguments (Egeberg 2012, Bovens 2007).

To explain the autonomy of ERAs from external actors, expertise itself becomes an explanatory factor (Chapters IV and V). In a first step, I introduce the distinction between public ‘principals’ and ‘stakeholders’. While considering legal, organizational, and contextual explanations for agency autonomy, expertise forms the main focus of this study. If expert knowledge plays a central role in agency decision making, it might turn into a powerful means to protect and/or increase the autonomy of ERAs from external influence. This argument partly resembles claims from agency theory and provides an intuitive explanation for agency autonomy. Nevertheless, this link between the two operational cornerstones of ERAs – their expertise and their autonomy – has not received any research attention. To explain autonomy, other explanatory factors have been considered. And the scarce research on knowledge utilization has so far only shown that national regulators might apply their expertise quite strategically (Boswell 2008, Schrefler 2010, Radaelli 2009). What the effect of the different types of knowledge use on agency autonomy might be, however, remains in the dark.

In the last empirical chapter I focus on the policy influence of ERAs. The importance of this part derives from the simple question: What does the ‘technocratic’ operation of an ERA matter, if they are irrelevant in regulatory decision making at European level? Next to the legal framework, the finding can hopefully be explained by looking at the political salience of the regulatory work.

Main Part

Depoliticizing the Public – Technocratic Organizations

ERAs are said to be ‘technocratic’ actors. In the introduction, we started with the broad understanding of technocracy as the displacement of public preferences by the assessment of scientific experts in public decision making (Shapiro, Guston 2007). The term has gained significant traction as scholars and practitioners alike observe a trend of ‘depoliticizing the public’ – shifting ever more decision making competences to ‘technocratic’ expert bodies (Flinders, Buller 2006). Expertise and autonomy have been identified as the main operational cornerstones of ‘technocratic’ organizations: they ought to base their decisions on expertise rather than public preferences (REF); and their decision making ought to be autonomous from external influence (REF (Majone & co). Starting from this broad understanding of technocracy, this study relies on an analytically more nuanced definition. For any organization to be considered ‘technocratic’ it ought to conform to three central expectations:

1. *Expert knowledge is central in decision making*
2. *Expert knowledge is applied (instrumentally) to achieve its mandate*
3. *The organization’s decision making is autonomous from external non-scientific considerations*

Each of these three expectations is necessary and none is exclusively sufficient to render an organization ‘technocratic’. The expectations suggest that one cannot only study the role and application of expertise alone (points 1 & 2), or focus solely on the autonomy of ERAs (point 3). The concepts are closely intertwined empirically, analytically, and normatively and deserve a combined assessment. These three expectations neatly fold into the two sub-questions outlined above. While the first two expectations link to the internal operation of ERAs, the latter expectation refers to the autonomy of ERAs from external influence.

The Concept of Expertise – and what ‘Technocracy’ does NOT mean

At this point a disclaimer is required: The concept of ‘technocracy’ as applied here does in any way build upon an epistemological divide between the ‘objective’ scientific world and the ‘subjective’ world of politics. As has been argued elsewhere, these positivistic understandings of ‘neutral’ science (or ‘absolute’ autonomy) bodies falls short (Fischer 2009, Brown 2009). Contrary to the often ascribed status of science as “neutral, objective, and technically virtuous” (Shapiro, Guston 2007), neither science itself nor ‘technical expertise’ derived from it are objective social facts. As a consequence, expertise is inherently contested – scientifically and politically – and thus prone to challenges from both scientists and non-scientists.

A more sophisticated understanding of socially constructed expert knowledge, however, offers promising ways to make expert knowledge amenable to social science inquiry.

This, however, “mistakenly suggests the possibility of science advice that is entirely free of politics” (Brown 2009). Contrary to the often ascribed status of science as “neutral, objective, and technically virtuous” (Shapiro, Guston 2007), neither science itself nor ‘technical expertise’ derived from it are objective social facts. As a consequence, expertise is inherently contested – scientifically and politically – and thus prone to challenges from both scientists and non-scientists.

Expert knowledge

While expertise is commonly contrasted with lay knowledge, the specific boundary between those two bodies of knowledge is difficult to draw and cannot be universally established (REF (Guston 2000?)). Nevertheless, expertise builds on two defining features. Firstly, expertise – or expert knowledge – is held by ‘experts’ or professionals (Radaelli 2009). These experts dispose of certain professional qualifications (e.g. a PhD) as well as institutional affiliations. While they frequently work for research institutes, universities, or think tanks, they can also be employed by specialized government agencies. Regardless of their specific education or affiliation, experts are required to provide some ‘credentials’ (Boswell 2009). Secondly, expert knowledge is defined via its substantive claims: According to Schön, experts engage “in instrumental problem solving made rigorous by the application of scientific theory and technique.” ((Schön 1983): 21; see also: (Abbott 1988, Noordegraaf 2007)). Accordingly, one can distinguish a substantive and a procedural dimension of expertise. While substantive expert knowledge concerns the ‘content’ of scientific inquiry, procedural expert knowledge deals with the procedural standards of its application. This closely resembles the concept of ‘procedural rationality’ (Simon 1978).

While these substantive and procedural standards are not ‘objective’, they nevertheless impose substantive as well as procedural requirements on ‘research’, or ‘expert knowledge’ (Gieryn 1999:

2)” (Boswell 2009: 24). As Brown convincingly argues: “Science is constructed, but that does not mean that one cannot subject it to scrutiny regarding its reasoned arguments” (Brown 2009: 202).

This study follows this approach: Rather than adhering to objective standards, the study limits itself to study whether ERAs (are perceived to) adhere to the scientific standards set out in the founding regulations.

Experts form part of professional communities (Noordegraaf 2007: 767). In line with Haas’ work on epistemic communities, I here assume that experts in professional communities share a set of normative beliefs and a common policy enterprise, as well as causal beliefs and common notions of validity (Haas 1992: 3). Weible & Sabatier similarly speak of causal and deep core beliefs when defining their advocacy coalitions (Weible, Sabatier 2009). One can identify two levels of beliefs in both frameworks: A more abstract level of ‘normative’ (Haas) and ‘deep core’ beliefs (Sabatier), as well as a more applied set of ‘causal’ beliefs and notions of validity. When speaking of ‘expertise’, from now on I refer to these causal beliefs. While both levels of beliefs are shaped by social processes, the more abstract beliefs are considered to be rather constant over time.¹ Expertise – the causal beliefs – is more prone to change, potentially varying across actors, countries, and over time (Haas 1992; Ladeur 2006). Accordingly, controversies “can arise out of ‘honest philosophical differences’ (Jasanoff 1995) – even within rather homogeneous expert communities. This assumption is supported by empirical evidence from ‘prospect theory’, suggesting that experts rely on different heuristics to interpret the same scientific data (Levy 1997). “[R]egulatory science is particularly susceptible to divergent, socially conditioned interpretations [...] since standards for assessing quality tend to be more fluid, controversial, and subject to political considerations” (Jasanoff 1995). At the same time, as Haas suggests “[s]cience [only] remains influential if its expertise and claims are developed behind a politically insulated wall.” (Haas 2004).

➔ The Haas Quote indicates that one needs autonomy (normative discussion?)

➔ Mention that the design of ERAs is too simplistic since it suggests that they operate in an objective manner!

Normative Discussion HERE:

Why would we want technocratic bodies?

¹ These structural beliefs are partly enshrined into the agency design, and therewith lie beyond an individual agency’s competences. It might of course happen that activities referring to the core scientific work of the agency transcend into more general principled belief systems and policy goals. Since the design of this study does not properly allow covering the longer timespan to observe those changes, observations in this direction will only be elaborated on in passing.

I. The Internal Dimension

The first threat to ‘technocratic’ agencies: The Internal Operation of ERAs?

In line with the ‘technocratic’ expectations outlined above, this section studies the degree to which ERAs’ internal operation conforms to two criteria outlined above. Firstly, expert knowledge ought to rank central in their operation. Secondly, ERAs ought to apply this knowledge in a way that directly contributes to the achievement of their regulatory mandate – rather than pursuing organizational self-interest. This section assesses each criterion in turn.

As a preparatory step, I provide a descriptive framework to locate the ‘expertise’ within the organizational structure of ERAs. The second part then looks at the centrality of scientific expertise in agency decision making, and seeks to develop explanatory factors. This part focuses on the scientific committees. The third part elaborates on the different ‘applications’ of expertise, elaborating on the distinction between ‘instrumental’ and ‘strategic’ application of expert knowledge. That part will further draw on the concepts of epistemic communities and advocacy actors to conceptualize the behavior of ERAs.

i. Locating the Expertise

Secretariat & Committee Relationship

ERAs can be considered network organizations. As outlined above, they are composed of a secretariat, located at the agency headquarter, and scientific committees, convening sporadically. The Secretariats of ERAs are by design not expected to lead the scientific work, but can be seen as the ‘organizational backbone’ of an agency. ERAs entertain a wide array of formal and informal cooperation mechanisms to gather the crucial scientific expertise. The most strongly institutionalized ones are the ERAs’ scientific committees, who formulate the agencies’ scientific decisions. These committees are not composed of agency personnel. Rather, they are staffed by members of national competent authorities (NCAs) or research institutes. Since these external experts constitute ERAs’ central decision-making bodies, they become inherent part of the agencies themselves. This section looks into the actual relationship between the Secretariats and

the committees: First, I show how this bipartite structure affects the self-perception of agency members. Do they consider themselves a coherent organizational entity and construct their primary organizational identity via the agency? Findings might allow for conclusions regarding agencies' role in the so-called executive center formation (Egeberg, Trondal 2011). Second, I look into the working relationship between the two entities: Does the Secretariat stick to its supporting role formally prescribed, or does it scientifically engage with the Committees on eye-level, perhaps even influencing the committee decisions? This exploratory section considers various factors that might affect the relationship, i.e. whether the secretariat chairs the committee meetings, or simply acts as an observer. An additional point is the political salience of issues at hand: An increasing external interest (salience) might alter the collaboration between secretariat and committee.

i. Centrality of Expertise – the Committee Operation

The second part refers to the scientific committees themselves, who officially formulate the agency opinions. How closely do the committee members stick to the decision making criteria specified in their mandate and guidance documents? In the agencies under study here, these criteria are centrally the 'risks' and/or 'hazards' of substances or products, and their (medicinal, chemical, or nutritional) 'benefits'. These criteria are labeled 'scientific'/'technical'. 'Non-scientific' arguments potentially include economic or political interests, private cost-benefit calculations, and/or individual preferences.² As these non-scientific arguments are outside the regulatory mandate, their consideration in decision making limits the 'technocratic' character of decision making. Accordingly, it is crucial to study the degree to which the agency committees consider non-scientific arguments in their decision making. At first sight, ERAs conform to many criteria imposed on epistemic communities: they are composed of experts, these experts share the educational background, they entertain formal and informal relationships among themselves and to other scientists, and they feed their expert-advice into the EU decision making process (Cross 2012: 18). In fact, ERAs form an inherent part of the regulatory decision making in the EU. Next to the degree of non-scientific considerations, one needs to know the factors that seem to trigger/prevent these tendencies. Two factors receive particular attention here: 1. the committee design, and 2. professional accountability among experts.

1. The committee design crucially affects its heterogeneity with regard to scientific, organizational, and national backgrounds. Heterogeneity might increase the potential for scientific disagreement and contestation. Next to substantive claims, disputes might address test

² The one exception is ECHA SEAC, which ought to consider socio-economic aspects.

procedures, experiments, or methods of information gathering (Kjaer 2010) – or the weighting of these. However, the heterogeneity could also introduce non-scientific arguments into the decision making. The role of national competent authorities (NCAs) is of special interest here. NCAs form part of the national regulatory arena, often closely coordinating with their respective parent ministry. Frequently, their tasks involve risk management and therefore go beyond the risk assessment tasks in ERA committees. This tight **embedding** within the national regulatory arena might put NCA experts in ERA committees in an ambiguous situation. Given their socialization within the national debates, as well as an institutional attachment to certain positions within national debates, they might be prone to introduce their ‘political’ arguments or positions into committee discussions. While they might primarily identify themselves as ‘experts’, they are also government employees (Gornitzka, Sverdrup 2011, Brandsma 2010) . This second identity (government employee) might be strengthened if committee members act upon a ‘mandate’ from their national principal. They might become more explicitly ‘political’. If, to the contrary, the committees are composed of experts from research institutes, neither of these two expectations applies. I summarize my first expectation as follows:

E1: The involvement of NCA staff in the committee breaks path for national ‘interests’.

As outlined above, the three ERAs have differently designed committees and apply different recruitment mechanisms. At EMA, the committees are composed of experts affiliated with national regulatory agencies. For the main committees, every Member State *delegates* one expert to the committee. EFSA committees, to the contrary, are composed of experts of any organization. Potentially affiliated with national regulatory, EFSA committee members could hence also work for universities. As a consequence, not every member state is automatically ‘represented’ in the scientific committees. EFSA recruits committee members via an open call of application. One reason for this difference in committee composition as well as the recruitment mechanism can be found in the BSE and Dioxin crises, leading to the establishment of EFSA. While committee members from NCAs have until then been seen as ‘independent’ scientific experts, the BSE and dioxin crises have led to a change in perceptions: Rather than contributing to science-driven discussions, NCA experts began to be seen as agents of national interests (Demortain 2008: 9). ECHA, as the most recent agency, pursues a hybrid committee design: Whereas every MS delegates an expert to the agency’s main scientific committees (RAC & SEAC), these experts need not come from the respective national regulator. France could, for instance, ask a Spanish expert to participate in the Risk Assessment Committee on its behalf. For ECHA’s Member States Committee, the composition is more clearly based on member states representation.

2. This tendency towards ‘interests’ might be countered by a process of professional accountability (Bovens 2007). As Noordegraaf suggests, “professionalism is about control, or more precisely, institutionalized or disciplinary control of professional practices by professionals” (Noordegraaf 2007: 767). In other venues (comitology), scholars have already shown experts’ (at least partial) self-perception as ‘experts’ rather than delegates (Brandsma 2010, Trondal, Veggeland 2003}). Given the more technical nature of ERAs (as opposed to comitology), this perception seems stronger. In a study conducted among EU agency officials, Egeberg and Trondal report 78% of their respondents being highly concerned with professional/expert considerations (Egeberg & Trondal 2011: 877). In a similar survey study, Wonka and Rittberger report 86% of their respondents feeling accountable to professional standards (Wonka, Rittberger 2011) . This self-perception as ‘expert’ might stimulate the committee to abstain from non-scientific arguments. If one member introduces political or economic arguments into the scientific discussions, his peers will remind him of the non-scientific nature of these arguments. This leads to the second expectation:

E2: Professional accountability limits the relevance of ‘interests’ in the committees.

ii. Application of Expertise

But even if expert knowledge forms the central organizational resource (first criterion fulfilled), ERAs might not operate in a technocratic manner. Rather than pursuing their mandate, ERAs might pursue selfish organizational goals. In fact, a long tradition of organizational scholars argues that any other public organization pursues its own agenda, e.g. by securing organizational routines and norms (Weber 1946 (in West article)), organizational autonomy (Kaufman 1982, Groenleer 2009), or reputation (Carpenter 2010).

“Once an agency is created, the political world becomes a different place. Agency bureaucrats are now political actors in their own right: they have career and institutional interests that may not be entirely congruent with their formal missions, and they have powerful resources - expertise and delegated authority - that might be employed toward these "selfish" ends. They are new players whose interests and resources alter the political game.” ((Moe 1995): 143)

In line with these suggestions, ERAs might in fact might behave like an advocacy coalition. Advocacy coalitions, similar to epistemic communities, share beliefs and a policy enterprise. Also, expert knowledge can form a central resource in both communities. A central distinction between epistemic communities and advocacy coalitions can be seen in the *utilization* of expertise for their

respective policy enterprise. One can identify two broad categories of knowledge utilization: (a) instrumental; and (b) strategic.

The concept of instrumental knowledge utilization developed in a long tradition of rationalist accounts of the policy process (for an overview, see Boswell 2009). The main assumption is that public institutions rely on expert knowledge to improve their performance, be it regarding the mandate, to improve problem solving capacities, or simply to learn (Schrefler 2010: 315f). This instrumental use of expert resources resembles Schön's definition of expert work as "instrumental problem solving" ((Schön 1983): 21). It reflects a 'technocratic' style of policy making (Fischer 1990): "On this account, traditional ideological cleavages are no longer the major axis of political debate. Instead, governance has become increasingly technocratic, with debates typically revolving around the most efficient mechanisms for service delivery or the allocation of resources." (Boswell 2009: 6).

Recently, this instrumental account has been challenged by alternative types of knowledge utilization, most prominently introduced by scholars from Science and Technology Studies (REF einfügen: Weiss, Guston, etc.) (Schrefler 2010, Boswell 2008). These *strategic* uses of knowledge serve either political or substantiating goals (Schrefler 2010). The *political* use refers to the interests of the agency in the political arena, and might e.g. serve to secure its budget, autonomy, or reputation (Sabatier, Kaufmann, ...). The substantiating use is closely related to individual decisions, where knowledge is used "in order to justify and support a predetermined/preferred policy solution (Haas 2004: 573)" (Schrefler 2010: 315). In simple terms, strategic use hence describes a *non-instrumental* application of expertise.

In line with the established ideal-type dichotomy, epistemic communities develop their policy goals by applying the 'scientific logic' in an *instrumental* manner. This is in line with a 'technocratic' logic of operation. Advocacy coalitions, to the contrary, tend to apply expert knowledge *strategically* to pursue their organizational or policy-related goals. These goals, in turn, derive from ideological/interest-based considerations rather than scientific arguments (Cross 2012: 6; Weible & Sabatier 2009). Accordingly, advocacy actors deviate from a 'technocratic' operation.

While ERAs might thus come close to the 'technocratic ideal' of epistemic communities, it is easy to imagine them to shirk by applying their expertise strategically. In fact, the few empirical studies focusing on knowledge utilization in public agencies – albeit at national level – suggest that agencies indeed act strategically under certain circumstances (Boswell & Schrefler).

ERAs' use of knowledge is believed to depend on the regulatory context. In his seminal article, Gormley (Gormley 1986) identifies two relevant scope conditions: issue complexity and public salience. In line with Gormley, a "highly complex issue is one that raises factual questions that cannot be answered by generalists or lay persons" (Gormley 1986: 598). Given the overall highly technical nature of regulatory tasks, 'complexity' is assumed a constant in the context of ERAs.³ Public salience, however, might vary considerably within and across the regulatory fields. Salient issues here are considered to be ones with a broad scope and intensity of conflicts (Gormley 1986: 598). This can be either for economic or political reasons (see Heretier & Coen, WP). High salience correlates with the motivation of external actors to induce their interests onto the agency. When salience is low, an ERA can focus on its regulatory tasks, applying its expertise instrumentally. In 'politically competitive environments', however, expertise is used strategically (Radaelli 2009, Boswell 2008). The expectation reads:

Ex: While generally applying expertise instrumentally, high political salience triggers ERAs to behave more strategically.

To be clear, the strategic application of expertise is *not* per se negative. In fact, a strategic application of expertise in order to achieve scientifically derived goals might be quite desirable. In this vein, an ERA might use its resources to fence off external influence from political and economic interests alike. But if ERAs act strategically to pursue organizational goals that conflict with their scientific mandate, they turn into advocacy actors. Scientific arguments would lose centrality in ERA decision making, potentially undermining their expert authority and legitimacy.

³ For a convincing application of 'complexity' to explain knowledge utilization, please see: (Schrefler 2010).

II. The external Dimension – Threats on Agency Autonomy

Even if ERAs behave like epistemic communities internally and hence concord to the first two ‘technocratic’ standards, they can suffer from low autonomy by falling prey to the influence of external actors, and even to capture (REF).

Autonomy is a relational concept and essentially means whether and to what extent an agency is free from constraints by external actors. Analogue to the internal centrality of expertise, an agency is autonomous if its decision making is not influenced by external arguments that deviate from the decision making criteria specified in its mandate. Accordingly, an ERA is not required to operate in isolation. In fact, ERAs need external expert-advice to achieve their prescribed goals. They merely ought to prevent ‘biased information’ by individual actors and thus ‘capture’.

(a) Autonomy is commonly distinguished between legal, financial, personnel, as well as decision-making autonomy with regard to choosing policy instruments and/or setting policy goals (Verhoest, Peters et al. 2004).⁴ This study focuses on policy autonomy⁵, which is closely linked to the concept of ‘policy influence’. As Haas points out (Haas 2004), “the more autonomous science is from policy, the greater its potential influence”. Carpenter {{513 Carpenter, Daniel P. 2001, 5}} even argues that autonomy is quintessentially about “independent policymaking power”. Some authors have subsumed ‘influence’ as a sub-dimension of autonomy (REF (Kutsal, etc.)). This study, to the contrary, considers autonomy and influence as two separate concepts. Autonomy describes the degree to which an agency manages to prevent external influence on its own operation. Policy influence, to the contrary, refers to the influence that ERAs can wield over other actors/processes. Now focusing on agency autonomy, I will turn to policy influence in the last section of this theoretical framework.

I study two dimensions of policy autonomy: the (a) procedural autonomy of ERAs, and their (b) scientific autonomy. The procedural dimension refers to the interpretation, application, and modification of guidelines and procedures that lie within the formal competences of ERAs. One can identify three level of legal rules that guide the work of ERAs. 1. The general regulatory framework; 2. Agency-wide rules; and 3. Within-agency rules (e.g. committee specific). The table below provides an overview of the competences of ERAs in rule-making, as well as examples for each category (The boxes in green refer to rules within the competences of the agency, whereas the blue documents are beyond her formal reach).

⁴ One can also identify a normative dimension of autonomy as to why actors should (not) be autonomous. Positive manifestations of autonomy can be assessed against this normative benchmark.

⁵ This dimension of autonomy is believed to be most important when studying the technocratic operation of ERAs. The others, while potentially having a marginal effect, are rather negligible (REF!)

Level of Rule	EMA	EFSA	ECHA
<i>Beyond Agency (e.g. EU Regulation)</i>	Founding Regulation/ Directive (+ Amendments)	Founding Regulation (+ Amendments)	Founding Regulations/ Directives (REACH, CLP, Biocides, ...)
<i>Agency-level</i>	Access to documents policies, CoI-Policies, Stakeholder consultative mechanisms, Procurement Rules	Access to documents policies, CoI-Policies, Stakeholder consultative mechanisms, Procurement Rules	Access to documents policies, CoI-Policies, Stakeholder consultative mechanisms, Procurement Rules
<i>Committee-/Area-specific</i>	Committee rules of procedure, Standard Operating Procedures, Guidance Documents	Committee Working procedures, Guidance documents,	Committee Working procedures,

Procedural Competences of ERAs 1

All three ERAs are bound by their founding (Council) regulations, which have set up the agencies in the first place. Along with the regulations, some initial guidance documents and procedures have been introduced to the freshly created regulatory bodies. Within this broader regulatory framework, each ERA enjoys the formal capacity to interpret and modify these rules independently. In addition, each ERA can introduce new or additional guidances, rules of procedures, or policies that are in line with the broader regulatory requirements established by the founding regulations. An ERA is thus autonomous in practice, if it interprets these rules or introduces new ones regardless of other actors' views. If an ERA, however, simply adopted (e.g.) the Commission's or stakeholders' views, it would experience a low degree of autonomy.

The scientific autonomy of ERAs refers to formulation of the scientific opinions in the agency committees. These scientific opinions form the central agency output, are within the sole competence of the individual ERA, and should hence dispose a high degree of autonomy. At the same time, the scientific opinions are at least partly shaped by the regulatory rules. As these are partly established and applied by ERAs, procedural autonomy and scientific autonomy might be linked: a low procedural autonomy might seriously challenge the scientific autonomy of an ERA.

(d) formal and informal autonomy

Initially, autonomy has primarily been scrutinized regarding its formal characteristics. The real autonomy experienced by agencies during their operation, however, is not merely a function of its legal bases (Yesilkagit 2004, Groenleer 2009, Busuioc 2009). Legal documents determine the agency design at the time of its creation, t0. That, however, does not preclude autonomy from changing during an agency's operation, t1 (Carpenter 2001, Carpenter 2010). While formally sticking to the legal boundaries, in day-to-day practice agencies' autonomy often seems to

'deviate' from their legal foundations. As Carpenter indicates, the actual degree of autonomy an agency experiences in its day-to-day operation "is external to a contract and cannot be captured in a principal-agent relationship" (Carpenter 2001). This indicates the potential 'gap' between formal autonomy as granted by institutional design and de facto autonomy during agency operation (Groenleer 2009).

The European Regulatory Network

ERAs are "not designed to operate in isolation, nor to replace national regulators but enjoy **supreme nodality** at the centre of transnational regulatory networks" (Flinders 2004). In fact, enjoying a high centrality within these networks seems to be a precondition to become relevant (Maggetti 2009). Already by design ERAs hence entertain close links to a variety of external actors.

One can broadly distinguish between two types of external actors: 'technocratic' and advocacy actors. In line with the main assumptions tested in this project, 'technocratic' actors are assumed to behave like epistemic communities, deriving their goals from and operating according to the 'logic of science' (DAVIS CROSS 2012). These actors generally include technical agencies, research institutes and universities, as well as international standard setting bodies. Given their assumed 'technocratic' operation, these organizations might be able to contribute to the expertise of ERAs. At the same time, pose no harm to the autonomy of ERAs, since they operate in line with the same 'logic of science'.

Advocacy actors, however, are believed to pose an explicit threat to the autonomy of ERAs. As defined here, each advocacy actor strives to pursue his/her own goals. This is a more or less rational assumption (game theory, agency theory, ...? **Elaborate & REF!**)

One can identify two groups of advocacy actors dealing with ERAs. The political actors – namely the European Council (& the Member States), the European Parliament, and the European Commission – have formally established the ERAs. In line with delegation theory, these bodies can hence be considered the 'principals' of ERAs. While ERAs are legally independent organizational entities directing their own budgets and staff, these principals still enjoy some

oversight roles. Member States, the European Council and the European Parliament are limited to an observer status, except for the yearly budget discharge by the EP. The European Commission, however, has a variety of formal tasks regarding the ERAs. As the ‘guardian of the treaties’, it oversees whether ERAs comply with the requirements imposed on them in the EU legislation.

But they also touch upon the core tasks of ERAs. In the three policy fields under study here, the Commission takes the legally binding regulatory decisions in the EU, assisted e.g. by regulatory committee procedures. As a consequence, the Commission is the formal recipient of the scientific opinions of ERAs, and processes these during its own decision making process. In some agencies, it even formally receives the applications and dossiers by the applicants and merely forwards them to the respective agency (e.g. EFSA). It hence tasks the agencies to develop scientific opinions. Given the exposed role of the Commission as the central ‘principal’ of ERAs (and the presumably limited role of the other political actors), the empirical analysis will focus on the Commission.

Next to the political advocacy actors, one can identify two sets of private actors: industry companies (and federations), as well as non-governmental organizations (NGOs). As the regulated entities, industry plays a central role in the regulatory procedures: they submit product applications and dossiers to authorize substances. Similar to NGOs, they also provide additional information through public consultations and stakeholder meetings. At the same time, both industry and NGOs are limited to a role as ‘stakeholder’: they have no formal oversight or agenda setting powers over ERAs.

All external actors are assumed to pursue their own goals. In line with Sabatier, one can distinguish between ‘material’ actors – those striving for material (e.g. economic) goals – and ‘purposive’ groups, more committed to i.e. ideological convictions (Sabatier 1998): 116). Here, I assume that political actors such as the Commission as well as NGOs fall into the latter category, each pursuing its own ideological goals. Industrial companies and federations, to the contrary, are assumed to pursue their material interest.

As each advocacy actor pursues her own preferences, each one poses a potential threat to the autonomy of ERAs. In fact, many authors have shown that ERAs experience significant threats to their autonomy from public and private actors alike (REF). Accordingly, this study focuses on public and private ‘advocacy actors’ to study the autonomy of ERAs.

Explaining Autonomy (from advocacy actors)

Expert knowledge (and its application) is a precondition for ERAs to regulate effectively (Majone 1997). At the same time, I consider it the central explanatory factor for the autonomy of ERAs from the advocacy actors mentioned above. Surprisingly, this relationship between expertise and autonomy has not been explored to date. As outlined above, expertise research has limited itself to observe different applications of it. It has refrained, however, from linking this behaviour to autonomy. At the same time, autonomy research has disregarded expert resources when investigating the effects of organizational factors on agency autonomy (Egeberg 2012, Egeberg, Trondal 2011). Next to structural arguments (Egeberg 2012), an agency's demography seems to matter: here, socialization (Selden 1997)) and 'education' seem to be central (Suvarierol 2008). Groenleer (2009) argues that autonomy changes over time due to a process of 'institutionalization' (Groenleer 2009).

Despite these tentative insights from organizational theory, the field experiences a lack of research investigating the effects of organizational resources on actual decision behaviour (Egeberg 2012). This section aims to fill this gap by elaborating on the effects of expertise on autonomy. Next to its focus on expertise, other legal, organizational, and contextual factors to explain autonomy are taken into account.

Expertise

As outlined above, expert knowledge is understood as the central organizational resource. This resource contributes to agency autonomy in two ways. Most centrally, expert knowledge increases agency autonomy by establishing 'information asymmetries'. Additionally, (regulatory) expertise of ERAs enables them to engage in a process of 'procedural insulation'. This 'insulation' is believed to contribute to the scientific autonomy of ERAs. While expertise forms a necessary condition to enable ERAs to engage in insulation, this mechanism heavily relies on the formal rule-making competences of ERAs. Neither of these two mechanisms is universally applicable to both types of expertise and autonomy (scientific and procedural), nor do they address public actors and private stakeholders in the same way. Accordingly, I will establish a more nuanced reasoning below.

Information Asymmetries

ERAs have been established as ‘technocratic’ organizations that ought to pool substantive expert knowledge required for effective regulation. This expert knowledge might establish a classical ‘information asymmetry’ towards external actors. Such an asymmetry puts ERAs in a hegemonic position and reduces the ability of external actors to exert influence (Shapiro, Guston 2007). Even if it does not come to this theoretically appealing asymmetry, ERAs might nevertheless hold enough expert capacities to (a) question the arguments put forward by external actors, and to (b) develop counter-expertise where necessary. Accordingly, even where traditional information asymmetries do not materialize, ERAs might be in a position to fence off external influence. This mechanism applies to procedural autonomy as well as to scientific autonomy of ERAs. Whether (and towards whom) this asymmetry materializes in practice, however, depends on the dimension of expertise concerned.

Procedural Autonomy

Regarding the procedural autonomy, the procedural expertise of ERAs becomes central. In general, I expect that a legal information asymmetry emerges towards external actors that are not heavily involved in legal/regulatory issues in their day-to-day work. Industry as well as NGOs are believed to fall short in procedural expert knowledge. They are hampered to participate in the regulatory process on eye-level with ERAs. At the same time, ERAs are able to fence off their procedural choices by identifying flaws in the reasoning of private actors and developing counter arguments. This way, ERAs are believed to enjoy a rather high degree of autonomy from private actors.

E: ERAs enjoy high procedural autonomy towards private stakeholders (via inf. Asymmetries).

Towards the Commission, ERAs do not benefit from such an asymmetry. As the ‘guardian of the treaties’, the Commission ought to hold significant legal expertise. Moreover, the Commission acts as the ‘principal’ of the ERAs. It enjoys the competences to decide whether ERAs interpretations and modifications of rules and guidelines are in line with the expectations raised in the broader regulatory framework. This formal leverage is complemented by the vast experience of the Commission in applying the European regulatory framework. While ERAs might hold the expert knowledge to (a) question the legal arguments put forward by the Commission and potentially develop counter-expertise, they are nevertheless expected to be heavily influenced by the Commission in their regulatory decision making.

E: ERAs enjoy low procedural autonomy towards the commission.

- *Dealing with each facet of the regulatory process, ERAs moreover accumulate substantive regulatory ‘experience’.*
 - *To complicate the relationship to the Commission even further, ERAs might increase their autonomy over time as their regulatory experience increases.*

Scientific autonomy

Scientific information asymmetries towards external actors materialize in the opposite way.

Regarding the scientific autonomy from the Commission, ERAs are expected to benefit from a clear information asymmetry. *This assumption is supported by the most frequently proposed reason for agency creation, establishing a functional division between an agency and its principals.*

In its specialized area of operation, the agent develops superior expert knowledge (REF). Moreover, the Commission lacks the formal competence to assess the quality of the scientific work done by the agency (contrary to the legal decisions referred to above). Accordingly, ERAs ought to benefit from information asymmetries towards the Commission, enjoying a high degree of autonomy.

Regarding the expertise of private stakeholders, delegation theory becomes less vocal. The interest group literature suggests that – at least concerning industry – one cannot speak of a classical asymmetry. In fact, industry seems to hold major scientific expertise. This is partly rooted in the design of the regulatory system: It is the industrial companies that not only develop the products and substances – they also perform the scientific tests required by the regulatory system. Accordingly, they pool extensive scientific capacities. Holding high-quality expertise themselves, ERAs might nevertheless be in a position to (a) question scientific arguments put forward by industry and potentially develop counter-expertise. Moreover, an ERA can (b) identify and dismiss ‘non-scientific’ arguments that go beyond the decision making criteria specified in the agency regulations and guidelines.

Accordingly, I assume that the agency’s scientific expertise protects it effectively from external influence: towards the Commission, I expect to observe a clear information asymmetry. Towards private stakeholders, ERAs *merely* hold sufficient scientific resources to counter challenges by industry or NGOs.

E: ERAs enjoy high scientific autonomy towards the Commission (via inf. Asymmetries).

E: ERAs enjoy high scientific autonomy towards private actors (via ‘counter expertise’).

Procedural Insulation

In addition to these information asymmetries, ERAs can engage in a process of ‘procedural insulation’. This insulation builds on already existing extensive regulatory provisions as well as the (active) use of their legal expertise to interpret and modify the regulatory provisions over time. Based on the synthesis between a static regulatory framework and its active modification, this ‘insulation’ combines a legal and organizational element to explain autonomy.

As procedural insulation draws on rules and provisions, it primarily serves to explain the scientific autonomy of ERAs from private stakeholders. At the same time, however, a certain amount of procedural autonomy is required to successfully engage in procedural insulation. If ERAs did not have the autonomy to interpret and modify their rules autonomously, they could not apply them for the purpose of insulation.

The regulatory framework

From their outset, ERAs benefit from extensive regulatory provisions already established through the initial delegation contract. These provisions include the broader regulatory framework, the formal mandate of ERAs, and specific guidelines and procedures. These specify the required test methods, time frames for the assessment process, and regulate the interactions with external stakeholders. This static formal framework with its plethora of rules and procedures ought to restrict the behaviour of ERAs towards achieving their mandates. At the same time, however, the rules always bring about a certain discretionary space for the agency to interpret them (Gehring, Krapohl 2007, Huber, Shipan et al. 2001, Yatanagas 2001). It is this autonomy to interpret and modify rules that “is external to a contract and cannot be captured in a principal-agent relationship” (Carpenter 2010). In that sense, rules not only limit the behavioural choices of an agency; they simultaneously protect these very choices from external influence. As Kaufman explains: “What is red tape to one person may be a treasured procedural protection to another” ((Kaufman 2001): 34). This static protection of ERAs via the regulatory framework is far from novel. In fact, various scholars show that the agency mandate shapes the operational autonomy of ERAs to some degree (Yesilkagit 2004, Christensen, Laegreid 2007, van Thiel 2004). Overall, however, its effect on the operational autonomy of agencies seems limited (Egeberg, Trondal 2011). At the same time, the effects of more detailed rules and procedures on agency autonomy remain in the dark. In day-to-day operation, these are believed to provide ERAs with a substantive protection from external influence towards all external actors.

E: The static rules and procedures contribute to the scientific autonomy of ERAs from all external actors.

Active Insulation

But the regulatory framework is not limited to a static role. All rules require interpretations and many ask for modifications once an ERA has gained more experience in implementing the regulatory framework. What is more, within their formal competences established in the larger legal framework (set by the European Institutions), ERAs can develop entirely new rules to structure their operations. This dynamic view on the regulatory framework provides ERAs with significant ‘agency’ to shape the regulatory framework.

By interpreting and modifying existing rules and introducing new ones, ERAs can effectively raise procedural standards, limiting the access of external actors. Accordingly, external actors might lose their ability to exert influence on the agency. ‘Procedural insulation’ refers to this process of increasing scientific autonomy by raising procedural standards.

“Bureaucrats have various means of insulating themselves from these and other sources of political uncertainty. They can promote further professionalization and more extensive reliance on civil service. They can formalize and judicialize their decision procedures. They can base decisions on technical expertise, operational experience, and precedent, thus making it "objective" and agency-centered. They can try to monopolize the information necessary for effective political oversight.” (Moe 1995: 144f)

This active insulation is effective towards private stakeholders, as these are ‘regulated’.

E: Relying on regulatory expertise, ERAs increase their autonomy by raising procedural standards ('procedural insulation').

Towards the Commission, the mechanism loses relevance. As the ‘principal’ of the ERAs, the Commission enjoys the competence to decide whether the ERAs navigate the rules and procedures in line with the expectations raised towards them in the regulatory framework. This oversight role undermines the potential of procedural insulation towards the Commission. This argument further supports the above expectation that ERAs enjoy a limited procedural autonomy from the Commission.

This lack of procedural autonomy from the Commission does not necessarily undermine the effective use of the mechanism towards private stakeholders, though.

➔ Shared interest by Commission and ERAs might induce cooperation (to prevent litigation!)

- Make this part of insulation / make it an independent explanation? / leave it for the exploratory part...

‘Procedural Insulation’ can affect the autonomy in two different ways. As ‘technocratic’ actors, ERAs might adapt rules in an instrumental manner to improve the regulatory quality. In this vein, they could even provide stakeholders for more access to documents, or introduce novel platforms to exchange information. If this instrumental application of the legal framework increases agency autonomy, this effect is an ‘externality’ to the goal of good regulation. But ERAs could also act like advocacy actors, interpreting and modifying the rules strategically in order to promote their organizational self-interest (Boswell 2008, Schrefler 2010).

Non-Expertise-Based Explanations for Agency Autonomy

Next to the expertise based explanations outlined above, this study considers additional organizational as well as contextual explanations for agency autonomy. The organizational explanations refer to ‘organizational proximity’ as well as a ‘shadow of hierarchy’, whereas the contextual explanation refers to ‘political salience’.

a. Organizational Proximity

Next to expertise, the organizational proximity between ERAs and external actors is believed to affect the autonomy of ERAs. Organizational proximity describes actor interactions facilitated by formal and informal rules and routines of behaviour, potentially fostering cooperation (Knoben, Oerlemans 2006). Reflecting the amount as well as quality of contact, organizational proximity is closely related to the concept of ‘access’ to decision makers (Braun 2012). It includes the number of meetings, the formality/informality of these, etc.

In addition, proximity is increased via the phenomenon of ‘revolving doors’. If former employees from external actors start to work for ERAs, these external actors are expected to have a closer link to the respective agencies. The basic assumption is that the influence of any external actor on agency decision making increases with its proximity to ERAs. This argument applies to both

public and private actors, and former research suggests that it can be observed universally (REF). Literature **REVIEW** In theory, it moreover applies to procedural as well as scientific autonomy.

Industry and NGOs are considered to experience a rather high distance to ERAs. The application procedures as well as (public) consultative mechanisms seem highly formalized and limit the contact points between stakeholders and ERAs. At the same time, revolving doors between industry and ERAs seems a wide-spread phenomenon. Accordingly, this part abstains from formulating an explicit expectation, and limits itself to an exploration of the facets observed during the empirical analysis.

The study of the proximity between ERAs and the Commission requires two additional considerations. Firstly, the formal arrangements regarding the partner-DG differ sharply among the three ERAs under study here: EFSA has been linked to DG SANCO since its creation. EMA, to the contrary, has shifted towards DG Sanco in 2010. Before that, it dealt with DG Industry. ECHA is the only ERA having two ‘partner’-DGs: DG INDUSTRY and DG ENVIRONMENT. This variation in parent-DGs might directly affect the proximity of ERAs and Commission. Moreover, the partner-DGs might also vary in expertise, therewith altering the effect of expertise on autonomy.

This mechanism might affect both types of autonomy.

Secondly, ERAs operate under a ‘Shadow of Hierarchy’. While the procedural decisions considered here are formally taken by the ERAs themselves, the Commission still has the authority to decide whether these decisions are in line with the regulatory framework. In this vein, the Commission can also refer agency opinions back to the agency (referrals), if they seriously doubt their procedural integrity. This ‘shadow of hierarchy’ might have two consequences: ERAs are either very responsive to the interests of the Commission, or they even try to anticipate them. As this ‘shadow of hierarchy’ is limited to the procedural decision making of ERAs, the scientific autonomy might remain intact.

The empirical chapters will explore to what extent this general expectation holds.

- Revolving doors with Commission...

Political Salience

In addition to legal and organizational factors, the regulatory environment affects agency autonomy. One factor repeatedly put forward is the political salience of regulatory issues (Verhoest, Roness et al. 2010). As defined above, salient issues are the ones with a broad scope and intensity of conflicts (Gormley 1986: 598). This can be either for economic or political reasons (see Heretier & Coen, WP). Given the high stakes in salient issue areas, salience is believed to correlate with the intensity of external actors to induce their preferences into agency decision making. As a consequence to this increased external pressure, ERAs might lose scientific autonomy.

At the same time, however, the ‘agency’ of ERAs to adapt their behaviour might provide them with the leverage to counter these pressures. As outlined above, ERAs are expected to engage in strategic (rather than instrumental) behaviour more likely when political salience is high (Radaelli 2009, but see (Gormley 1986)). As outlined before, this strategic behaviour might well allow the ERAs to protect their autonomy. Accordingly, one can derive to rather contradictory expectations:

E: High political salience reduces the scientific autonomy of ERAs.

E: High political salience does not affect the scientific autonomy of ERAs, as these adapt their behaviour accordingly.

The focus on these mechanisms should not be seen as exhaustive. The partly exploratory empirical analysis might reveal additional ways in which either expertise affects autonomy or other factors might contribute to the latter. Moreover, the relationship between expertise and autonomy goes beyond a one-way causal link. In fact, both concepts are linked in an interdependence model: While expertise is hypothesized to increase autonomy, autonomy might also contribute to expertise (e.g. by increasing the ‘scientific’ reputation, attracting high-level scientists). This study restricts itself to the ways in which expertise affects autonomy.

III. The influence of ERAs

So far, the chapter has focused on whether ERAs provide the regulatory decision makers with their opinions as ‘technocratically’ as expected from their mandates. The primary focus laid on the internal operation as well as the procedural and scientific autonomy from external actors. But even if ERAs operate in a highly scientific matter, one crucial question remains: How influential is the scientific opinion of ERAs (and thus the ERAs themselves) in the regulatory decision making at EU level? While ERAs are mostly deprived of formal decision making powers, I will identify three elements that might shape the influence of ERAs: (a) the formal mandate of ERAs; (b) the organizational buy-in of regulatory decision makers; (c) the primacy of scientific arguments in the regulatory issue area.

(a) Firstly, the agency mandate plays an important role. Despite the lack of formal decision making powers, ERA opinions have to be considered during comitology. What is more, by relying on a ‘comply or explain’ mechanism, the legislation even imposes requirements if the policy maker wants to deviate from agency opinions (Orator 2010). Accordingly, my base-line expectation reads:

E1: Generally, ERAs experience a high degree of policy influence.

(b) Secondly, the organizational buy-in of political decision makers into the agency decision making is rendered relevant. In simple terms, ‘organizational buy-in’ refers to an actor’s degree of

involvement in agency decision making. Since these decision makers are Member States (in one way or another), I focus on the buy-in of these MS into agency decision making. The more strongly Member States (MS) are involved in the work of an ERA, the more difficult it is for them to deviate from the agency opinion during later comitology procedures. If MS ‘buy into’ the scientific agency opinion at an early stage, the influence of this opinion increases in the subsequent decision making.

Generally, all major ERAs provide a substantive buy-in for Member States: they form the regulatory ‘hub’ linking national competent authorities, ministries, and other stakeholders at various functional levels. Accordingly, coordination mechanisms are varied: Most management boards are (at least partly) composed of MS representatives. Various institutionalized fora facilitate managerial as well as technical exchange among National Competent Authorities (NCAs) and other public actors. Moreover, ERAs share implementation competences with national authorities, creating additional functional demands for coordination. This close coordination is believed to contribute to the ‘expert’-capacity of ERAs. At the same time, one can observe differences among the three ERAs under study here. Most centrally, the composition of the scientific committees differs (as shown in another Chapter of my PhD). While ECHA and EMA recruit their committee members from NCAs, EFSA contracts experts (officially) regardless of their institutional affiliation. Given this central difference between the agencies under study, the expectation regarding the organizational buy-in focuses on the scientific committees:

E2: A high MS buy-in into the committee decision making of ERAs increases the policy influence of ERAs.

(c) Thirdly, the political salience of the regulatory issue (area) might affect the influence of ERAs (for the original argument, please see (Gormley 1986)). Regulatory activities of ERAs can attract a high salience for various reasons. Firstly, they imply high economic stakes. For instance, the restriction of a chemical can incur substantive substitution costs on industry corporations. It could also affect the competitiveness of individual companies or entire industry sectors. Secondly, a regulatory action might touch upon political or ethical aspects, such as the general desirability of a certain product (e.g. GMO). While some examples might easily be sorted into either of these two categories, many activities appeal to both at least to some degree. In line with these two types of salience, salience is believed to correlate with the degree of lobbying activities.

The potential effect of political salience on policy influence can most easily be explained by

paraphrasing Shapiro and Morrall: the gaining weight of politics may ‘crowd out’ the relevance of science since decision makers are more concerned with being responsive to interest groups than to the results of ‘technical’ risk analyses ((Shapiro, Morrall III 2012): 196).⁶ Accordingly, under low political salience the technical opinion of ERAs is believed to be the main decision making criterion in the comitology process. High salience, to the contrary, might render this type of (scientific) information less central compared to other (political) arguments. A main expectation of this study hence reads:

E: High political salience reduces the policy influence of ERAs.

In fact, under salient circumstances scientific expertise might even be used strategically by other actors as an ex-post justification rather than as a substantive basis for decision making (Nutley 2007: 39).

➔ Analogue to the internal strategic behaviour above.

Building upon the first expectation that the mandate provides ERAs with a substantive degree of policy influence, the two additional mechanisms are displayed in the following truth table:

Organizational Buy-in	Political Salience		
		<i>Low</i>	<i>high</i>
	<i>low</i>	Medium/high policy influence A1	Low policy influence A2
	<i>high</i>	Very high policy influence	Rather low policy influence

⁶ Elsewhere, I show that ERAs strategically apply their expert resources to fence off increasing external (lobbying) pressure on their decision making. When talking about the committee system, however, ERAs lack this ability – and might simply lose their influence.

		A4	(slightly higher than A2) A3
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A Methodological Note – How can we tell?

The study compares three different ERAs ('cross-case'), but also engages in observing variation within each organization ('within case'). While providing a detailed understanding of each case, it also strives for external validity ((Gerring 2007): 20ff). The selected cases are the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), and the European Food Safety Authority (EFSA). All three agencies selected operate in highly technical regulatory fields, qualifying them as 'extreme' cases (Gerring 2007: 101). This reliance on highly technical cases also supports the analytical distinction between 'scientific' and 'non-scientific' arguments, which is most intuitively studied among these cases. Cases are selected based on a most-similar-system-design to control for most alternative explanations for agency autonomy: (a) all three ERAs operate in a similar environment (industry structure, stakeholder activities). (b) The ERAs hold similar mandates. (c) Explanatory factors linked to organizational structure are also controlled for (specialization, cooperation, size, budget, ...). Holding these factors constant, the ERAs differ in their degree of institutionalization, and they show variation regarding their types and application of expertise and experience.

The analysis is based on a variety of data sources including interviews and formal documents (COM decisions, agency regulations & guidelines, as well as scientific opinions). In total, 37 semi-structured interviews have been conducted: with agency officials, covering committee members, management and scientific staff working in the secretariats, and members of the management boards. In addition, I spoke with representatives from the Commission, the EP, industry groups, and NGOs. Interview data (analogue to survey data) potentially suffers from biased information, being prone to social desirability. In the context of this study, agency staff might hence have a tendency to overestimate their expertise and autonomy. In addition, interview data is inherently perceptual. While this is a prerequisite for some perceptual variables of interest, the potential downsides regarding other factors are controlled for as far as possible: Speaking to a variety of agency members as well as external stakeholders allows to (partly) control for a potential bias. By triangulating the interview data with official agency documents, a potential bias inherent in any interview data is believed to be accounted for.

The analysis is based on the structured ‘coding’ of the perceptual data.⁷ Interviewee statements referring to the relevant concepts and mechanisms are categorized according to a pre-established theme (where possible). (To give you an idea: the concepts of expertise and autonomy are each scaled ‘low’, ‘middle’, and ‘high’.) Primarily, the interview data provides narrative substance to assess my claims. Therefore, the analysis is heavily based on individual quotes of agency staff or external actors closely involved into the aspect under scrutiny. In addition, the structured coding allows for some (tentative) correlational observations. These complement the narrative.

⁷ Accordingly, autonomy is not measured by defining actor preferences and comparing these preferences with the final decision output.

Chapter II – Theoretical Framework

- I. Theoretical framework (incl. literature review as benchmark) 10.000 words**
1. Theoretical approach
 - i. General reliance on organizational and delegation theory
 - ii. Definition of concepts accordingly (expertise (demographic factor & org. resource); autonomy; policy influence; political salience)
 2. Technocratic logic of operations ('scientific rules' & Autonomy) derives from the (here assumed) rationale for agency creation. Short discourse on why this logic might be threatened (high stakes, diverging interests) and the preconditions for this (access to agency).
 3. How is it assured that ERAs nevertheless provide expert-based advice?
 - Internal dimension:
 - Org. theory: structure (e.g. committee design) & Demography
 - External Dimension
 - Delegation & org. theory: asymmetries; rules (inherent to delegation) provide discretion (-> autonomy)

➔ *Both dimensions refer to agency behaviour and therefore explicitly rely on the notion of instrumental & strategic behaviour*

 - Policy Influence
 - Centrality of technical knowledge in decision making -> Salience dependency of policy influence (theoretical underpinning?)

➔ *Limitation of my focus: Even if ERAs operate scientifically and autonomously according to their mandate (my focus), their setup already incorporates certain (non-neutral) regulatory frames.*

➔ *Always be explicit where I am 'deductive' and where I am open to explore... (e.g. internal dimension more deductive than later ones)*

Definition of politicization:

Neither conflict nor power -> unpolitical

Conflict but no power -> unpolitical

The latter might be present in scientific committees:

“it allows one to see how science is not political. When conflicts of opinions on a science advisory committee are amicably resolved through fair and open discussion, and when none of the participants is able to impose his or her view through exercising power, such conflicts are probably best deemed nonpolitical. Voting on science advisory committees, in contrast, amounts

to the political resolution of conflicts through the equal distribution of power.” (Brown 2009: 190f)

Given their tight involvement in the so-called regulatory networks, ERAs are an extreme case when studying the link between expertise and autonomy. On the one hand, the network, which includes many expert organizations, gives ERAs access to the crucial ‘policy good’ of information (BRAUN 2012) and contributes to the expertise of ERAs (Thatcher, Coen 2008).

As the mandates specify this for the three agencies under study here:

“In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. “ (EMA Regulation 726: page 4: “Whereas: 14”)

“In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.” (EFSA Regulation 178/2002: “whereas 18”).

Normative discussion here?

They derive their authority from this expertise-driven behaviour.

➔ *Overview on discussion (-> Eriksen has a nice summary)*

While this study focuses on the empirical side of expertise, findings obviously speak to the normative debate.

Normative Discussion

➔ *Why should we (not?) have autonomous expert bodies?!*

Next to its empirical relevance, expertise forms the linchpin to assess the legitimacy of ERAs. As outlined above,

While ERAs are widely expected to operate autonomously from 'undue' external influence, they should not be 'on the loose'. "To the extent that public challenges to expert claims receive an adequate response, such challenges may actually strengthen expert authority. Conversely, insulating experts from public accountability is likely to eventually undermine their authority." (Brown: 2009, 217)

