The division of labour in the practice of scientific advice to policy in the European Union

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‘I, Alessandro Allegra confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.'

Abstract

Scientific advice to policymaking plays a central role in modern techno-scientific societies, informing and legitimizing policymaking. Yet its appropriate role and how to institutionalize it remains problematic, with a fundamental tension existing between its appeal to scientific authority and the neutrality of science, and the need for policy relevance and democratic accountability. Studies of scientific advice have demonstrated that it is both an epistemic and a political activity, and its effectiveness rests on carefully constructing and managing the boundary between science and policymaking. However, scholarly attention has mostly focused on institutional structures. Based on personal experience of working in scientific advice in the European Union and following the "practice turn" in policy studies, this thesis proposes to go beyond organisational features of advisory mechanisms to explores the practices used in the construction of scientific advice.

The thesis combines document analysis, interviews, and autoethnographic observation to explore the micro-dynamics and practices of expert advice in two detailed case studies of scientific advice in the context of European Union (EU) policymaking, namely the European Food Safety Authority (EFSA) and the European Commission's Scientific Advice Mechanism (SAM). This analysis shows how, despite their near-invisibility in the frontstage of the scientific advisory process and in its outputs, secretariats have substantial influence in its construction. In particular, it argues that in the context of EU scientific advisory committees, whose members are mostly drawn from laboratory science and lend scientific credibility and political legitimacy to the advisory process through their independence from policy, secretariats play a key and necessary role in ensuring policy relevance. The division of labour between advisors and secretariat is therefore interpreted as an important boundary management strategy to ensure the effectiveness of advisory mechanisms.

Impact statement

The work described in this thesis has relevance for both the scholarly debate on scientific advice to policy, and for policy practice itself. On the scholarly side, it contributes to the emergent "science of science advice" by further expanding existing theories (the CRELE framework and the concepts of boundary organisations and boundary management), applying them beyond institutional design features to investigate advisory practices. It also provides an empirically novel account of an important but yet understudied organization, the European Commission's Scientific Advice Mechanism (SAM).

On the policy side, as discussed in the conclusion this thesis offers some important considerations on what needs to be taken into account to design and institutionalize more effective scientific advice mechanisms in the EU, by giving due attention to the role of secretariats and of the policymaking context and culture in which they operate. By recognizing the importance of a division of labour between advisors and their secretariat for the effectiveness of the advice, the conclusions of this thesis provide a strong argument in favour of increasing the professionalization of scientific advice and the creation of dedicated professional roles for science advice secretariats.

The knowledge and expertise acquired through this research has direct impact on EU policymaking by informing my current work in the European Commission, where insights from this research on the determinants of effective scientific advisory mechanisms are currently informing my work on conceptualizing future scientific advisory arrangements at the Commission, as well as a separate project on how to strengthen and better connect scientific advice ecosystems in Europe. This allows me to act as a reflexive practitioner and directly bridge between scholarly work and policy practice to ensure applicability and impact. Furthermore, I am planning to disseminate my research results and the insights gained about scientific advice mechanisms and the role that secretariat play in them through internal seminars to relevant science advice practitioners, including staff from the SAM, EU advisory agencies and from the Commission's Joint Research Centre.

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1. Introduction: Rationale and relevance of the thesis

1.1. Scientific advice in contemporary societies

Science plays an important role in informing policymaking on a wide range of issues, ranging from healthcare to climate change to the regulation of new technologies. In recent years, there has been growing recognition of the importance of scientific advice to policymaking from both policymakers and scholars. Although science plays an increasingly important role in all areas of policy (OECD 2015), the provision of effective scientific advice remains challenging (Gluckman 2014). Scientists can play multiple and sometimes controversial roles in policymaking (Pielke 2007), spanning from 'honest brokers' to advocates, and the issues they are called to deal with often pertain to what has been referred to as *'post-normal science'*: where *"facts are uncertain, values in dispute, stakes high and decisions urgent"* (Funtowicz and Ravetz 1993: 744). This makes the provision and institutionalisation of effective scientific advice an ongoing challenge. The appropriate role of scientific advice in democratic societies, and how to best institutionalize it remains problematic, with a fundamental tension existing between its appeal to scientific authority and the neutrality of science, and the need for policy relevance and democratic accountability (Pamuk 2021).

The explosion of the COVID-19 pandemic in 2020 and the ensuing scramble by governments worldwide to contain and combat it threw scientific advice in the spotlight, and put to test many of the assumptions and frameworks developed to understand the science-policy interface. The crisis has thrown in sharp relief the many unresolved issues at the interface between science and policymaking, and the inadequacy in most countries of the scientific advice institutions working at this interface. Countries with existing and well-developed scientific advisory mechanisms, such as the UK with its SAGE (Scientific Advisory Group for Emergencies), found them being stress-tested to a degree never seen before. Others such as Italy, where such mechanisms were not clearly institutionalized before, had to quickly create and scale up them. Anecdotal evidence even suggests the hypothesis that pre-existing scientific

advisory structures might have constrained and limited the flexibility needed to respond to the pandemic.[1]

According to many scholars and commentators (The Lancet 2020), COVID-19 was probably the biggest test of science advice in decades, with its global nature allowing for large-scale international comparison. The rapid deployment and evolution of scientific advice mechanisms, and the intense public attention and scrutiny they received in many countries, revealed many of the unspoken assumptions underpinning the functioning of the science-policy interface in most countries. The legitimacy of decisions taken on the basis of expert advice has been challenged in many countries, and the inner workings of scientific knowledge productions have been dissected publicly, with scientific uncertainties debated in the media and accusations being made of both science being politicized and politics hiding behind the science. These examples highlight the need for a better understanding of how science, policy and politics interact in the practice of scientific advice, and how scientific advice achieves political and scientific legitimacy.

These concerns are particularly prominent in the context of European Union (EU) policymaking, in which scientific expertise and advice play a central role. As discussed in chapter 4, despite the efforts put into the institutionalization of the EU scientific advice ecosystem, the provision of scientific advice to EU policy remains fragmented at an institutional level. To this day, the provision of scientific advice to EU institutions remains a crucial and contested issue.

1.2. Focus of this thesis

The central problem addressed by this thesis is to explore what determines the effectiveness of scientific advisory mechanism, and how such knowledge can be used to design and institutionalize better ones, with a specific focus on the context of EU policymaking. Studies of scientific advice have demonstrated that it is both an epistemic and a political activity (Jasanoff 1990), and its

[1] See note of the 2020 meeting of the European Science Advisor Forum (ESAF) https://esaforum.eu/wp-content/uploads/2020/07/Highlights-Virtual-ESAF-Meeting-24-june-2020.pdf

effectiveness rests on carefully constructing and managing the boundary between science and policymaking (Cash et al. 2002; Bijker, Bal, and Hendriks 2009; Owens 2015). To be effective, scientific advice needs to combine scientific credibility, policy relevance, and political legitimacy (CRELE) (Cash et al. 2002).

Scholarly attention has mostly focused on institutional features of scientific advisory mechanisms, and/or on the role played by scientific advisors and members of advisory committees. However, empirical studies of the science-policy interface have demonstrated that effective mobilisation of scientific knowledge in policymaking requires individuals able to work and communicate across the boundaries between these different domains (Cash et al. 2003), in order to facilitate co-production (Jasanoff 2004a) and uptake of relevant knowledge. Based on personal experience of working in scientific advice and following the "practice turn" in policy studies (Freeman, Griggs, and Boaz 2011), this thesis explores what determines the effectiveness of scientific advice mechanism *in practice*. Specifically, the thesis addresses the question of how CRELE is constructed in the practice of scientific advice.

As discussed in Chapter 3, this thesis focuses on scientific advice in the context of EU policymaking, both because scientific advice plays a central role there, and because of the direct and unique access I have to its inner working and practices. In particular, the thesis combines document analysis, interviews, and auto-ethnographic observation to explore the micro-dynamics and practices of scientific advice in two case studies of the work scientific advisory bodies in the context European Union (EU) policymaking, namely the European Food Safety Authority (EFSA) and the Scientific Advice Mechanism (SAM).

This analysis shows how, despite their near-invisibility in the frontstage (Hilgartner 2000) of the scientific advisory process and in its outputs, secretariats have substantial influence in its construction. In particular, it argues that in the context of EU scientific advisory committees, whose members are mostly drawn from laboratory science and lend scientific Credibility and political

Legitimacy to the advisory process through their independence from policy, secretariats play a key and necessary role in ensuring policy Relevance. The division of labour between advisors and secretariat is therefore interpreted as an important boundary management strategy to ensure the effectiveness of advisory mechanisms.

1.3. Knowledge gaps: the need for a "science of science advice"

On the scholarly side, the broad themes of expertise and the science-policy interface have received extensive attention from multiple disciplines. Attention to researching scientific advice has been developing since the 1990s (Spruijt et al. 2014), and in recent years a number of essay collections and special issues have provided a focal point for research in the field (Lentsch and Weingart 2011; Doubleday and Wilsdon 2013; Wilsdon and Doubleday 2015; Gluckman and Wilsdon 2016).

However, it is acknowledged that the practice and theory of scientific advice as such have not yet received adequate treatment (Owens, in Lentsch and Weingart 2011). Scientific advisory systems and networks have been identified as a priority topic for further research in a science policy research agenda developed by Sutherland et al. (2012) after extensive consultation with scholars and experts in the field. Specific questions identified by Sutherland et al. (2012) include:

- *"Which commissioning and operational arrangements lead to the most effective use of science in policymaking?"*
- *"What are the consequences of different approaches to institutionalising, professionalising, and building capacity in the exchange of knowledge between science and policy?"*
- *"What factors (for example, openness, accountability, credibility) influence the degree to which the public accept as trustworthy an expert providing advice?"*
- *"What governance processes and enabling conditions are needed to ensure that policymaking is scientifically credible, while addressing a*

perceived societal preference for policy processes that are more democratic than technocratic?"

In what can be interpreted as a reflexive turn in science policy, the US government research funding agency, the National Science Foundation, has since 2005 been promoting and supporting the development of a *"science of science policy"*, a rigorous understanding of what works in terms of the funding, management, and utilisation of research (Marburger 2005). In a similar vein, Sheila Jasanoff (in Doubleday and Wilsdon 2013) called for the development of a *"science of science advice"*, grounded in the social sciences and particularly in the field of science and technology studies (STS). In the same essays collection, Geoff Mulgan admits that *"the science of scientific advice is [currently] patchy"* and highlights the need to learn more systematically from existing research and practice *"on why certain kinds of knowledge and advice are acted on, and others are not"* (ibidem: 33).

While for Mulgan the key issue at stake is effectiveness and relevance of scientific advice, for Jasanoff it is democratic accountability. If the role of scientific advice is to hold politicians and policymakers to high standards of evidence and reason, who ensures the integrity and rationality of science advisers? In her words: *"if judges may not presume to stand above the law, still less should science advisers seek to insulate themselves from the critical gaze of the sciences of science advice"* (in Doubleday and Wilsdon 2013:12). Her suggestion is that the academic field of Science and Technology Studies (STS), with its insights into the internal and external dynamics of policy-relevant scientific production, can play a valuable critical role in scrutinising and strengthening scientific advice to policy. This programmatic statement is the inspiration and the starting point for the research work proposed in this thesis.

1.4. Structure of the thesis

The thesis is structured in seven chapters. This first chapter provides an introductory overview of the rationale and context for the study of scientific advice to policy making, and a discussion of the specific approach and research

question. Chapter 2 comprises a review of the relevant literature to develop a conceptual and analytical framework to understand scientific advice in theory and practice. Chapter 3 discusses the central role of scientific advice in EU policymaking and provides the rationale and background for the specific case studies selected for the thesis. Chapter 4 discusses the methodological approach adopted to conduct the research, namely the focus on practices and case studies, and the use of documents, interviews, and auto-ethnography. Chapters 5 and 6 zoom in into two detailed case studies of the working of EU scientific advisory bodies, focusing respectively on the European Food Safety Authority (EFSA) and the European Commission's Scientific Advice Mechanism (SAM). Finally, Chapters 7 draws conclusions and key learnings from the analysis of the case studies, discusses their limitations, and presents some considerations for future research and policy practice.

2. Literature review and theoretical framework

2.1. Introduction

To explore the determinants of effective scientific advice in the context of EU policymaking it is important to broadly understand what scientific advice is, what role it plays in policymaking, how it is practiced and institutionalized, and what factors account for its authority and impact. As a practice at the intersection between science and policy, scientific advice can and has been approached from multiple disciplinary perspectives, and extensive literature exists on the science-policy interface. Although the labels ‘science advice’ and ‘scientific advice’ are commonly used in both the academic and policy literatures, research self-identifying as focused on scientific advice represents only a part of the complex landscape of research that can contribute to the understanding of the phenomenon. This chapter presents an overview of some of the key concepts useful to understand the dynamics of scientific advice and address the key question of the thesis, and proposes a theoretical framework to address the main research questions.

Section 2.2 introduce some key concepts from the social studies of science and technology (STS) exploring how scientific knowledge is socially constructed, and how it is differentiated from other forms of knowledge and social domains such as policy through boundary work. Section 2.3 discusses the main theories of the role of science in policymaking, while sections 2.4, 2.5 and 2.6 present a definition and conceptualization of scientific advice and its effectiveness. Section 2.7 draws insights from the policy studies literature to explore the challenges of ensuring the policy relevance of scientific advice, and section 2.8 discusses the importance of looking beyond organizational aspects to study practices and the specific role of secretariats. Finally, section 2.9 draws conclusions from the literature and its main limitations, uses the concepts presented in the rest of the chapter to outline a theoretical framework for the study presented in this thesis, and reframes the initial question in theoretical terms providing a further refinement of the research questions.

2.2. Science as a social activity

2.2.1. The construction of scientific knowledge

Science and technology are a constituent and inextricable part of the contemporary world (Beck 1992). Yet, disputes about the proper role of science in policymaking are common, and a tension appears to exist between the traditional image of a disinterested knowledge-pursuing activity and the active role that science is called to play in the contemporary world. This underlying tension has surfaced in the latter part of the 20th century in light of the expansion of both the capability of science to shape the world we live in, and of the remit of the state (Jasanoff 1987; Lentsch and Weingart 2011). To understand the interface between science and policy, and this apparent tension, it is important to consider some key insights into the process of production, validation, and usage of scientific knowledge. The fields of philosophy of science and the social studies of science and technology, also referred to as science and technology studies (STS), offer a rich literature of empirical and theoretical work exploring these dimensions.

Scientific knowledge is, by its own nature, limited and uncertain. It is well established in the philosophy of science that empirical observation of a finite number of phenomena (often referred to as “empirical facts” or simply “facts”) does not logically guarantee the validity of general statements (“explanations” or “theories”). This is known as the problem of induction (Popper 1962). Moreover, from a logical point of view, multiple incompatible explanations are always possible for any given set of observed phenomena, and empirical considerations alone cannot determine the choice between competing explanations. This is known as the Duhem-Quine thesis, or underdetermination problem (Quine 1951).

The implication of this is that extra-empirical factors and non-factual (and therefore value-based) judgements are always required to accept or reject the validity of a scientific claim. These include for example conformity with existing knowledge and higher-level theories, criteria of simplicity, sociological factors,

and considerations of the aim for which explanation is being sought (Douglas 2009). The appropriate role and weight of these different factors is a central and debated issue in the study of scientific knowledge. Yet, discussion of science, and especially of its role in policymaking and scientific advice, often maintain that scientific knowledge is in some way “objective”, i.e., based on empirical grounds alone, with values having no place in its production, in contraposition to other activities such as politics.

Douglas (2009) traces this often-held conception that science should be separated from social and political considerations (referred to as the “value-free ideal”) to a dominant current in modern philosophy of science focusing exclusively on the internal logic of science (context of justification), divorcing science from its practice and social context. In her analysis, such a separation rests on a misunderstanding of the role that values play in scientific practice. She argues that a legitimate place for values exists in science that does not undermine its legitimacy, especially in policy settings. Recognising this role that values can play in science is important to properly frame discussions of scientific advice and will require the introduction of some concepts originating from the social studies of science.

While philosophical approaches have attempted to explain scientific activity in purely rational terms, limiting the role of ‘external’ social factors to explaining errors and deviances, the sociology of scientific knowledge (SSK) advocates that social factors can explain not only the context but also the content of science, both its successes and its failures. The scholarly tradition initiated by so-called “strong programme” in the sociology of knowledge (Bloor 1976) has attempted to shed light on the problems discussed above by approaching not only the practice of science, but also the knowledge it generates, as a social phenomenon to be explained empirically, rather than as a purely rational exercise. Employing historical, sociological and ethnographic approaches, several authors have explored what scientists do when producing scientific knowledge, and what dynamics are at play in the establishment of scientific claims (Sismondo 2004).

In their seminal ethnographic study of laboratory life for example, Bruno Latour and Steve Woolgar (1979) examine how scientists approach the production of scientific knowledge in their daily practices, and how they move from the observation of individual phenomena to general statements about nature, eventually published in the form of scientific papers. As no amount of empirical observation alone can unequivocally establishing a general statement, and to establish what counts as evidence for a claim requires a judgement of its relevance, in Latour's account establishing a claim as a scientific fact means convincing oneself and others of its validity. This is done by creating a network of associations between previously established claims, data from experimental apparatus, and individual's credibility, to support the claim. In Latour's words, therefore, scientific claims are socially constructed. Similar conclusions are reached by other authors such as Knorr-Cetina (1981) using similar methods of empirical observation of scientific practice.

A judgement on the reliability of each element of the network, and its relation to the others, is needed to accept a scientific claim. In the same way, claims can also be challenged by attacking the network of associations that are invoked to support them (Latour 1987). This deconstruction happens both in purely scientific controversies, and in political controversies involving disputed scientific evidence and knowledge (Jasanoff 1990). Establishing who has the authority to make and challenge such judgements in a given context, therefore, becomes crucial to establish or challenge the validity of scientific claims, and thus the credibility of any policy advice based on them. This reveals science as an intrinsically social and political activity and blurs the distinction between truth and power. As remarked by Collins and Evans (2002), the key insight from the sociology of scientific knowledge is that establishment of scientific truths requires political work, as well as scientific work. This insight is particularly important for the study of scientific advice to policymaking, as it calls into question the separation between the domains of science and policy on which its traditional image rests.

2.2.2. Establishing the authority of science in society

Acknowledging the socially constructed and political nature of scientific knowledge thus requires establishing criteria to distinguish it from other forms of knowledge, and to distinguish science from other social domains such as the political sphere. The concept of epistemic (or cognitive) authority*, "the legitimate power to define, describe, and explain bounded domains of reality"* (Gieryn 1999:1), proves important to understand both the internal dynamics of knowledge-making in science, and its standing in society and policy. Attempts to explain and justify the epistemic authority of science have come from several perspectives. Providing epistemological criteria to distinguish (or "demarcate") science from other intellectual activities has been a key problem of 20th century philosophy of science (Popper 1962), to which different school of thought have proposed different solutions based on some intrinsic feature of the scientific method. Early sociologists of scientific knowledge, such as Robert Merton (1973 [1942]) have instead appealed to some universal sociological features (norms) of the organisation of scientific enquiry.

Yet, as recognised by sociologist Thomas Gieryn (1999), such essentialists approaches have failed to provide a satisfactory explanation for the epistemic authority of science, especially given that what appears epistemologically intractable (demarcating science from non-science) is actually done daily by scientists, for example when deciding what to fund and what to include in educational curricula. For Gieryn (in Jasanoff et al. 1995: 405), the *"task of demarcating science and non-science is reassigned from analysts to people in society, and... focuses on episodes of 'boundary-work' [which] occurs as people contend for, legitimate, or challenge the authority of science - and the credibility, prestige, power, and material resources that attend such a privileged position."* In a seminal paper analysing a number of historical cases, Gieryn (1983) shows how demarcation is achieved in practice by the mobilisation of rhetorical resources to establish a boundary between science and non-science, by attributing to it a number of distinguishing features. Such "boundary work" allows a group or individual to establish its cognitive authority to assert their claims.

Therefore, epistemic authority is the result of successful boundary work, not a cause (Gieryn 1995). Rather than an essentialist explanation of the epistemic authority of science, a constructivist one is provided. Crucially, boundary work is a dynamic process: boundaries require maintenance and are redrawn continuously. In (Gieryn 1983:792) *"The boundaries of science are ambiguous, flexible, historically changing, contextually variable, internally inconsistent, and sometimes disputed".* A useful further elaboration of the concept of boundary work, based on work by Shapin (1992), is proposed by Halffman (2003, quoted in Hoppe 2005:206), who recognizes it as consisting of both excluding unwanted participants and interference (demarcation), and of making interactions across boundaries possible (coordination).

The dynamics of boundary work apply not only in disputes between the authority of science and religion, or within science between competing approaches and explanations, but also in the policy domain to establish the proper role of science in it (Jasanoff 1990). As recognised by Hoppe (2005: 205) *"one domain in which scientists have to guard their cognitive authority is their role as scientific advisors in the boundary transactions with policymakers and politicians."*

Studies of the science-policy interface have revealed that the existence of a strict separation between science and other social activities, including policymaking, is often assumed in these contexts and interpreted as the basis for the authority of scientific advice. Science is perceived as separate from society and politics, governed by different logics and dynamics, and the interaction is understood as being linear, with 'facts' established by science on purely objective grounds, before being passed downstream for societal use, be it in technological or policy applications (Jasanoff in Lentsch and Weingart 2011). This linear dynamic is mirrored in traditional models of science-based risk governance, as discussed in section 2.3.3. However, as recognised by Pielke (2007), such representation of the relationship between science and its application to policy and society follows the same logic as the so-called linear

model of innovation (Godin 2006), which has been criticised by several scholars (see for example Stokes 1997) on the grounds of being descriptively inaccurate and normatively undesirable.

If, as discussed above, social and political factors are intrinsic to the practice of science, the very distinction between science and other social activities such as policymaking is called into question. Moreover, scientific knowledge underpins and enables most activities in contemporary societies. Indeed, for authors like Jasanoff science is seen as an integral and inextricable part of modern societies, and social and scientific order are *"co-produced"* (Jasanoff 2004). A more sophisticated account of science and of its interaction with society in policy contexts is therefore needed.

2.3. Science and policy

2.3.1. Modes of science

Several authors have characterised how understanding and dealing with complex policy issues requires a mode of knowing that is fundamentally different from the traditional image of scientific enquiry aimed at gaining knowledge for the sake of understanding the natural world.

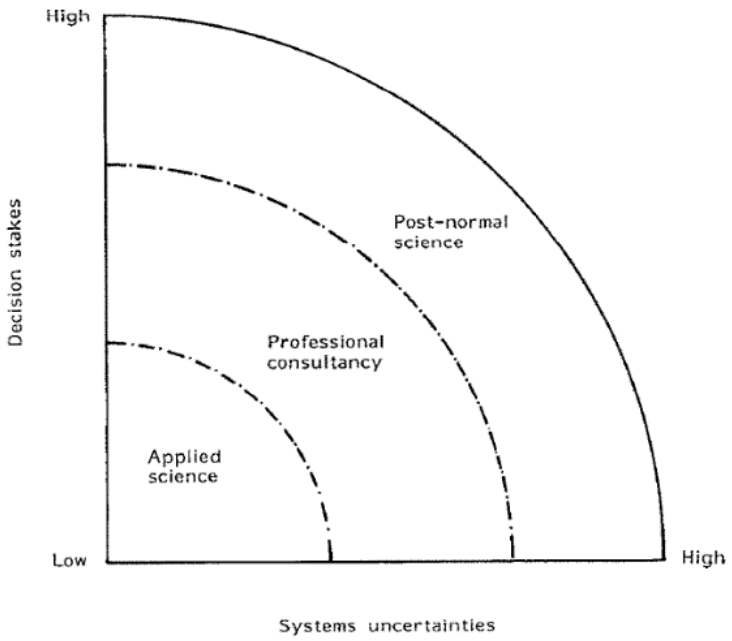
One of the earliest of such characterisations was provided by nuclear physicist Alvin Weinberg in his seminal 1972 essay on *"Science and trans-science"*. Weinberg characterises as *"trans-scientific"* those issues existing at the interface between science, technology, and society, that *"hang on the answers to questions which can be asked of science and yet which cannot be answered by science. […] though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science"* (Weinberg 1972: 209). These include the management of technological risk, environmental and health issues, and social policy. In trans-scientific situations, social and political considerations (and therefore value judgements) have a legitimate role to play alongside scientific judgement in addressing the issues at stake. Yet, Weinberg maintains that a

separation between the scientific and trans-scientific aspects of an issue is possible, and that scientists' role is that of defining and elucidating the scientific portion for the benefit of social deliberation. Although acknowledging the limits of scientific knowledge in addressing policy issues, he maintains a privileged role for scientists in defining authority.

A more recent and widely accepted characterisation of the nature of policy-relevant science, which found its way into current policy discussions, is the concept of "post-normal science", developed in the 1990s by Funtowicz and Ravetz (1993). Their analysis distinguishes between two dimensions that characterise approaches to the production of scientific knowledge, or what they refer to as 'problem solving strategies'. On the one hand, they consider the level of uncertainty, and what the uncertainty is about. This ranges from situations where the uncertainty is of technical nature and can be reduced through further research, to uncertainty about which methods to apply, to fundamental ethical and epistemic uncertainty. On the other hand, they consider the decision stakes involved, i.e., the potential consequences of decisions taken on the basis of such knowledge, and the level of conflicting purposes between the stakeholders. Knowledge production aimed at addressing real-world issues is defined by these two dimensions.

Funtowicz and Ravetz (1993) label the mode of scientific enquiry characterised by low stakes and low uncertainties as "applied science", and that dealing with high stakes and high uncertainty as "post-normal science". Each mode requires a different approach to knowledge production and problem solving, and different ways to ensure quality and outcomes. In post-normal science, they argue, extra-empirical considerations (and therefore extra-scientific in the traditional sense) are necessary to reduce uncertainties, as facts alone are not sufficient, and the consequences of error need to be factored in. Indeed, the facts/values distinction blurs in such situations (see below for further discussion). To ensure quality and legitimate outcomes, stakeholders engagement becomes an intrinsic part of knowledge production, through what they refer to as the extension of the relevant peer community.

Figure 1: Post-normal science



Source: Funtowicz and Ravetz 1993:745

Similarly, Gibbons et al. (1994) identify the emergence of a new mode of knowledge production in the latter part of the 20th century, which they refer to as *"mode 2"*, in contrast with the earlier *"mode 1"*, which it does not supplant but rather supplement. What differentiates mode 2 is that the aim is not knowledge for its own sake, but rather for addressing concrete challenges. The context of application permeates the knowledge production process, thus breaking with the idea of a linear model where knowledge is produced first and applied later. While mode 1 is located mainly in universities and responds to academic and disciplinary logics, mode 2 is transdisciplinary and takes place in a variety of settings, from industry to government agencies to consultancies. In a similar note to what suggested by Funtowicz and Ravetz (1993), the quality of the knowledge produced in this mode is determined by actors and criteria beyond those employed in traditional academic settings.

What these conceptualisations have in common is to challenge an idealised and monolithic image of how science does and should operate, responding only to its internal logics, to which the knowledge production should conform in

all contexts. Instead, it recognises that production and usage of scientific knowledge, be it in industrial or policy settings, cannot be separated, and criteria of quality should include driven by considerations of use. Accepting that epistemic approaches are different in the context of policy relevant science defuses the apparent tensions between the normative model of “good science” often held in science policy discussions, and the reality of science and policymaking. This more sophisticated picture of the internal dynamics of science and its interaction with society discussed in this section is necessary to fully understand the practice of scientific advice to policy.

2.3.2. The role of scientific evidence in policymaking

While the field of STS takes the production of (scientific) knowledge as analytical point of departure, a subfield of policy studies known as knowledge utilisation studies focuses on how it is used in policymaking. Although originally concerned mostly with the role of social scientific knowledge (Weiss 1979), its insights are relevant to discussions of science and expertise more broadly (Hoppe 2005).

As suggested by Cairney (2016), from a policy studies perspective the interface between science and policy is best understood by taking into account the many functions that research and evidence can play in policymaking. The most straightforward function, which is often represented by researchers as the only or at least the ideal one, is when existing evidence has a direct impact on a specific piece of policy. Although not impossible, such direct hits are rather uncommon. This should not however be interpreted as a failure, as evidence can have many other legitimate functions, including to inform solutions to a problem identified by policymakers, as part of a broader range of information as part of policy network, as “ammunition” in political debates, as a tactical resource to show that a problem is being addressed, and shaping how actors frame issues and think about them in the long term (Weiss 1979). Evidence can also be used as a tool to evaluate plans and policies, and to legitimise activities by lending credibility and authority (Cairney 2016). In each case, it would be naive to think that the evidence could ever speak for itself, or that its

producers *"control how their ideas are interpreted, modified and used by others, particularly when issues are salient"* (Cairney 2016: 24).

Despite policymaking being sometimes portrayed as a purely technocratic activity, policy studies have shown how it is instead an intrinsically political activity (Parkhurst 2017). In most cases, factual knowledge can only determine the course of action in situations where there is consensus about the desired outcomes, and reasonable certainty about the causal relationship between actions and outcomes. As recognised by many authors, the relationship between scientific knowledge and advice and policy actions is not always linear. Pielke (2007) for example draws a distinction between situations he refers to as "tornado politics", where there is agreement over valued outcomes and science can elucidate the causal pathways to achieve such outcomes, and those he refers to as "abortion politics" where the outcomes themselves are disputed. Science can compel action only when there is general agreement on valued outcomes, and low uncertainty about outcomes of actions. This makes the provision of scientific advice in post-normal science situations, where "facts are uncertain, values in dispute, stakes high and decisions urgent" (Funtowicz and Ravetz 1993: 744), particularly challenging (see 2.1.5). Far from being a failure of rational decision makings therefore, the fact that evidence is only one of the factors determining policy action reflects the fact that policy decisions are irreducibly political.

More broadly, political studies recognise that science is used not only instrumentally to achieve goals, but also mobilized rhetorically as a political resource. Ezrahi for example argued that Western governments in particular had used *"scientific knowledge and skills not so much to enhance the instrumental effectiveness of democratic governments as to ideologically defend and legitimate uniquely liberal– democratic modes of public action"* (Ezrahi 1990:1). For Ezrahi the recourse to science and technology as rhetorical resources to 'depoliticise' action is a central political strategy of the modern state, whose authority rests on *"the illusion that social and political problems like scientific problems are inherently solvable"* (Ezrahi 1990: 51).

The idea that policymaking can benefit from being informed by robust evidence is intuitively appealing and widely accepted (Oliver, Lorenc, and Innvær 2014). However, an important caveat that emerges from the study of the use of evidence in policy is the recognition that what counts as "evidence" is not universal, varying across different contexts of academic research and policy. In scientific discussions, the term normally refers to structured and documented information, systematically collected and validated through rigorous processes of scientific reasoning and some form of peer review. In the context of governmental and parliamentary activities, the term gains a broader meaning and is commonly used to describe all information being considered in a given case (akin to the judicial meaning of evidence). This includes for example legal and economic analysis, stakeholders' perspectives, anecdotal experiences, expert opinions, as well as peer review scientific data (Nutley, Powell, and Huw 2013; Stevens 2011).

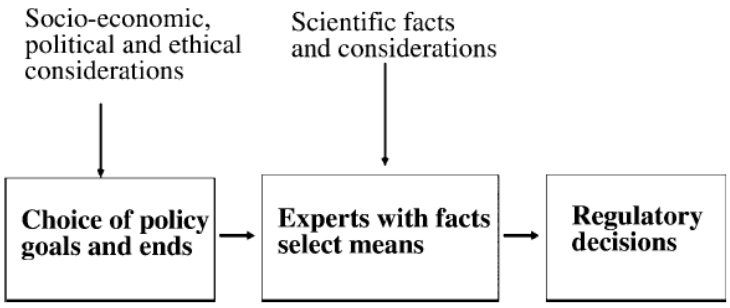
An ethnographic study of the use of evidence in a department of the UK Government for example counted 15 types of "evidence" that were entered into policy debates: in addition to internally collected government data and externally produced academic analysis, the list includes opinion polls, reports from think tanks and management consultants, previous governmental policy papers, independent enquiries, police reports, internal and externally commissioned evaluations, reports from abroad, press reports, TV programmes, personal experience and opinion (Stevens 2011). A similarly wide range of meaning was identified in a study on the use of research in the UK Parliament (Kenny et al. 2017).

2.3.3. The evolving role of science in risk governance

Descriptive and normative accounts of the relationship between science and policymaking and of its institutionalization, especially in the field of risk governance, vary considerably and have evolved over time. Millstone (2007) identified four models of the role of science in policy, used both descriptively and normatively.

In the first half of the 20th century, two intellectual traditions influenced how the role of science in policymaking was interpreted, which Millstone (2007) refers to as the “decisionist” and “technocratic” models of science and policy.

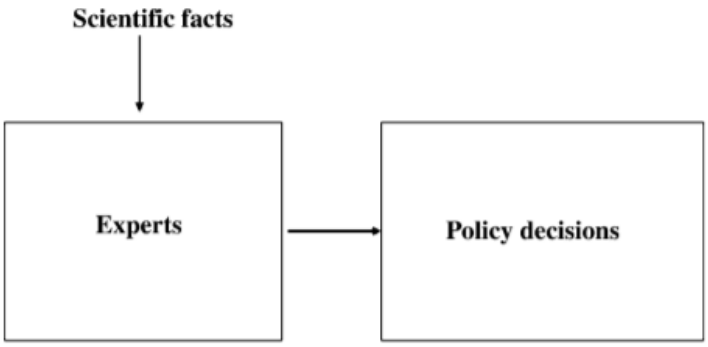
Figure 2: The Weberian "decisionist" model



Source: Millstone 2007:486

In the “decisionist” model, based on Weber’s (Weber 1946) conception of the role of bureaucracy, a strict separation exists between goal-setting, which happens upstream and is the domain of political values, and selection of means, which takes place downstream and is the domain of scientific knowledge and expertise. Bureaucrats and scientific experts are subordinate and accountable to democratically elected representatives, which in turn are accountable to citizens. However, this model encounters limits in explaining how policy decisions should be taken in situations of incomplete or uncertain scientific knowledge and does not address situations in which the goal-setting itself requires technical and scientific advice, as often the case in technologically advanced societies. This raises the question of the extent to which experts should contribute to goal setting, the modalities to do so, and what role remains for policymakers in the face of complex policy challenges that can be understood only in scientific terms.

Figure 2: The Technocratic model



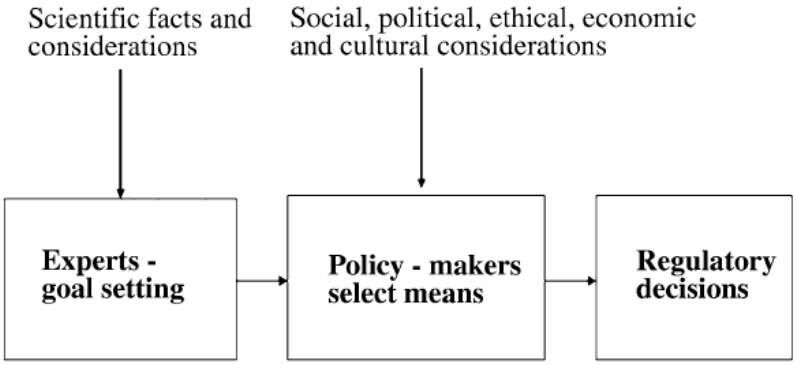
Source: Millstone 2007:488

A “technocratic” model of risk policymaking, informed by Positivism, emerged in response to these questions, postulating that policy should be based on and only scientific expertise (Millstone 2007). Policy decision making should be the sole responsibility of scientific and technical experts, as they are the only ones who possess the necessary knowledge, and the role of elected representatives should be limited to selecting the best experts and implementing their advice. This model is underpinned by the assumption that a full separation is possible between facts and values, science and politics, and that facts are fully knowable. This makes it vulnerable to the observation that science is uncertain and sometimes unreliable, experts’ judgement can be biased, and disagreement among experts is common.

Yet despite these limitation, the technocratic model remains rhetorically popular, and is often invoked by politicians and policymakers claiming that risk policy is based only on “sound science” (Jasanoff 2011), often as a strategy to de-politicize issues and avoid blame (Millstone 2007). The limitations of the technocratic model are not only practical, because even if facts could be fully established by science, risk policy is often concerned with the acceptability of risk and trade-offs that inevitably require value judgements (see 2.2). This means either reintroducing a role for democratically accountable elected representatives or accepting that the scientific experts make such judgements based on their own values. Historically, the main reason why technocratic models and rhetoric have lost much of their plausibility is because of the

emergence of evidence showing that the relevant sciences are uncertain, incomplete, equivocal, ambiguous, or unreliable. This was clearly shown after the introduction of the Freedom of Information regime in the 1970s in the US, which revealed the uncertainty in the science used to support much policymaking and led to a shift to an alternative model of the relationship between science and policy in the US (Millstone 2007). In Europe, a similar shift only took place in the late 1990s and early 2000s, largely in response to a number of food and chemical safety issues (see 3.3).

Figure 3: Inverted decisionist model



Source: Millstone 2007:492

In response to these challenges, a new model of the relationship between science and policy was developed in the US, in which the roles of scientists and playmakers are inverted in respect to the decisionism model. In the "inverted decisionism model", experts set the goals by deciding what is safe or unsafe based on scientific facts and considerations, while policymakers are left to select the means to implement the experts' advice, taking into account non-scientific considerations such as costs and public views. In this model, policymakers are held accountable through democratic means both for seeking and following the advice of experts, and for their downstream value judgements. Scientific experts on the other hand remain accountable only to the scientific community itself, meaning that the judgement of the most eminent of the scientific community is effectively definitive. The relationship is linear and unidirectional, with the experts upstream assumed to provide scientific advice that is entirely independent of political considerations or other interests. In this

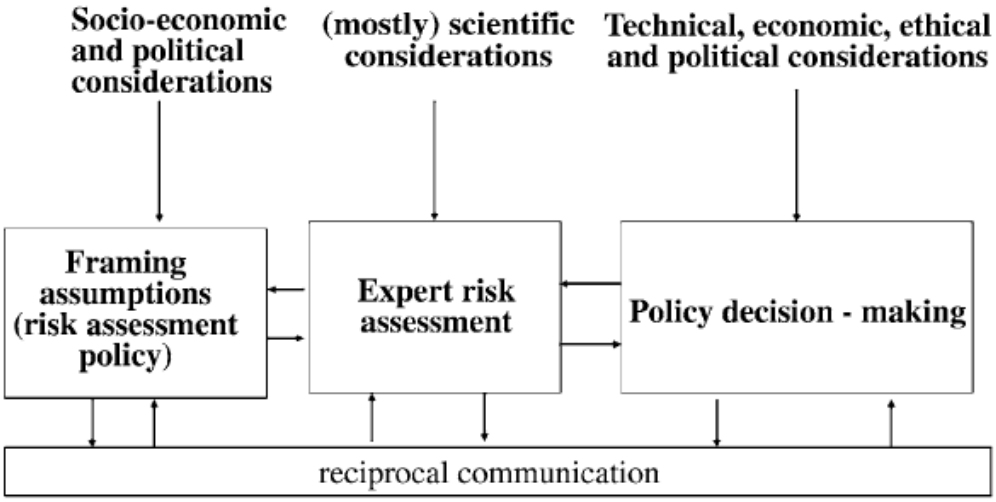
account, the supposed neutrality and objectivity of science justifies its role in providing legitimacy to the policies it informs.

Figure 4: The Red Book model

Source: Millstone 2007:495

This model was adopted not only rhetorically, but as the guiding principle for the design of risk governance institutions and their procedures. Although it has effectively become the "contemporary official orthodoxy" (Millstone 2007) since the 1970s, its vocabulary has evolved by referring to a binary division of labour between two distinct activities referred to as "risk assessment" (RA) and "risk management" (RM). One of the most influential articulations of the inverted decisionist model can be found in the US National Research Council influential report "Risk Assessment in the Federal Government: Managing the Process" (US National Research Council 1983), referred to as the "Red book" because of its cover. The ''Red Book'' model presupposes a strict separation and linear relationship between three distinct phases: risk assessment, based on scientific considerations only; and risk management and risk communication, which are informed by economic, political, social, and ethical considerations (see illustration below). Their relationship is unidirectional, with RM being informed by, and based on, scientific RA, while the RA is represented as taking place in a "complete political vacuum" (Millstone 2007, 2010).

Figure 5: The co-evolutionary model



Source: Millstone 2007:498

This model is challenged by the evidence from science policy research and STS that scientific deliberation is indeed influenced by political considerations (see 2.2). For example, choice of questions, framing assumptions, are not in the hand of the scientists. According to Millstone, the only policymaking context in which the existence of up-stream framing assumptions has been explicitly acknowledged has been at the Codex Alimentarius Commission (CAC), the central part of a joint food standards programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organisation (WHO) to protect consumer health and promote fair practices in food trade. The Codex Procedural Manual acknowledges that scientists' assessments of risks from food products are framed by prior up-stream framing assumptions that Codex calls ''risk assessment policy.'' On the basis of this acknowledgement, Millstone argues for a co-evolutionary model, which can make risk policy both scientifically and democratically legitimate. In this model, scientific deliberation by experts is informed by an explicit risk assessment policy upstream, which is determined by socio-economic and political factors and spells out the framing assumptions underpinning RA and RM.

The relationship between risk assessment policy, RA and RM is dynamic and goes in both directions, allowing for feedback loops. This model recognises the

political context in which scientific deliberations take place and makes it explicit. This recognition highlights that such context should addressed by institutions which derive their legitimacy through democratic accountability. In Millstone assessment however, in most countries this is not the case, and RAP are effectively decided by the scientific advisory bodies themselves, thus lacking the necessary democratic accountability. Millstone (2010) identifies three distinct types of upstream framing assumptions: substantive, procedural, and interpretive risk assessment policies. Substantive risk assessment policies concern determining the scope of RA, such as what counts as admissible and relevant evidence and what does not, or whether benefits can be considered alongside risks, or only the latter is relevant. Procedural risk assessment policies are concerned with the processes by which RA is conducted and reports, such how decisions are taken, how uncertainties are taken into account, and what degree of openness and transparency is required. Interpretative risk assessment policies are concerned with what is relevant and/or sufficient data support recommendations.

2.3.4. The role of experts in policy and society

In terms of theoretical classification of the roles that scientific advisors play in the science-policy arena, one of the most influential is the typology presented by Pielke (2007) in his seminal book *The Honest Broker*. Recognising that scientific knowledge can compel action only when there is general agreement on the desired outcomes, and low uncertainty about the actions to achieve them (see above), Pielke's analysis centres on the role of experts in presenting options to policymakers and guiding the choice between them.

His analysis is based on two dimensions, namely the conception of democracy and the conception of science in society. To understand the role of (scientific) experts in democratic society, it is important to explore the conception of how democracies reconcile conflicting demands. On the one hand, there is a conception of democracy as dominated by competing factions, where experts align themselves with their favoured side and expertise is used as a resource in debates between factions. On the other hand, is a conception of democracy

where the public, through its representatives, chooses between alternative course of action. The role of scientific experts in this context is to outline these possible courses of action and their implications. The second dimension, regarding the conception of the role of science in society, builds on many of the STS concepts discussed above and contrasts a linear model with a more sophisticated stakeholders' model, which holds that users have a role in the production of policy-relevant knowledge, and consideration of use are important to understand the take up of science in decision-making.

By combining these two dimensions, he distinguishes between four ideal types: the pure scientists, the science arbiter, the issue advocate, and the honest broker of policy alternatives. Although it is acknowledged that none of these roles exists as such in the real world, they are proposed as reflecting practical differences approximating real world advisors. In Pielke's characterisation*, "the defining characteristic of the honest broker of policy alternatives is an effort to expand (or at least clarify) the scope of choice for decision-making in a way that allows for the decision-maker to reduce choice based on his or her own preferences and values"* (2007:2). His analysis warns that, as it is impossible to completely exclude value considerations from scientific enquiry (see above), both the pure scientists and the science arbiter risk in practice to become issue advocates, although perhaps unwarily.

Although powerful in bringing conceptual order to the complex world of scientific advice, and often popular with practitioners themselves, some authors have highlighted that the limitation of such theoretical approaches is the lack of empirical confirmation of their validity. In an attempt to build a more empirically grounded typology, Spruijt et al. (2013) sampled a number of scientific advice practitioners working in environmental policy in the Netherlands to explore the existence and perception of different expert roles. By analysing the extent to which responded self-identified with a number of statements inspired by the ideal typologies developed by Pielke (2007) and Weiss (2006), Spruijt and colleagues identified six roles (autonomous scientists, pragmatist expert, action-oriented expert, engaged expert, instrumental expert, and deliberator)

that combine and partially reflect elements of the theoretical typologies. They conclude that, although empirical evidence exists of the existence of diverse roles, larger scale studies will be necessary to determine their characteristics and how they vary depending on the cultural and historical contexts. A study carried out by Hoppe (2009) to capture the perception of their role by actors involved in scientific advice in the Netherlands confirms a resemblance between the discourse employed by the actors to define their roles, and the theoretical typologies developed by academic analysts.

These empirical studies of how experts themselves perceive the different roles scientists might play when engaging in policymaking focus largely on Western developed nations. As explored in a paper I co-authored (Akerlof et al. 2022), what role is considered acceptable for scientists and experts to play in regard to policymaking varies from country to country. Based on a previous survey of international legislative science advice experts (Akerlof et al. 2019; 2020), our study investigates the expert's preferences and rationales for how scientists can be helpful to policy processes in legislatures, testing for effects of expertise and national development on role choice. Almost 80% of respondents, which included science advice researchers, providers of scientific information to government, and users of scientific information within government, said that scientists should work closely with policymakers and others to integrate scientific results in policy decisions. The next most preferred role was that of reporting and interpreting results, chosen by over half of the respondents. The primary reasons given for scientists' engagement were to improve decision-making and communication of science, while only a small proportion of respondents (18.6%) said that scientists should advocate for specific policies. Interestingly, the study identified a difference between experts from developing and developed nations, with the former being more accepting of 'advocacy' roles and less supportive of scientists that solely publish in academic journals.

2.4. Defining and typifying scientific advice

Despite the growing interest in scientific advice, conceptualising and researching it remains difficult. The term "scientific advice" itself (and "science

advice", which is often used interchangeably), remains ambiguous and contested. The term is used by both practitioners and analysts to denote a broad set of phenomena, and refers to both a set of practices and a normative discourse about the role that science does or should play in policymaking. In this regard, the concept of scientific advice shares many features with the related and sometimes overlapping concept of "science diplomacy" (Flink 2021), with both concepts often associated to the same community of practitioners (for example the INGSA network, which covers both domains and often blurs the distinction between the two).

The literature focusing on scientific advice covers a wide variety of advisory bodies and practices, spanning large international endeavours like the Intergovernmental Panel on Climate Change (IPCC) (Pearce, Mahony, and Raman 2018), scientific committees and agencies advising on technical regulations (Jasanoff 1990; Hoffman et al. 2018), collegial bodies producing advisory reports (Hilgartner 2000; Bijker, Bal, and Hendriks 2009), and the personal advice given by senior scientists to ministers (Gluckman 2014; Doubleday and Wilsdon 2012). Some authors intend scientific advice as the direct recommendations given by scientific experts (individually, or collectively as a committee) to policymakers (again, either individually or as a general group), while for others scientific advice is used as a shorthand for any scientific consideration having a bearing on public policy, such as for example the role of experts' opinions in public debates. Moreover, scientific advice is approached from different perspectives, for example in terms of roles, activities, functions, and institutional arrangements.

A general common key feature of scientific advice is some form of recourse to expertise perceived as external to the decision-making progress, therefore implying a distinction between the expert advisor(s) and the advised decision-maker(s). Recognising this, Petersen (2017) broadly defines scientific advice as *"practices involving individuals, organisations and structures that mobilise natural and social scientific and engineering knowledge into public decision-making"*. Although scientific input is needed to inform policy decisions in most

areas, it is recognised that some classes of issues are particularly prone to requiring scientific advice. Spruijt et al. (2014) identify those issues that, because of their nature, do not lend themselves to straightforward solutions and require expertise to be tackled. As such expertise is rarely found within a single organisation, external advisors have to be brought in, often (but not exclusively) from the scientific community. Common characteristics of such issues is that they are ill structured, knowledge is uncertain, risks are high, and they span the boundary between environmental, social, economic and political domains.

As mentioned, scientific advice in its broadest sense takes many forms and comes in a variety of institutional arrangements. Advice can come from individuals (either in a formal role as advisors or informally), committees, agencies, research institutions, think thanks, NGOs, private companies, academies, and learned societies. Lentsch and Weingart (2011) for example, identify three basic kinds of advisory organisations (collegial bodies, hierarchical research-based organisations, academies), alongside individual advisers to ministers or head of government (Chief Scientific Adviser (CSAs)/presidential advisers). Building on their classification, an overview of the institutional forms of scientific advice and some examples are listed in the table below.

Table 11: Institutional forms of scientific advice

Institutional form	Examples
Individuals	CSAs, presidential advisers, academics
Collegial bodies	Committees, commissions, international panels (e.g., IPCC)
Research-based organisations	Scientific and regulatory agencies, think tanks, research institutes, “What works” centres
Scientific academies	National academies and learned societies

Source: Author’s elaboration, based on Letsch and Weingart 2011

Each of these arrangements has its own unique dynamics, in terms of how their advice is produced, communicated, and legitimised. Each individual advisory

arrangement is characterised by certain features that influence how it is structured and how it operates. For example, the level of resourcing and staffing has a big impact on the capacity of an advisor to work effectively (see Glover in Wilsdon and Doubleday 2015). As discussed below, such institutional features of scientific advisory systems have a clear role in ensuring their effectiveness. Building on work by Glynn, Cunningham, and Flanagan (2003), a non-exhaustive list of such features is presented in the table below.

Table 22: Institutional features

Feature	**Explanation**
Hierarchical structure	Is it organised in a collegial or pyramidal structure?
Formality	Does the advisory activity take place within a formal institutional framework?
Formality of the advice	Is the advice provided through formal or informal means?
Jurisdiction	Does it operate at the subnational/ national /international level?
Funding	Where does the funding come from? Is it permanent or fixed term?
Legal status	Is the arrangement statutory?
Resourcing and staffing	What is the level of staffing and resources available?
Composition	Are the individuals involved employed directly, appointed externally, elected, or members ex officio?
Advice commissioning	Is the advice provided proactively (push) or is it solicited (pull)?
Openness	Is the advice public or confidential?
Outputs	Is the advice contained in reports/ media communications/ personal communications?
Target audience	Is the advice aimed at government/ agencies /public / parliament?
Main function	Is advising its primary or secondary function?

Source: Own elaboration based on data from Glynn, Cunningham, and Flanagan (2003) and OECD (2015).

2.5. Conceptualizing scientific advice

A systematic review by Spruijt et al. (2014) of the academic literature on the "roles of scientists as policy advisers on complex issues" presents an overview of the richness of disciplinary and conceptual approaches employed in the study of scientific advice. Using scientometric methods, the review identifies five groups of authors, labelled on the basis of the author groups' self-proclaimed research approaches: Post-normal science, Science and technology studies, Science policy studies, Politics of expertise, Risk governance. According to the review, authors in the different clusters agree that the role of scientific advisors varies in different contexts, but each offer different explanations for such variation. These include the degree of expertise, level of public and stakeholder involvement, and value systems.

2.5.1. Scientific advice as boundary management

By bringing attention on the socially constructed and negotiated nature of scientific knowledge, and the role that values play in its production, STS scholarship brings key insight to the conceptualization of scientific advice. From this perspective the authority of scientific advice to inform policymaking cannot be explained by appealing to a pre-existing separation between facts and values. Instead, this authority needs to be understood as the product of an active construction by the actors involved. From this perspective, the scientific advisory process is therefore analysed as the management of the boundary between science and policy to assert epistemic authority.

As discussed above, based on the assumption that a separation of facts and values and the role they play in determining policy decisions is possible, a distinction is often drawn between advice and decision, or between assessment and management of risk. Instead, from a STS perspective this distinction should be understood as the product of boundary work. As recognised by Jasanoff (1990:249) "*The notion that scientific advisors can or do limit themselves to addressing purely scientific issues, in particular, seems fundamentally misconceived",* and rests on the refuted idea of a complete separation between values and facts. Instead, the advisory process should be

understood as *“a locus for negotiating scientific differences that have political weight.”* (Jasanoff 1990: 249).

2.5.2. Scientific advisory bodies as boundary organizations

Regardless of their specific institutional setup, scientific advisory bodies, and more generally science-policy interfaces (SPIs), are often described and conceptualized as “boundary organizations” (Gustafsson and Lidskog 2018), particularly but not exclusively in the environmental governance domain. The concept of boundary organizations was introduced by Guston (1999) in his analysis of the role of technology transfer offices in stabilizing the boundary between politics and science in the US. It represents an extension of the concept of boundary object (Star and Griesemer 1989), i.e. an object spanning two different social worlds, such as science and policy, which serves different functions for actors on each side while maintaining its own identity. Examples of boundary objects in the context of science policy include models, data visualizations, and scientific assessment reports. In Guston’s analysis (1999; 2001), entire organizations can serve as boundary objects at the science-policy interface, stabilizing the boundary between these two domains.

While Jasanoff (1990) recognizes that a certain degree of flexibility in the boundary between science and policy is necessary for scientific advice, excessive blurring risks the "politicization of science or the reciprocal scientification of politics" (Guston 2001), understood here as the unreflexive incorporation of the norms and practices of one domain into the other. Boundary organizations address this challenge by providing a site, and sometimes the incentives, for actors from the scientific and policy domains to work together and collaborate (dual agency or dual participation) to co-produce scientific and social order (Jasanoff 2004), and create and use boundary objects, while maintaining the stability of the boundary between science and policy outside the organization. Boundary organizations stabilize the boundary by internalizing its negotiation *“at the lowest level and the greatest nuance within the confines of the organization"* (Guston 2001).

Successful boundary organizations exist at the frontier of politics and science with distinct lines of accountability to each (dual accountability) *"pleasing two sets of principals and remain[ing] stable to external forces astride the internal instability at the actual boundary*" (Guston 2001). While demarcation between the scientific and policy domains is an important part of the work of boundary organization, its stability and effectiveness come not from isolating itself from external political authority, but rather from its coordination between, and responsiveness and accountability towards, both domains. Boundary organizations thus engage in both coordination and demarcation at the same time, and have to manage the tensions between the two activities.

Despite its wide adoption in science policy and environmental studies, the concept of boundary organization presents some limitations. As identified by Gustafsson and Lidskog (2018) in their review of its development, the main critiques of the boundary organizations concept are that it is too static and fails to capture the dynamic nature of the processes; it fails to account for the differences and boundaries existing *within* the domains of science and policy; it doesn't adequately account for power dynamics; and it neglects that boundary organizations often deal with multiple boundaries, stakeholders and scales simultaneously.

2.5.3. From boundary organizations to boundary management

In response to these limitations, several authors have further expanded the meaning and usage of the concept of boundary organizations by developing it further and shifting the focus to the dynamics within boundary organizations and the socio-organizational processes by which science-policy relations are managed. In particular, as recognized by Miller (2001), the concept of boundary organization has been developed in a US context and does not necessarily adequately translate in international contexts where the social domains of science and policy are not as neatly distinct and static as in US political culture, and fails to account for the differences existing within each of these domains.

Miller proposes to expand on it by introducing the more dynamic concept of *hybrids management*. Hybrids refers to *"social constructs that contain both scientific and political elements, often sufficiently intertwined to render their separation a practical impossibility"* (c.f. Latour 1993). Focusing on hybrids instead of binary boundaries emphasizes the multiplicity of relations, actors, and social domains at stake. Miller describes four hybrid management strategies used by organization to uphold their accountability and relationships with multiple actors, and to facilitate the construction of boundary objects: i) hybridization (bringing scientific and political elements together to create hybrids); ii) deconstruction (opening up hybrids to reveal the implicit and value-laden assumptions embedded in their construction); iii) boundary work (creating and maintaining boundaries between the scientific and political domains to preserve their distinction and establish authority, for instance by assigning respective responsibilities); and iv) cross-domain orchestration (coordinating the activities occurring in the separate domains to enhance the effectiveness of the process).

Foregrounding management strategies places emphasis on processes, thus putting the focus on the social arrangements and practices internal to boundary organizations. By complementing Guston's theory with the more dynamic concept of hybrid management it is thus possible to expand the explanatory power of the concept of boundary organizations beyond the US context in which it was originally developed. Importantly, these strategies are "case- and context-sensitive" (Wehrens, Bekker, and Bal 2014), meaning that the same strategy can lead to different results and be used for different goals depending on the circumstances, and the effectiveness of a given strategy depends on the context. Moreover, as recognized by Parker and Crona (2012) the balance needed to stabilize boundaries is dynamic, and the point of equilibrium between the interests of different actors is not symmetrical but skewed by power relations and continuously shifting.

2.5.4. Limitations

However, even taking into account these expanded and more dynamic concepts, the question of which distinct organizational structures and institutional designs make an organization a boundary organization remains largely unaddressed. Gustafsson and Lidskog (2018) argue that, while the literature utilising the concept of boundary organizations to study SPIs and scientific advisory mechanisms recognizes that organizational and institutional dimensions are not irrelevant for the functions and effects of boundary organizations, and that how the work is performed and organized has major implications for its outcomes, it does not per se give any guidance for how to institutionalize and organize science-policy interplay. Moreover, they argue that the concept is often used as an empirical label to describe organizations, rather than as a theoretically-informed analytical concept or as referring to a specific form of organizational or institutional structure. Instead, the label is used to signal and describe what the organization's goal is (to mediate science-policy interface), signalling a specific positive value of inclusion. In this regard, the concept serves as a boundary object itself, *"that it works performatively and that it risks black-boxing, or concealing, instead of exploring what takes place"* (Gustafsson and Lidskog 2018). This is particularly relevant in the context of EU scientific advisory structures such as the Joint Research Center (JRC), which are often described as boundary-spanning organizations, thus posing the science-policy boundary as pre-existent and negating the constructivist dimension of the concept. They thus argue that future studies should theoretically elaborate the meaning of boundary organizations and more deeply investigate the importance of institutional aspects and how they impact the organizations' identity and performance.

Moreover, despite a conceptual shift from institutional design features to processes and strategies, the literature offers limited insights into how to translate these into concrete practices, thus limiting its usefulness for actors on the ground. Guston (2001) concludes that *"Like Latour's (1987) Janusian visage of science itself, the boundary organization speaks differently to different audiences."* However, in this analysis boundary organizations are

taken as cohesive entities speaking with one voice, without further analysing who exactly does the talking to each of the different audiences on behalf of the organization, whether it is the same people or part of the organization liaising with the worlds of science and policymaking, or if instead a division of labour takes place inside the organization.

2.6. Effective scientific advice: the CRELE framework

The concepts of boundary organizations and of scientific advice as a boundary activity inform one of the most widely used frameworks to analyse and evaluate the effectiveness of science-policy interfaces (SPIs) and scientific advisory bodies, the so-called CRELE framework, which identifies **C**redibility, **Re**levance (also referred to as Salience) and **Le**gitimacy as the key attributes of effective scientific advice. Despite some acknowledged limitations (see below), the framework it is widely used to analyse and evaluate the effectiveness of a broad range of scientific advisory bodies. Examples of its usage include scholarly studies of the IPCC (Girod et al. 2009), of German biodiversity SPIs (Leibenath, Kurth, and Lintz 2020), of volcanic alert systems (Fearnley and Beaven 2018), and of Scientific Advisory Committees in general (Hoffman et al. 2018); and policy reports on advisory bodies such as the UK Council for Science and Technology (Government Office for Science 2021) and the Intergovernmental Science–Policy Platform on Biodiversity and Ecosystem Services (IPBES) (Busan Outcome 2010).

The framework is rooted in the analysis of scientific advice and knowledge mobilization in the field of sustainable development and environmental policy by Cash et al (2002; 2003), who argue that effectiveness of scientific advice should be assessed not simply in terms of the specific actions taken as a result of the advice (see **Error! Reference source not found.**), but rather in terms o f the long-term impact on how issues are defined and framed, and on which options for dealing with issues are considered. In this context, scientific advice is considered effective when it influences the behaviour of intended audiences through enhancing their knowledge of the consequences of their decisions (Sarki et al 2014).

2.6.1. Credibility, Relevance, and Legitimacy

Cash et al (2002) identify three attributes of scientific evidence and advice which is effective in achieving this, namely (scientific) Credibility, (political) Legitimacy and (policy) Salience (Relevance). These are referred to as attributes because they are not objective qualities of information, but rather involve actor-specific judgments using different criteria and standards, with different actors perceiving and valuing them differently. **Credibility** refers to information beings perceived as authoritative, believable, and trusted, i.e. meeting standards of scientific adequacy and quality. Credibility is normally assessed by proxy, as due to the very nature of SPIs most of the actors involved are often unable to independently evaluate it directly, and includes the credibility of both the knowledge producers and the knowledge production process. **Salience** refers to how relevant information is to an actor's decisions and to policy and societal needs. Information is relevant when provided at the right time to inform decisions (timely); concerns problems that are on the agenda of decision-makers; is not too broad or narrow in scope and at the right scale; and takes into account the decision makers' real-world context and constraints. **Legitimacy** refers to whether actors perceive the information producing process as "fair", unbiased and inclusive, and considering the values, concerns, and perspectives of different actors. Legitimacy is assessed against standards of political and procedural fairness, and judged based on who gets to participate or not in the information production processes, how choices are made, and how the information is vetted and disseminated.

Cash et al (2002) argue that, while Credibility is often assumed by scientists as being the most important attribute, *"with the guiding model being that good, credible science, untainted by politics, can inform the decision-making process about the technical aspects of problems and solutions"*, all three attributes are equally important, and only focusing on one at the expenses of the others undermines overall effectiveness. Crucially, Cash et al (2002, 2003) acknowledge that these attributes are both "*tightly coupled*" and in tension with each other, and trade-offs exist between them, with efforts to increase one

often negatively affecting the others. For example, a closer involvement of policymakers in defining the scope of advice can increase its Relevance by ensuring that questions useful to decision makers are addressed, but risks compromising the independence of the process which could then be perceived as biased, thus undermining its Credibility and Legitimacy. Conversely, defining the questions purely on the basis of scientific considerations can increase the Credibility of the advice, but undermine its Relevance to the needs of policymakers. At the same time, efforts to increase one attribute can also increase the others in a complementary manner. For example, including local experts can increase Credibility (by expanding the range of evidence being considered), Relevance (by including context-specific knowledge), and Legitimacy (by increasing ownership of the process). These tensions and complementarities are summarized in the table below:

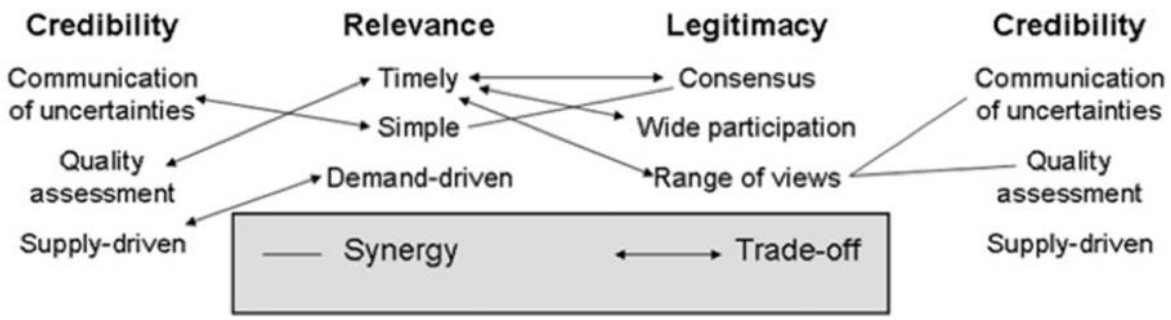
Table 3: Tensions and complementarities among salience, credibility, and legitimacy

Attempts to increase…	influence salience	influence credibility	influence legitimacy
salience	-	↓ by "tainting" science with politics; ↑ by including "place-based" knowledge	↑ or ↓ by increasing the inclusion of different decision makers
credibility	↓ by isolating the science and removing decision maker input; ↑ by including different scientific disciplines who ask different questions	-	↓ by limiting participation and thus decreasing process legitimacy; ↑ by increasing inclusiveness of expertise from formally excluded groups
legitimacy	↓ by changing the focus of the resulting information and therefore its usefulness to defined users ↑ by increasing inclusiveness ∴increasing participation of decision makers	↓ by "tainting" science with politics ↑ by increasing the inclusion of different knowledges	-

Source: Cash et al 2003.

Trade-offs and their balances are context specific, and depend on contextual factors such as the stage of the policy cycle and the specific values and culture of the stakeholders (Sarkki et al. 2014). The analysis of these trade-offs is further developed empirically by Sarkki et al. (2014), who identify four practical trade-offs between CRELE attributes: use of actors' time (interfacing VS other activities); clarity-complexity (simple message vs communicating uncertainty); Speed-quality (timely outputs VS in-depth quality assessment and consensus building); and push-pull (supply VS demand-driven). These trade-offs and synergies are summarized in the figure below:

Figure 6: Synthesis of trade-offs



Source: Sarki et al 2014.

They distinguish between trade-offs that are fundamental (i.e. they cannot be resolved under any circumstance), resource dependent (can be solved with additional resources), context specific (acute only in some contexts) or dynamic (changing with the evolving context).

2.6.2. Managing boundaries and constructing CRELE

Cash et al (2002, 2003) argue that the effective balancing of these trade-offs requires work to manage the construction, bridging and maintenance of boundaries between knowledge and action (science and policy) in ways that simultaneously enhance the Credibility, Relevance and Legitimacy of the information they produce. Their analysis focuses on the organizational structures and strategies employed by successful advisory organizations in the environmental domain.

In this analysis, effective scientific advisory bodies perform ‘‘boundary management’’ functions and are conceptualized as boundary organizations characterized by cross-boundary participation, dual accountability to both the scientific and policy domains, and acting as sites of co-production of boundary objects such as models and assessments. **Dual accountability** ensures effective information flows and force boundary managers to address the interests, concerns, and perspectives of actors on both sides of the boundary. The production and use of **boundary objects** can enhance the Relevance of the advice produced as it engages end-users early in defining needs, Credibility

by bringing multiple types of expertise to the table, and Legitimacy by involving multiple stakeholders in the production process. Moreover, as boundary objects can be “used by individuals within each for specific purposes without losing their own identity” (Star and Griesemer 1989), their flexibility allows different actors to value them in ways that best suit their interests and that mitigate trade-offs between Credibility, Relevance and Legitimacy.

Effective advisory organisations engage in communication, translation, mediation and coordination as **strategies** to perform their boundary management function. They ensure active, iterative, and inclusive **communication** between experts and decision makers to enhance the CRELE of their advice. One-way and infrequent communication can hinder Relevance, for example if experts unilaterally assume what questions would meet the needs of policymakers or address yesterday’s problems as communication only happens at the outset of the process, Credibility if questions are framed in terms that don’t lend themselves to a scientific characterization, and Legitimacy if stakeholders from either side see themselves as excluded from relevant dialogues. Working across boundaries requires overcoming differences in jargon, language, interpretation, and presumptions about what constitutes persuasive argument that can be a barrier to communication. Effective scientific advice requires **translations** that enables mutual comprehension despite such differences. Importantly, Cash et al (2002) recognize that translation capacities are facilitated by individuals who have experience and knowledge of the different domains and are comfortable conversing in multiple “languages”.

As trade-offs and tensions between the CRELE attributes are often fundamental and cannot always be resolved merely by improving understanding, addressing them requires **mediation** between conflicting interests. Mediation is achieved by actors making *“the boundary selectively porous, allowing bridging the boundary for some purposes (e.g., getting user research needs to researchers), but keeping the boundary solid for others (e.g., keeping the scientific process out of politics)”* (Cash et al 2002). A too rigid

boundary makes advice Credible but lacking Relevance, and a too porous boundary risks that policy interests undermine scientific Credibility. **Coordination** is necessary to take advantage of complementary expertises and conceptual frameworks, and to avoid multiple entities producing divergent or mutually incompatible outcomes.

2.6.3. Limitations and further developments

Despite its descriptive value and normative appeal, the CRELE framework has been criticized for being too abstract in its conceptualization of the trade-offs involved (Sarkki et al. 2014); and for not adequately capturing the attributes actually valued by policymakers (Dunn and Laing 2017). Sarkki et al. (2014) for example acknowledge that few studies address what the abstract trade-offs between CRELE attributes mean in practice, and propose to shift the focus from CRELE of scientific knowledge and advice to CRELE of the advisory organization and its processes and operations, and to operationalise the CRELE attributes by distinguishing between objectives, structures, processes and outputs (Sarki et al 2015).

Moreover, as recognized by Heink et al (2015), the concepts of Credibility, Relevance and Legitimacy used in the CRELE framework can sometimes be vague and ambiguous, making their consistent application challenging, especially for evaluative purposes. As they recognize, CRELE attributes are often given different meanings in different SPI contexts and their ambiguous use may result in contradictory findings about the fulfilment of criteria and thus the effectiveness of the SPI, and many perceived synergies between CRELE attributes might actually be cases when the concepts constitute each other. To mitigate this risk, they point to the importance of contextualizing these attributes for the specific SPI under study.

However, while recognizing that the CRELE framework is often used uncritically as a purely descriptive tool for the evaluation of SPIs and SAMs while ignoring its normative dimension, Tangney (2017) argues that critics miss the point of the framework, namely its ability to capture and describe the

tensions arising between political and expert authority in public decision making, and defends its use as a useful heuristic for the study of scientific advice.

Acknowledging these limitations, the CRELE attributes are employed in this thesis as a heuristic framework to guide the analysis and explore how scientific advice practices contribute in various ways to the effectiveness of scientific advice and to the management of tensions and competing demands between science and policy, rather than as rigorous analytical categories in themselves or as a strict evaluative framework. Their potential ambiguity and context-specific validity is recognized throughout the analysis, and reflected upon in the conclusions.

Throughout the thesis, the terms "credibility", "relevance" and "legitimacy" appear used both as actors' and analysts' categories (Collins 2008). When used to refer to the attributes conceptualized in the CRELE framework the terms are capitalized. On the other hand, when used by the actors in the documents and interviews cited the terms are left in lower case, and their meaning might differ from the CRELE usage. For example, while Credibility in the context of the CRELE framework refers mainly to the scientific domain and adequacy to scientific standards, some of the SAM documents analysed in the thesis refer to a broader idea of public credibility, which partially overlaps with the CRELE attribute of Legitimacy.

Despite these further conceptual refinements and articulation however, the literature on CRELE remains focused mostly on the level of institutions, which represent the main unit of analysis. Cash et al (2002) focus on “organizational structures and strategies”, while Sarki et al (2015) address “features” of SPIs. As discussed in the next two sections, this limits the explanatory power of the framework, which would benefit from considering the roles of the individual actors working within these organizations, and the specific practices through which they carry out the necessary boundary work.

2.7. Understanding policy to construct Relevance

As discussed above, for scientific advice to be relevant for policymakers it needs to timely reach them in the policymaking process, to address their needs and issues that are on their agendas, and to take into account the constraints and specificities of the policy context. Similarly, in their study of the authority of scientific advice Bijker, Bal, and Hendriks (2009) argue that for scientific advice to be useful it must be designed to help policymakers set and attain their goals. To ensure Relevance it is necessary that *"the practices to which the advice applies are already taken into account in the process of generating and articulating that particular advice*" (Bijker, Bal, and Hendriks 2009:44). It is thus necessary that those involved in producing the advice have an understanding of the specific policy cycle, actors and processes being targeted (Haas 2004), an appreciation of their needs and motives, and the ability to communicate their messages in a clear and timely manner.

However, as demonstrated by studies of evidence informed policymaking, (aspiring) scientific advisors and academic experts often lack exactly this understanding, instead relying on simplistic representations and idealized model of how policymaking should work. In a large proportion of the literature on the barriers to the use of evidence, for example, recommendations by scientists on how to improve the use of scientific evidence in policy are based on a simplistic understanding of policymaking, drawn either from the scientists own personal experience, which by its own nature is limited as they rarely have direct access to policymaking processes, or from outmoded models of policymaking, such as policy cycles, which focus on a centralised picture of policymaking divided in clear stages (Cairney 2016).

The empirical study of policymaking shows that the abstract idea of a policymaking “cycle” divided into discreet stages, as presented for example in the guidance issued by the UK Treasury (HMT 2003) and often employed by scientists in discussions of the science-policy interface, is of limited value. This is because it does not reflect the iterative and sometimes disordered dynamics

of the actual process. The limitations of such schematic and rational models of policymaking are widely acknowledged, both in general (see for example Hallsworth, Parker, and Rutter 2011) and specific context of the use of evidence in policy (Cairney 2016). Moreover, it is acknowledged that such rational models are of little use in guiding action: as they describe an idealised process that does not reflect real practice, following any guidance that rests on them would not lead to the desired outcomes (Hallsworth, Parker, and Rutter 2011). Instead, as recognised by Maybin (2015), these rational models of policymaking are invoked by civil servants to legitimise (internally and externally) work already done.

In contrast to these simplistic rationalization of the policymaking process, scholarly studies show that “policy” and “policymaking” encompass a much broader and more complex set of activities. At the most abstract level, policy can be intended as the sum of government actions to achieve a specified outcome. In practice, “policy” can mean anything from a major legislative initiative to the regulation of local activities, or to infrastructure spending. Policy might also be unstated, or require inaction rather than action (Hallsworth, Parker, and Rutter 2011). Although these outputs and activities might share some common features, each of them has its own specific dynamics. Policymaking is not a single act localised in space and time, nor the exclusive remit of an individual actor, such as a minister of permanent secretary. Rather, it is a complex, diffused, and often iterative process, where start and end can only be reconstructed in retrospect. It involves several actors, including individuals, groups, and organisations, and is governed by multiple institutions (Bevir 2012). Power is usually diffused across the system, rather than being firmly in the hands of those actors at the top of formal hierarchies (Cairney 2016).

A seminal ethnographic study of policy making in practice by Page and Jenkins (2005) for example, focusing on the work of mid-level civil servants in the UK government, challenges the often-held image of policymaking as a strongly top-down endeavour. One of the main points argued in the study is that, even in

large government organisations like the UK civil service, mid-level bureaucrats have substantial influence on the direction of policymaking. Rather than being limited to implementing or embellishing with details decisions taken at the top of the bureaucracy, in an almost mechanical way, these actors are constantly taking decisions that shape the course of policymaking. Formal guidance is often not effective in limiting discretion and produce consistent decisions as bureaucrats have signification discretion in how they apply the guidance and rely on their own judgment (Bernstein and Mertz 2011). Interestingly, civil servants themselves often resist such characterisation, as it is perceived as going against the ideal of democratic accountability where all decisions are taken by elected officials (Maybin 2015).

Moreover, policymakers are not simply passive receivers of advice and are often also experts themselves. Work by Page (2010), comparing the relationship between civil servants and experts in several countries and in the EU, shows how 'bureaucrats' can be experts in their own right (technical, legal, economic, or of policy process itself), mobilisers of expertise, receivers, or intermediaries. Recognising this means to accept that researchers and policymakers might have different views of how to achieve good policy, and what the proper role of science is in it. Political feasibility (whether a certain initiative is politically acceptable), for example, can be as important as technical feasibility (whether a certain initiative can have the expected outcomes) for a policymaker (Cairney 2016). As the two groups have different aims and different sense-making strategies, advisors bridging between them need to understand the epistemic logic of each group and successfully negotiate such differences to be effective (Pedersen 2014).

These complexities can be a significant barrier to the Relevance of scientific advice, especially for advisory mechanisms that rely heavily on scientific experts drawn from academia, who have limited or no knowledge of and access to the reality of policymaking processes and practices and are purposefully kept at arm's length from it to ensure their independence, as it's often the case in the European Union (see 3.2).

2.8. The study of scientific advice in practice and the role of secretariats

In the study of expert advice, the theatrical metaphor of distinguishing between frontstage and backstage has been employed as a useful heuristic tool to explore how expert bodies construct and enact their scientific and political authority by selectively revealing some of their workings (Hilgartner 2000). While part of the advisory process is externally visible, such as some of its meetings and the reports it produces (frontstage), a large part happens "behind the scenes" (backstage), for example the selection of the experts to be involved and the negotiations over what exactly is included and what is left out from the mandate or the advisory report. Understanding what happens in the backstage, and how what to move from back- to frontstage to be presented publicly is selected (stage management), is a powerful approach to understand the boundary management strategies are used in practice to construct the Credibility, Relevance and Legitimacy of the scientific advisory process and its outputs. The aim is to understand how the political and societal dimensions the advice is directed to are incorporated upstream in its production (Bijker, Bal, and Hendriks 2009).

Similarly, academic policy studies have in recent years taken a 'practice' turn, recognising that a focus on institutions, processes and outputs is not sufficient to explain the richness of policymaking (Freeman, Griggs, and Boaz 2011). This recognition has led to an increased attention to ethnographic studies of policy organisations, and the study of individual's decision-making in the context of behavioural psychology. These approaches provide important systematic insights into how the everyday practice of policymaking differs from theoretical models based on the study of processes and outputs. As recognised by Oliver, Lorenc, and Innvær (2014) *"understanding the daily lives and activities of policy actors can bring fresh insights into how 'evidence' is conceptualised, the potential roles it may play, and how it fits with the other drivers and triggers which affect policy".*

For these reasons, this thesis proposes to go beyond the institutional design features and abstract strategies identified in the literature on boundary management and CRELE, and look at the specific practices of the actors involved in the advisory process, and their respective roles.

In particular, this thesis focuses on the division of labour between the scientists and experts serving in a scientific advisory role (the advisors), and the professionals supporting them throughout the production of scientific advice and in interactions with policymakers (the secretariat). As recognized in the literature, secretariats play a central role in scientific advice organizations, and in particular in boundary management and contributing to CRELE. As recognized by Guston (2001), one of the characteristics of boundary organizations is that they involve not only actors from both sides of the science-policy boundary (dual participation), but also *"professionals who serve a mediating role".* Cash et al (2002) acknowledge that "*While more research needs to be completed on the role of individuals, preliminary findings suggest that is often individuals who have legitimacy or credibility on both sides of a boundary that are especially useful in making this bridge*", and *"translation capacities are facilitated by […] people, who as individuals, bridge boundaries and are comfortable conversing in multiple "languages"."* As shown in this thesis, members of advisory bodies secretariats have exactly these features. As recognized by De Donà (2021) the role played by secretariats in science-policy bridging is currently poorly understood and would therefore benefit from further research.

2.9. Conclusions and reframing of the research questions

The literature discussed in this chapter provides a range of useful insights and concepts to understand the dynamics of scientific advice. The social studies of science have convincingly shown the socially constructed and value-laden nature of scientific knowledge, and what this means for the separation between science and policymaking. The work of STS scholars such as Jasanoff (1990) has clearly established the political nature of the work of scientific advisors, and the implications of this for contemporary democratic societies and the role of

scientific expertise in them. Scientific advice is conceptualized as a boundary management activity, and its effectiveness understood as the balance between Credibility, Relevance and Legitimacy (CRELE).

However, while the literature on scientific advice remains focused mostly on institutional design features and abstract strategies, with little indication of who does what in practice, both STS and policy studies point to the importance of a fine-grained understanding practices. While the CRELE framework is a useful heuristic for analysing and assessing the effectiveness of scientific advice, to fully realize its analytical potential its focus needs to be expanded beyond institutional features and abstract strategies to include all actors involved in the advisory process (not just experts and policymakers), and the day-to-day practices they employ in their boundary management.

In light of the insights from the literature and the theories of scientific advice reviewed above, the key terms of the original question “What determines the effectiveness of science advice mechanism?” can be unpacked and reframed through these theoretical lenses. For the purpose of this thesis, scientific advice is conceptualized as a boundary activity between science and policymaking, requiring constant work to establish its epistemic authority and effectiveness. The specific arrangements in place to carry out this boundary management are culturally dependant and unique to each specific context. The effectiveness of scientific advice is framed in terms of the CRELE attributes (Credibility, Relevance and Legitimacy), acknowledging their inherent tension, local specificities, and the need to constantly manage the trade-offs.

To address the gaps identified above, this thesis proposes to extend application of the CRELE framework from the institutional features of SPIs to the practices of scientific advice, focusing on the roles of the different actors involved in the advisory process to interpret how each contributes to its effectiveness. In particular, the thesis focuses on the division of labour between the scientists and experts serving in a scientific advisory role (the advisors), and the

professionals supporting them throughout the production of scientific advice and in interactions with policymakers (the secretariat).

The central research question is therefore rephrased in theoretical terms as follows:

How are Credibility, Relevance and Legitimacy constructed in the practice of scientific advice to policy?

This main research question is further declined in the following sub-questions:

- How is each attribute operationalized in the given context?
- How is each attribute constructed in practice?
- How are boundary management strategies used in practice?
- What are the respective roles of the various actors involved?

As discussed in the next chapter, these questions are investigated in the specific context of policymaking in European Union institutions.

3. Scientific advice in European Union policymaking

As discussed in the introduction, the geographical and empirical focus of this thesis is on scientific advice in the context of policymaking in the European Union (EU) and its institutions. This chapter provides an overview of the central role played by scientific knowledge and expertise in EU policymaking and its evolution, and articulates why the EU makes a particularly interesting locus for the study of scientific advice to policymaking. It then presents the rationale for choosing each of the two specific case studies analysed in this thesis, and some background necessary to contextualise the detailed empirical analysis provided in the subsequent chapters.

3.1. The role of scientific advice in EU policymaking

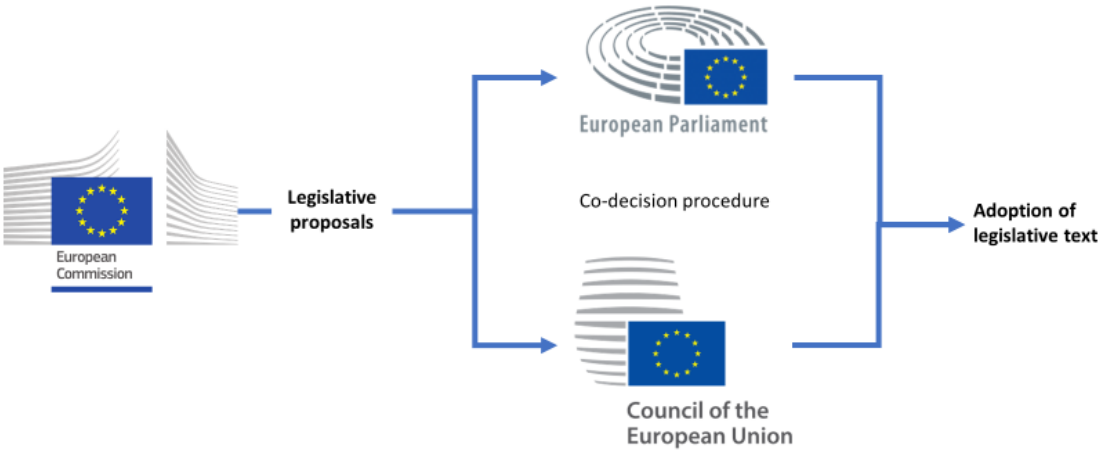
Scientific advice plays a particularly central role in the policymaking processes of the European Union (EU). Due to the supranational nature of the EU and its history of integration, EU policymaking tends to cover a large number of technical areas relying heavily on expert advice, such as setting common standards (Kaiser and Schot 2014) and regulations for the integration of the common market (see for example Alemanno 2008). Some scholars even describe the EU as a "regulatory state" (Majone 1997) which exercises its power mainly through regulations, rather than through providing its citizens with services as in the traditional contemporary model of welfare state. Advice from scientific and technical experts therefore plays a central role in EU policymaking (Alemanno 2014), making it an especially interesting site for research on scientific advice. As recognized by the former Chief Scientific Adviser to the EU President, Anne Glover, *"EU policies are much more technical than national policies; this is because the bulk of them are about standardisation and harmonisation, which at the end of the day boils down to scientific-technical matters. Science is therefore crucial at the EU level"* (in Wilsdon and Doubleday 2015).

The EU institutions themselves recognize the centrality of scientific evidence and expertise in EU decision- and policy- making. For example, the 2002 *Communication on the Collection and use of expertise* sets out the

Commission's guidelines and principles for improving the knowledge base for better policies, aiming to "*encapsulate and promote good practices related to the collection and use of expertise at all stages of Commission policy-making*".[2] More recently, in the 2021 Communication on the *"better regulation"* agenda, the overarching framework for good policymaking at the EU level, scientific evidence is explicitly recognized as a *"cornerstone"* of good policymaking, *"vital to establishing an accurate description of the problem, a real understanding of causality and therefore intervention logic; and to evaluate impact*".[3]

The EU policymaking process follows the so-called *co-decision procedure* (now referred to as *Ordinary Legislative Procedure*).[5] The Commission, which represents the executive branch of the European Union, elaborates and adopts legislative proposals. This involves consulting with stakeholders and the public, and assessing a policy's potential economic, social, and environmental impacts. To become laws, the proposed text needs to receive the approval of both the European Parliament, directly representing the citizens of the EU, who elect its members, and the European Council, representing the governments of EU member states. A schematic overview of this process is presented here:

Figure 7: EU legislative process



[2] European Commission Communication on "the collection and use of expertise by the Commission: principles and guidelines - Improving the knowledge base for better policies" (2002) - https://op.europa.eu/en/publication-detail/-/publication/969f5240-ec81-4998-911e-6831d9318919/language-en/format-PDF/source-search (retrieved on 12/11/2023)
[3] European Commission Communication on "Better Regulation: Joining forces to make better laws" (2021) - https://commission.europa.eu/system/files/2021-04/better_regulation_joining_forces_to_make_better_laws_en_0.pdf (retrieved on 12/11/2023)

Source: Author's elaboration

Within the broader domain of EU policymaking, this thesis focuses on scientific advice to the European Commission. As the EU executive branch, the Commission has the prerogative to propose legislation (referred to as legislative initiative) to the European Parliament and Council and is responsible for implementing their decisions. For this reason, the Commission can be considered the most "technical" of EU institutions, akin to national ministries and government departments, relying heavily on the expertise of civil servants and external experts. This has also led to the perception of it being an excessively "technocratic" institution, lacking adequate democratic accountability. The Commission receives scientific advice from multiple sources including specialized scientific and regulatory agencies; advisory committees; its own in-house scientific service, the Joint Research Centre (JRC); and the Group of Chief Scientific Advisors (GCSA, which operates as part of the Commission's Scientific Advice Mechanism).

3.2. European civic epistemology

As discussed above (2.2), the credibility of scientific claims is socially constructed and always the product of value judgements. The political and cultural context in which such judgments are made is therefore important to understand how credibility of scientific advice is constructed in each specific context. Despite its appeal to universal notions of science, scientific advice is deeply cultural, and the structures and practices through which knowledge is produced and validated tend to be shaped by the political and institutional cultures from which the scientific advisory system emerges. In her seminal comparative study of biotechnology governance in the US, UK, and Germany, Jasanoff (2005) recognises that the social framing of scientific issues of policy relevance is different across countries, as are the reasoning styles used to legitimise knowledge in public decisions. For example, she identifies the UK system as relying on the scientific standing of individual experts to legitimise their advice, while Germany employs a more collegial approach with a range of experts representing the social parts involved.

These public reasoning styles are referred to as *civic epistemologies*, *"the institutionalized practices through which members of a given society test and deploy knowledge claims used as a basis for making collective choices"* (Jasanoff 2005:255). Such practices include the ways to produce, express, validate and challenge public knowledge claims; the availability and functioning of accountability mechanisms; the accepted standards of objectivity; and the criteria concerning what counts as expertise and it is publicly performed. Miller (2005) further articulates the concept of civic epistemology as *"the broader array of activities, social processes, informal practices, and institutionalized procedures by which people collect, aggregate, validate, and wield claims to knowledge about nature and society in public and policy settings."* The concept proves useful to understand the variability of approaches to scientific advice existing at the EU level, and the context-dependency of the perception of CRELE attributes, of their trade-offs, and of the strategies to construct and manage them.

As a unique multi-level governance structure without a well-defined common polity or political sphere, the EU does not necessarily have a single cohesive culture of how scientific knowledge and evidence is used in policymaking, and its many diverse national civic epistemologies still play a prominent role. The EU is characterised by both a broad political and cultural diversity among its constituent parts, and the need for common policy decisions to be taken. This tension is well captured in its motto *"United in Diversity"*.[4] While objective (and therefore shared) factual knowledge is often appealed to in the attempt to reconcile these diverging and sometimes conflicting values and reach common decisions, the challenges emerging from this diversity are well-recognised. The 2001 *White paper on European governance*[5] recognizes the principle of plurality as one of the key tenets of expert advice in EU policymaking, while the 2002 *Communication on the Collection and use of expertise* acknowledges that "*Acting at the European level introduces additional challenges. European*

[4] https://europa.eu/european-union/about-eu/symbols/motto_en (retrieved 12/11/2023).
[5] European governance - A white paper (2001) - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52001DC0428 (retrieved 12/11/2023).

approaches must accommodate the diversity of national situations. Questions of comparison, harmonization, validation, and interoperability are often key elements in the policy process".[6]

Despite these challenges and complexities, however, as recognized by Joly (2016) some unique characteristics of a distinct civic epistemology emerging in the context of EU-level policymaking can be identified, namely a primacy of "laboratory science" over "regulatory science" (cf. Jasanoff 1990) in risk assessment, and an inclusive and pluralistic approach to expert assessment. Joly argues that, in the context of food safety policy, the authority of the scientific advice produced by the European Food Safety Authority (EFSA) rests on the centrality given in the risk assessment process to a committee of "laboratory scientists" drawn mostly from the academic sector, who are assisted by the EFSA staff in the evidence collection and analysis. This is markedly different from other contexts such as the US Food and Drugs Administration (FDA), where the bulk of the advisory work is done by in-house staff and outputs are validated by external peer review. The credibility of EFSA's experts is based on their scientific (mostly academic) credentials and their research expertise in a laboratory setting, which is then brought to relevance onto the regulatory domain, rather than on the in-depth expertise on the topic at stake or regulatory science more broadly. This choice was made when the EFSA was being designed because *"it was thought that by involving the "best scientists" (rather than experts in regulatory science), the confidence of the European public would be regained"* (Joly 2016:302).

3.3. The co-evolution of scientific advice and food safety policy in the EU

The institutional arrangements that underpin scientific advisory mechanisms are historical products, which continuously evolve to adapt to a dynamic scientific and political landscape. The EU institutional ecosystem of scientific advice, and the conception of the science-policy relationship and the civic

[6] European Commission Communication on "the collection and use of expertise by the Commission: principles and guidelines - Improving the knowledge base for better policies" (2002) - https://op.europa.eu/en/publication-detail/-/publication/969f5240-ec81-4998-911e-6831d9318919/language-en/format-PDF/source-search (retrieved on 12/11/2023)

epistemology on which it is based, have been evolving since the establishment of the EU. In particular, as recognized by Millstone (2007) in the late 1990s and early 2000s, a shift away from the technocratic model of science-policy relationship took place in Europe, largely in response to several food and chemical safety issues in previous decades.

In the context of EU policymaking, food safety represents a privileged policy area to research scientific advice, as it is framed in scientific terms and its evolution has influenced the broader normative and institutional development in the use of scientific knowledge and expertise in EU institutions. Historically, the creation of a common market for food and agricultural products has been a key component of the process of EU integration and required among other things the harmonisation of food safety standards to enable the free flow of products within the Union. For this reason, EU food policy is considered a key constituent area of EU policy, and its development and evolution are considered to offer an interesting window on EU regulation and EU policymaking more generally (Alemanno 2008: 24).

The food safety crises in the late 1980s and 1990s represent a watershed separating two distinct periods in the evolution of modern food safety policy institutions, and eventually led to a shift in the institutionalisation of expert advice and its relationship with the public in the EU (Millstone and Van Zwanenberg 2002; Stilgoe, Irwin, and Jones 2006).

In the old institutional ecosystem of scientific advice, the functions of risk assessment and risk management were normally in the hands of the same institutions, and scientific uncertainties were underplayed and often concealed to the public. Millstone and Van Zwanenberg (2002) identify several structural and procedural features characterising food safety policymaking and advisory systems until the 1990s. These included the conflation of consumer protection and industrial and trade promotion; a lack of openness and accountability; advice being provided by small group of scientists with industry ties; policy decisions presented as being based on "sound science" (Jasanoff 2011) alone,

concealing almost all of the conflicting policy objectives, implicit framings, uncertainties, and residual risks; policymakers hiding behind scientific experts; and more generally a conflation of risk assessment and risk management. According to Millstone and Van Zwanenberg (2002, 594), these arrangements meant that food policy decisions *"could be, and were, taken to advance commercial and political ends as distinct from the ostensible policy goal [of food safety]*". These factors severely undermined the democratic legitimacy of such systems.

A number of food safety crises in the late 1980s and 1990s, most notably the 1996 Bovine spongiform encephalopathy (BSE, also known as the Mad Cow disease) outbreak in the UK, provoked serious loss of public confidence in food safety and the policy institutions governing it, undermining the legitimacy and trustworthiness of the old system and leading to the establishment of the current food safety policy regime (Millstone and Van Zwanenberg 2002). This has led to a *"range of structural and procedural reforms to the ways in which public policies are decided, legitimated and communicated"* (Millstone and Van Zwanenberg 2002:594). As a key element of these reforms, the provision of scientific advice on food safety (RA) was separated from the process of making policy decisions about it (RM).

In the case of the European Union, food safety has always been an area of central policy concern, given the importance of setting common standards to enable a common market for agricultural products. Originally, food safety was responsibility of DG-III, the old Directorate-General responsible for industry and trade, thus conflating the regulation and promotion of the food sector under one institution. As part of the shift away from the technocratic model of science-policy relationship (see 2.3.3), the responsibility for providing scientific advice on food safety was moved to the Directorate-General responsible for health and consumer protection (later known as DG SANCO), while regulatory authority remained within DG-III. This initial move brought increased transparency and openness. Currently, the EU food safety policy regime is rooted in a 2000 White Paper published by the European Commission

(Commission of the European Communities 2000) following a further crisis over dioxin in animal feed (Millstone and Van Zwanenberg 2002). It stipulated a further separation of the regulation of food safety from sponsorship of relevant industries by moving the responsibility for consumer protection and food safety to DG SANCO. It also proposed establishing a separate entity to provide independent scientific advice, a European Food Authority, to act as a separate risk assessment body to advice the European Commission, with the latter retaining the function of risk manager.

After lengthy political negotiation, this led to the adoption of the 2002 General Food Law Regulation and the establishment in 2004 of the European Food Safety Authority (EFSA), thus enshrining a separation between RA and RM in the institutional architecture. As identified by Millstone and Van Zwanenberg (2002), this institutional shift was also followed by a change in the rhetoric used to legitimize food safety policy. The emphasis was on “independency” of the agencies and of the experts involved in the process, without however clarifying what previous dependencies they were now free from. This could be interpreted as independence from commercial and industrial interest, but also as independence from political pressures from politicians and government officials (see 5.5). The current regulatory framework of EU food safety tend to emphasise a strong separation between risk assessment, in the hands of advisory agencies such as the European Food Safety Authority (EFSA), and risk management, implemented by the European Commission (Alemanno 2008: 73).

These shifts in the institutionalization of scientific advice in the context of food safety policy influenced the broader conception of the relationship between science and policy in the EU, and motivated the development of the 2002 guidelines on the collection and use of expertise, referred as the “manifesto” of the EU’s regulatory epistemology by Morvillo (2020). For these reasons, EFSA’s work dynamics and scientific advisory process make it an interesting case study to explore the dynamics of scientific advisory committees in EU

policymaking and how CRELE is constructed in its practices, and can provide good insight into EU scientific advice more broadly.

3.4. From a Chief Scientific Advisor to a Scientific Advice Mechanism

In 2009 the then President of the European Commission, José Manuel Barroso, announced his intention, during his second term to review *'the way European institutions access and use scientific advice'* and *'to set up a Chief Scientific Adviser who has the power to deliver proactive, scientific advice throughout all stages of policy development and delivery'*.[7] In 2010, he established the post of Chief Scientific Advisor (CSA) to the President of the Commission, appointing the Scottish microbiologist Professor Anne Glover to the role.

The post was directly attached to the President's office, with a broad mandate which included provision of direct advice to the President; provision of scientific analysis and opinion on policy development and guidance on the interpretation of scientific uncertainties; involvement in strategic emergency planning; building relationship with advisory bodies and the EU and Member States level; scientific foresight; and acting as a public champion and ambassador of the value of science.[8] However, the post was not adequately resourced and institutionalized within the machinery of government of the Commission, leaving the incumbent with limited means to fulfil the mandate and leading to frictions with departments such as the JRC and the Directorate-General for Research and Innovation whose mandate it overlapped (Glover, in Wilsdon and Doubleday 2015).

Moreover, the incumbent got embroiled in a number of public controversies with Members of the European Parliament and NGOs regarding pesticides, endocrine disruptors, and Genetically Modified Organism (GMOs), leading to the Commission publicly distancing itself from her views and testing the limits

[7] Speech by José Manuel Durão Barroso President of the European Commission "Passion and responsibility: Strengthening Europe in a Time of Change" European Parliament Plenary Strasbourg, 15 September 2009 - https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_09_391 (retrieved on 13/11/2023)
[8] Press release, 5 December 201, Appointment of Chief Scientific Advisor - https://ec.europa.eu/commission/presscorner/detail/en/IP_11_1497 (retrieved on 13/11/2023)

of the independence of the role from the Commission itself (Wilsdon and Doubleday 2015). The advisory model centred an individual CSA, inspired by the UK and US, also lead to controversies regarding the appropriateness for the EU of what was perceived as a typically Anglo-Saxon model of scientific advice (see section **Error! Reference source not found.** for an overview of o ther institutional arrangements). In particular, several NGOs publicly criticized the model and called for its scrapping on the grounds that it was untransparent and concentrated too much power into a single unaccountable individual.[9]

At the end of Barroso's presidency in 2014, the incoming Junker Commission decided not to renew the CSA post. However, under pressure from the scientific community it created instead a new Scientific Advice Mechanism (SAM). In this process, the European Commission sought to explore *"how to better institutionalise future independent scientific advice to the Commission, based on the experience made in all Member States"*.[10] (Juncker 2015). The institutional architecture of the newly established SAM is peculiar in having a tripartite structure: a Group of seven Chief Scientific Advisors (GCSA), a consortium bringing together academies of sciences from across Europe (SAPEA), and a professional secretariat hosted by the Commission's Directorate-General for Research and Innovation.

The central element of the SAM, and the main element of continuity with other EU scientific advisory bodies, is the Group of Chief Scientific Advisors (GCSA). Its main task is to *"provide the Commission with independent scientific advice on specific policy issues where such advice is critical to the development of EU policies or legislation and does not duplicate advice being provided by existing bodies"*.[11] The Group is composed of *"up to seven, but no less than five*

[9] Letter from European NGOs to the President on the European Commission on "The position of Chief Scientific Advisor to the President of the European Commission", 22 July 2014 - https://corporateeurope.org/sites/default/files/attachments/ngo_letter_on_chief_scientific_adviser_-_final.pdf (retrieved on 13/11/2023)

[10] "Reply from the President of the European Commission to the Earl of Selborne, Chairman of the Science and Technology Committee and Lord Boswell, Chairman of the European Union Select Committee," January 16, 2015, http://www.parliament.uk/documents/lords-committees/science-technology/roleofchiefscientificadvisers/20150116-President-Junker-reply-role-of-CSA.pdf.

[11] Commission decision on the setting up of the High Level Group of Scientific Advisors (2015, amended in 2023) - Commission decision on the setting up of the High Level Group of Scientific Advisors (europa.eu) (accessed on 13/11/2023).

members, with an outstanding level of expertise and collectively covering a wide range of scientific fields and expertise". Members are *"independent experts, appointed in their personal capacity and who act independently and in the public interest*"[12] for a period of 3 to 5 years, and their mandate is not linked to working on a specific topic. Given the breadth of policy domains on which the SAM might be called to provide advice, subject matter expertise in a specific domain is less important than general scientific standing, as reflected in their selection criteria (see 6.3.1 for a discussion of how members are selected and appointed). The GCSA and the SAM as a whole are supported by a professional secretariat composed of a small number (5-8) of European Commission officials. The secretariat, often referred to as "the SAM unit" or simply "the Unit", plays a central role in ensuring the functioning of the SAM as explored in Chapter 6.

The transition from a single CSA to a committee model represented a better alignment with the Commission exiting practices and structures. The so-called "high-level expert groups" are a common feature of the Commission use of external expertise[13], and existing administrative frameworks and practices could be easily adapted to enable the creation of the GCSA. The Committee structure of the GCSA is an important feature of the SAM and contributes to its legitimacy in the eyes of the EU policy community. Such structural feature better reflects the "collective" style of decision-making in the EU and its pluralistic civic epistemology (see section 3.2) and mitigates against the risk of individual advisors holding idiosyncratic views or close ties to political or economic interest, thus addressing some of the criticism and controversies off the previous CSA post. From a legal and administrative perspective, the SAM is firmly centred on the GCSA, with the secretariat and the SAPEA consortium of academies representing ancillary support structure. The legal basis of the SAM is the 2015 "Commission decision on the setting up of the High Level Group of Scientific Advisors", which sets out the mandate, tasks and main

[12] Ibid.
[13] See the Register of Commission Expert Groups and Other Similar Entities - https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups-explained?lang=en (accessed on 13/11/2023).

working modalities of the Group. In its original 2015 version (slightly amended in 2018 and again in 2023) the concept of a broader SAM is only mentioned once, with no reference to the role of scientific academies and only a passing mention to "secretarial services" to be provided by the Commission.

The second leg of the SAM is composed by the consortium of European Academies of Sciences, SAPEA (Science Advice for Policy by European Academies). The consortium brings together a pan-European academy (Academia Europaea), and four networks of European scientific academies, representing the natural, medical, engineering, and social & human sciences respectively (in some countries one academy covers several of all disciplinary areas, while in others there is one academy for each area). SAPEA receives funding from the European Commission to support its secretariat (separate from the secretariat of the whole SAM, which is hosted directly within the European Commission) and organize communication activities and conferences. The main function of SAPEA is to provide, at the request of the European Commission, *"targeted scientific evidence in a timely and transparent manner to inform the production of science advice by the Group of Chief Scientific Advisors while ensuring the highest scientific quality, developed by complete and independent evidence analysis and synthesis."* To fulfil this function, *"SAPEA assembles interdisciplinary Working Groups of scientific experts"* to *"produce Evidence Review Reports or other scientific inputs for the Chief Scientific Advisors"*.[14] SAPEA thus provides the main link between the SAM and the scientific and research community across Europe.

The SAPEA consortium was created as part of the SAM establishment as a structured mechanism for national academies of science, which in many European countries provide scientific advice to their government, to engage with EU policymaking. SAPEA builds on pre-existing academies networks such as the European Academies Science Advisory Council (EASAC), which had been active for many years producing mostly unsolicited advice in the form of

[14] SAPEA grant agreement, quoted in the SAPEA Guidelines on advising policymakers and society (2019) - https://www.sapea.info/wp-content/uploads/qa-guidelines-2020.pdf (retrieved on 12/11/2023).

advisory reports. However, as observed having worked both for one of the members of EASAC between 2013 and 2015, and later for the SAM, acting at their own initiative without a clear mandate or involvement of policymakers, and often misaligned with the needs and timelines of EU institutions, the advice produced by such networks often had limited relevance and policy impact. At the time of the establishment of SAM, academies and their networks had been vocal about the importance of scientific advice to EU policymaking and their own role in providing it,[15] and bringing them into the newly established SAM was both a way to secure their support for the initiative and leverage their expertise in an institutionalized way.

3.5. Challenges for the institutionalization of EU scientific advice

Despite the efforts put into the institutionalization of the EU scientific advice ecosystem, the provision of scientific advice to EU policy remains fragmented at an institutional level, as starkly exposed during the COVID-19 crisis. The 2021 Commission Communication on "*Drawing the early lessons from the COVID-19 pandemic*" recognised that *"the early months of the crisis exposed the uneven level of research and advice in different Member States, as well as the different approaches taken to providing and using that advice. This meant that evidence was patchy, sometimes contradictory and often confusing as a result of different messaging in different Member States"*. The Communication calls for more coordination at the EU level on scientific advice and points to a *"need to bridge the gap between science and policymaking"*.[16] This fragmentation goes beyond the specific context of COVID and pandemic response and is a more general feature of the current EU science for policy ecosystem.[17]

[15] Letter from European Academies and Academies Networks to the President Designate of the European Commission, 4 July 2014 - https://easac.eu/fileadmin/PDF_s/Letter_Juncker_4July14_web_vs.pdf (retrieved on 12/11/2023).
[16] European Commission Communication on "Drawing the early lessons from the COVID-19 pandemic" (2021) - https://health.ec.europa.eu/publications/communication-early-lessons-COVID-19-pandemic_en (retrieved on 12/11/2023).
[17] European Commission Staff Working Document on "Supporting and connecting policymaking in the Member States with scientific research" (2022) - https://knowledge4policy.ec.europa.eu/evidence-informed-policy-making/commission-staff-working-document-science-policy-member-states-%E2%80%93_en (retrieved on 12/11/2023).

To this day, the provision of scientific advice to EU institutions remains a crucial and contested issue. On the one hand, science is presented as necessary to ensure good policy outcomes, especially in the face of the perceived rise in the politicization of facts and of fake news and misinformation (Group of Chief Scientific Advisors to the European Commission 2019). Reliance on experts and scientific advice is presented as a necessary bulwark against populism. The 2022 Commission paper on *Supporting and connecting policymaking in the Member States with scientific research* acknowledges that "*in this era of complex policy challenges, it is key that policymaking makes best use of scientific knowledge. This is not only a much-needed response to the complexity of climate change, global pandemics, artificial intelligence etc. It also recognises the complex political environment in which policymaking takes place now. A better use of science can help boost public trust in governments and their competence. It can help explain better the policy choices to the public, fight disinformation and improve support and implementation of adopted policies"*.[18] On the other hand, scholars and civil society groups have denounced how the processes and logic of scientific advice and use of science in regulatory processes have been captured by narrow interest groups (for example Saltelli et al. 2021), thus making them fertile grounds for lobbying in the name of "sound science" (Jasanoff 2011).

The EU is thus a particularly interesting locus for the study of scientific advice, as it comprises a diverse polity that nevertheless strives to reconcile plural values in common decisions over techno-scientific issues, to achieve epistemic and normative consensus despite underlying differences of both values and epistemology. For these reasons, this thesis focuses on the dynamics of scientific advice in the specific context of the EU. The research questions relating to the Credibility, Relevance and Legitimacy (CRELE) of scientific advice in the EU addressed here are not only of scholarly interest, but also

[18] European Commission Staff Working Document on "Supporting and connecting policymaking in the Member States with scientific research" (2022) - https://knowledge4policy.ec.europa.eu/evidence-informed-policy-making/commission-staff-working-document-science-policy-member-states-%E2%80%93_en (retrieved on 12/11/2023).

central to inform the design of better policy institutions in the EU and the furthering of the European political project.

3.6. Case studies of EU scientific advice

To understand how CRELE attributes are constructed in the practice of scientific advice to policymaking in EU institutions, this thesis analyses two detailed case studies of scientific advice in the EU context. Each case study focuses on a different organization providing scientific advice to EU policymaking, and specifically to the European Commission. These are respectively the European Food Safety Authority (EFSA) as a sector-specific advisory agency which provides advice on issues related to food safety policy (case study 1); and the Scientific Advice Mechanism (SAM), which provides more broad-ranging advice on a wide variety of policy issues (case study 2). The two organizations have similarities and differences, and these two case studies together provide a good perspective on the practices of scientific advice to policymaking at the EU level, and how CRELE attributes are constructed in this context.

3.6.1. Case study 1: the European Food Safety Authority (EFSA)

The first case study proposed for this thesis focuses on the work of the EU agency providing scientific advice on EU food safety policy, the European Food Safety Authority (EFSA). As discussed earlier in section 3, food safety represents a privileged policy area to research scientific advice in the context of EU policymaking due to its clear framing in scientific terms, and its evolution having influenced the broader normative and institutional development in the use of scientific knowledge and expertise in the EU institutions. As discussed, ESFA was established as part of a major shift in the conception of the relationship between science and policy in Europe in response to key incidents like the Mad Cow disease and has provided the model for the establishment of several other scientific advisory agencies in the EU.

Within the broader work of ESFA, the case study analysed here takes as an example of the EFSA scientific advisory process its work on producing a

scientific opinion on animal cloning for food purposes in 2008, and its subsequent follow-ups. The specific topic of cloning is chosen because, unlike other issues related to EU food policy such as the landmark disputes on genetically modified organisms (GMOs), cloning is a policy issue that emerges and plays out almost entirely at the level of EU policymaking, rather than "escalating" from the national level. As recognised by Joly (2016), cloning is different from other biotech governance cases like those of agricultural GMOs, stem cells and new reproductive technologies explored by Jasanoff (2005). While in these cases interactions between science and politics played out mainly at the national level, as highlighted by Jasanoff's focus on US, UK, and Germany as case studies, in the case of animal cloning for food purposes the issue initiated at the EU level, and Member States only played a "marginal or indirect role" (Joly 2016). For this reason, cloning is a particularly good example of scientific advice at the EU level, as European policy institutions and their scientific advisory mechanisms dominate the issue, rather than national ones.

3.6.2. Case study 2: the Scientific Advice Mechanism (SAM)

The second case study focuses on the Commission's Scientific Advice Mechanism (SAM), a relatively novel and broad-ranging advisory organizations in the EU. The work of "sectorial" scientific advice bodies like EFSA, which focus on a specific policy area and mostly cover the domain of regulatory science is complemented by that of advisory bodies with a more wide-ranging and strategic remit. As discussed above, while sectorial scientific advice has a long history in the context of EU policymaking, it is only recently that a more "strategic" scientific advisory function has been introduced to complement existing structures of more technical nature and specialized agencies such as EFSA. Given its recent establishment, no in-depth academic studies of the SAM and its functioning have yet been published, and the available scholarly literature refers to the initial debates around its establishment rather than its functioning.[19] Yet the establishment of the SAM represents an important

[19] A search in the Scopus and Web of Sciences databases using the terms "scientific advice mechanism" OR "science advice mechanism" AND "European Commission" in the abstract, title and keywords fields returned 6 and 11 results respectively. These results are either news items commenting on the establishment of the SAM, or articles citing or engaging with the specific content of its advice without discussing its production (search performed on 13/11/23).

development in the landscape of scientific advice in the EU, and its unique features make it an interesting case study to understand the functioning of scientific advice in EU policymaking. This thesis proposes to address this gap in the literature by exploring an empirically novel case study of the structure, functioning, and internal dynamics of the SAM.

The choice of SAM as case study to research the practices of scientific advice in EU policymaking, and how CRELE attributes are constructed in this context, is dictated by a number of reasons. The SAM's function to provide strategic and cross-cutting scientific advice to the political leadership of the European Commission distinguishes it from other advisory bodies operating at the EU level. While the advice provided by specialized bodies like EFSA is clearly targeted at informing a specific piece of regulation or policymaking, SAM's advice is often more open-ended and systemic, cutting across several policy areas. This has interesting implications for how the policy relevance of its advice is constructed. The SAM also presents some unique institutional design features that combine continuity and discontinuity with previous EU scientific advisory bodies, representing both an instance of path-dependency and of policy experimentation. The SAM combines a traditional scientific advisory committee model, which represents a mainstay of scientific advice in EU institutions and EU policymaking more broadly with a novel institutionalized mechanism to engage the scientific and academic community at large, supported by a dedicated secretariat. In this regard, the SAM is explicitly designed around the concept of boundary organizations.

Beside these intrinsic features that make the SAM an interesting case study of scientific advice in the EU, a further reason for its selection is the unique access I enjoyed to its inner working, having worked as part of its secretariat for a total period of 26 months (first as a trainee between March and July 2018, and then as Policy Officer between October 2020 and June 2022). This privileged access allowed me to observe first-hand and partake into its working practices behind the scenes, thus affording me unique perspective from which to explore the key

questions of how CRELE attributes are constructed in the practice of scientific advice to EU policymaking.

3.6.3. Similarities and differences between the two case studies

The two proposed case studies of EU scientific advisory bodies present both commonalities and differences. Most importantly, both advisory bodies are centred on a committee of (mostly academic) scientists supported by a secretariat, a central feature of EU scientific advisory bodies. Both provide advice to the European Commission as their main policy client, and act at its request. However, while EFSA mostly provides advice on specific issues linked to regulatory policy, the SAM has a broader remit to provide scientific advice on more strategic policy issues.

In terms of the institutional design features described in section 2.4, the two advisory organizations share a number of features, as indicated in the table below:

Table 4: Features of EFSA and SAM

Feature	EFSA	SAM
Hierarchical structure	Pyramidal structure of collegial advisory committees	Collegial structure (tripartite)
Formality	Advisory activity takes place within a formal institutional framework	
Formality of the advice	Advice is provided through formal means	
Jurisdiction	European Union	
Funding	Funded from core budget, permanent	Funded from EU research and innovation budget (Horizon) - fixed term
Legal status	Statutory (General Food Law)	Statutory (Commission Decision)
Composition	Externally appointed experts	
Advice commissioning	Advice provided at the request of the European Commission (pull)	Advice provided both proactively (push) and at the

		request of the European Commission (pull)
Openness	Public advice	
Outputs	Published advisory reports	
Target audience	European Commission (DG SANTE)	European Commission (College of Commissioners, individual DGs)
Main function	Scientific advice as primary function	

Source: Own elaboration.

3.7. Conclusions of the chapter

This chapter illustrated the centrality of scientific advice in EU policymaking, how it evolved in light of developments in food safety policy in the region, and why the EU is a particularly interesting context to study the dynamics of scientific advice and the functioning of scientific advisory bodies.

In particular, the European Food Safety Authority (EFSA) and the Scientific Advice Mechanism (SAM) were chosen as complementary case studies to be examined in depth in this thesis to understand how CRELE attributes are constructed in the practice of scientific advice to policymaking in EU institutions, and specifically to the European Commission. While the EFSA is as a sector-specific advisory agency providing advice on issues related to food safety policy, the SAM provides more broad-ranging advice on a wide variety of policy issues.

The next chapter discusses the methodology adopted and data sources used to build and analyse the case studies. Next, each case study is explored in a separate chapter and interpreted through the lenses of the CRELE framework, describing how each advisory body is structured and operates, the process of constructing science advice, and the respective roles of actors involved.

4. Methodological approach

This chapter presents a reflection on the methodological approach employed in the research conducted for this thesis, the strengths and limitations of the methods and data sources used, and how they are combined to analyse the practices of scientific advice in EU policymaking. The methodological approach for this thesis focuses on the qualitative analysis of two case studies of scientific advice, using documents, interviews and autoethnographic observation as the main sources of data. Personal experience of working in scientific advice is also used to inform the research design and its interpretation and contextualization.

In line with the overall approach in the field of Science and Technology Studies (Latour 1987), and reflecting the conceptualization of scientific advice as a boundary activity presented in chapter 2, this thesis takes a constructivist approach to the study of scientific advice. In this context, what is of analytic interest is not necessarily the scientific phenomenon itself, but rather how society makes sense of it, and according to what (or whose) terms and values it does so. This means that the object of the study are the processes through which the social actors involved attribute such sense and value, thus bringing into the analysis the researcher's own experience and understanding of the phenomenon in question. From an epistemological perspective, an interpretivist approach fits best the purpose of this research as it prioritizes agents' subjective interpretation of facts, understandings of the value and channels through which scientific advice plays a role in policymaking. Consequently, it requires the use of rich qualitative data to allow for an in-depth analysis of the various subjective meanings attributed to scientific advice by different actors within specific contexts to be discussed in the next chapters. Additional qualitative research methods are employed to explore questions outlined next.

The starting point for the research presented here is that the production of scientific knowledge, its mobilization into the domain of policy (scientific advice) and policymaking itself are all social activities requiring boundary work. As the

main focus of this study is to understand the role of actors', practices, actions and decisions in the process of scientific advice, it is necessary to understand their subjective perspective on the topic, i.e., how they attribute meaning to their context and actions (Corbin and Strauss 2015).

4.1. Research design

To address the question of how Credibility, Relevance and Legitimacy (CRELE) are constructed in the practice of scientific advice to policymaking in the EU, this thesis employs a multimethod approach to provide a fine-grained analysis of two case studies of EU scientific advisory organizations, the European Food Safety Authority (EFSA) and the European Commission's Scientific Advice Mechanism (SAM). Primary data for the case studies is collected using three complementary sources, namely documents, interviews, and (in the case of the second case study) autoethnographic observations. Together, these different sources allow to build a more complete picture of the case studies examined, and the triangulation of claims. Data from these different sources is brought together by a common analytical framework (see 4.5) based on the attributes of Credibility, Relevance and Legitimacy (CRELE) of effective scientific advice, and on the boundary management strategies used in their construction (see 2.5). Secondary data from published sources and reports is used to contextualize the case studies, in particular in Chapter 3.

4.2. Case study approach

As discussed, this thesis is based on the analysis of two specific case studies of scientific advisory organizations in the EU to explore how Credibility, Relevance and Legitimacy (CRELE) are constructed in practice in their advisory processes. Case studies are a qualitative research method that involves an in-depth exploration and analysis of a particular instance or phenomenon within its real-life context.

Focusing on case studies is a common approach in the field of STS, especially in the study of scientific controversies, and has fruitfully been used to study both the production of scientific knowledge (examples include Latour and

Woolgar 1979; Wynne 1996; Collins 1981), and its uses in policymaking and expert advice (Jasanoff 1990; Hilgartner 2000; Bijker, Bal, and Hendriks 2009; Camporesi, Angeli, and Fabbro 2022). Case studies are also commonly used in public policy research to study policymaking processes, and understand how policies are designed and implemented. This allows to gain insight not only into the underpinning decision-making processes, but also the political and organizational contexts in which these processes take place (Mills, Durepos, and Wiebe 2010). Indeed, as argued by Yin (2018), case studies are particularly suited when the boundaries between the phenomenon being studied and the context are not clearly evident. This is particularly relevant in the context of the study of scientific advice from an STS perspective, which takes as its point of departure that the distinction between science and politics, and between scientific advice and policymaking, is the phenomenon to be explained rather than the source of explanation (see 2.2.2).

Case studies as a research method are particularly appropriate for explanatory studies aimed at investigating “how” questions, especially in cases where the researchers has limited or no control over the events or phenomena being studied, but direct observation or access to the participants is possible (i.e. contemporary rather than historical events) (Yin 2018). This is particularly relevant for the study of how CRELE attributes are constructed in the practice of scientific advice in the EU. As discussed in the literature (see 2.6), the perception of CRELE attributes and their trade-offs, and the strategies and practices used to construct and manage them, are highly context specific. A case study approach is therefore particularly suited to explore these questions, as it allows for their study in a specific real-life context of scientific advice. Moreover, case studies allow for an in-depth exploration of the phenomenon, providing a rich and nuanced understanding of the subject under investigation, thus allowing an in-depth analysis of the specific practices and roles of the different actors involved. This is particularly important given the dynamic nature of the advisory processes being analysed and the plurality of actors involved.

Case study research presents some limitations, most notably about the generalizability of any finding beyond the specific case study. This can be mitigated by the careful choice of case studies that are representative of the broader phenomenon being analysed, comparing findings from multiple case studies, and by testing the findings against established theoretical frameworks and other instances of the same phenomenon. The choice of two case studies of scientific advice in EU policymaking (see 3.6), presenting both similarities and difference (see 3.6.3), represents a valuable cross-section of scientific advisory practices in EU policymaking, and allows to mitigate these limitations by contributing to building a fuller picture of the phenomenon under study. Moreover, while findings from case studies have limitations to their generalizability, they often have direct applications to their specific real-world situations. The detailed insights gained from the study of ESFA and the SAM can thus inform practitioners and policymakers working in them to improve the design of their scientific advisory processes.

The relevance of each of the two cases to the study of scientific advice more broadly, and to the specific research questions of this thesis is explained in section 3.6. As discussed, the selection of the SAM case study is dictated not only by its relevance, but also to the personal circumstances and privileged access enjoyed that allowed for direct observation of its internal practices (see 4.4).

4.3. Data sources

Case study research relies on multiple sources of evidence to assemble a full picture, with data from multiple sources needing to converge in a triangulating fashion to avoid biases from single sources or testimonies.

4.3.1. Documents

The policymaking and scientific advisory processes at the core of both case studies analysed here consists largely in the production of written documents (minutes, meeting reports, policy papers, advisory reports, press releases), and all official institutional communications happen in written form (letters,

briefings). Moreover, their functioning is described in guidelines. However, in the same way as scientific papers only show “ready-made science” while obscuring “science in the making” (Latour 1987), scientific advisory reports are only the frontstage of the scientific advisory process, carefully revealing only those parts of its backstage construction that the actors deem useful to establish its authority (Hilgartner 2000). Public documents alone allow only to reconstruct the frontstage dynamics of the scientific advisory process, as they don’t capture most of what happens in the backstage. Indeed, selectively deciding what to reveal in public documents, such as minutes and meetings reports, is a key element in the “stage management” used to construct the authority of scientific advice (see 2.8). For these reasons, understanding how documents such past policy documents, grey literature and academic research are read and interpreted in practice by policymakers, and how output documents are produced, is also crucial to understand policy formulation and how evidence is considered (Freeman and Maybin 2011).

Documents are used as the starting point for both case studies to provide an initial description of the advisory process being studied. All of the documents consulted where in the public domain, or had already been made public following freedom of information requests by other parties. Together, these documents allowed a detailed reconstruction of the timeline of events, the key issues at stake, and to identify most of the key actors involved. This was complemented by the use of interviews as described in the next section. Analysis of the collected documents has been carried out alongside other sources as described in section 4.5.

Documents for case study 1 – EFSA

The collection of documents for the first case study started from the online institutional repositories of the main policy institutions (European Commission, European Parliament) and advisory bodies (European Food Safety Authority (EFSA), US Food and Drug Administration) involved in the cloning case. Keyword searches were conducted both on the internal search engine of each institution (main keywords “cloning”, “animal cloning”, “Somatic Nuclear Cell

Transfer", "SNCT", "cloning AND "food"), and on Google, combining the keywords above with the name of the institutions (e.g., "cloning AND EFSA"). For this initial search, results not related to the application of cloning to farm animals for food purpose were discarded (for example related to medical applications of cloning animals for transplant organs), as were documents published before 2005 (when cloning started to be applied to farm animal for food purposes). The analysis was limited to English-language documents as the main focus of the case study was the scientific advisory process at the EU level, which takes place entirely in English.

This approach was combined with "snowballing" and tracing the genealogy and context of key documents. The reports produced by the scientific advisory bodies (EFSA, European Group on Ethics in Science and New Technologies), as the main products of the scientific advisory process, provided the starting point to reconstruct the documentary trail upstream, looking at the mandate letters requesting the advice and the contextual policy documents cited in the reports, and downstream, looking at the press releases, media coverage and policy documents taking up or discussing the scientific advice. In parallel, publicly available documents related to the production of the scientific advice, such as meeting agendas, minutes, slides, and interim reports were also collected. The aim was to comprehensively gather all publicly available documents directly concerning or describing the topic of the case study, to build a full picture of its development.

The documents have been retrieved in digital format from websites and archives and were downloaded and archived for easier retrieval. They have been catalogued in a spreadsheet based on their publication date, issuing body, title and type (e.g. advisory report, press release, correspondence, meeting report, research paper). Specifically, the following documents directly related to the cloning case study have been considered, alongside a number of other contextual documents considered during the initial scoping phase:

- Policy documents by the European Commission and its agencies (analyses, briefings, impact assessments, policy proposals)

- Advisory reports [9]
- Official press releases [8]
- News coverage
- Research papers directly linked to the cloning case [2]
- Meeting reports [9], agendas and minutes
- Presentation slide decks [2]
- Legislative proposal text [1] and amendments
- Records of parliamentary debates and resolutions [5]
- Parliamentary briefings [2]
- Institutional websites
- Evidence submissions by stakeholders
- Institutional correspondence [9]
- Results of Opinion polls [2]
- Other (calls for data, consultations, FAQs) [3]

Documents for case study 2 – SAM

For this case study a range of publicly available documents gathered during my experience working int the SAM have been used, as outlined in the table below. Specific documents are referred to in the footnotes of the empirical chapter.

Table 55: Documents used for the SAM case study

Document	Description	Example
Procedural documents and guidelines	Documents outlining the working of the SAM	Rules of Procedure of the Group of Chief Scientific Advisors (September 2020)
Scientific opinions	Scientific advisory reports produced by the Group of Chief Scientific Advisors (GCSA)	Scientific opinion on the Biodegradability of plastics in the open environment (December 2020)
Evidence review reports	Summary of the published scientific evidence on a given topic produced by the SAPEA consortium of scientific academies	Evidence review Report on the Biodegradability of plastics in the open environment (December 2020)

Scoping papers	Documents outlining the scope and mandate of a request for scientific advice	Scoping paper on the Biodegradability of plastics in the open environment (December 2019)

Source: Own elaboration

4.3.2. Interviews

The focus on practices of this thesis requires direct access to the actors experiences, which cannot be obtained by documents alone. As discussed above, in order to understand policymaking practices and access the backstage of the scientific advisory process it is necessary to go beyond the "paper trail" of documentary evidence and the institutional design features of advisory organizations. Qualitative interviews provide a unique insight into how actors involved in scientific advice both give meaning to and produce the CRELE attributes in the specific context under study.

In qualitative research in general, and interviews specifically, the researcher is the main "instrument" in both the collection and analysis of the data (MacCracken 1997). This allows flexibility to follow what is interesting and relevant to the specific issue being researched. Although a powerful method in qualitative research, interviews have some intrinsic limitations. From a practical perspective, interviews can be very time intensive, both in their execution and in the subsequent analysis, especially if full transcription is needed. This was mitigated by conducting most interviews either remotely or clustering them into a small number of research trips and limiting the duration of each to a maximum of 90 minutes (further details below). As the primary purpose of the interviews conducted for this research was to gather insight into the participants' experience of the scientific advisory process, rather than on analysing their discourse on topics, only partial transcription was required, thus limiting the effort required. Another limitation of interviews is obtaining access to the appropriate participants, as discussed in more detailed below.

In terms of the content of the interviews, potential biases, and failure to recollect by the interviewee needs to be taken into account (Ruben 2005). This is

especially relevant for interviews concerning past events, and for sensitive topics for which the interviewee might filter or withhold information. These limitations can be mitigated in a number of ways. Careful selection of the research participants can ensure that individual claims can be integrated, triangulated and corroborated from the perspective of several actors. Triangulation with other data sources such as documents can further mitigate this. A strong anonymization protocol can reassure participants that their identity will be protected, thus lessening the risk of them withholding or filtering information.

The aim of participants selection was not necessarily to assemble a representative sample of all those involved in the process, but rather to investigate multiple perspectives to build a more complete picture of how the actors interact with the process. Given the focus of the research on the "backstage" of the scientific advisory process and the role of secretariats in its construction, particular emphasis was given to recruiting participants from these groups.

For the purpose of this thesis, two distinct sets of interviews were carried out in different phases of the research. Interviews have been conducted in accordance with existing ethics protocols, as described below. Subject to having obtained informed consent, interviews have been recorded, and (partially) transcribed for later analysis and easy comparison with other textual data sources. The topic guides for each set of interviews can be found in Annex 4.

Interviews for case study 1 - EFSA

The first case study on the European Food Safety Authority (EFSA) is based on a selection of a set of 23 interviews conducted in the period between June 2019 and April 2020 with key actors involved in the EFSA scientific advisory process around the regulation of animal cloning in the EU. Interview participants include actors from both the scientific advice "supply" side (EFSA staff and committee members) and the policymaking "demand" side (European

Commission staff), as well as members of the broader scientific and policy communities involved in the case (European Parliament staff, civil society, external experts).

Specifically, interviewed participants included:

Table 6: Participants interviewed for the EFSA case study

	Approached	Interviewed
European Commission secretariat (current and former)	14	8
EFSA staff (current and former)	8	4
EFSA scientific advisors	3	2
Members of the European Group on Ethics (EGE)	4	3
Staff from the European Parliament	3	2
Civil society organization representatives of civil society and external experts	5	4

Source: Own elaboration.

Interviewees have been identified from a range of sources, including organograms and institutional webpages (e.g., members of relevant advisory committees, staff of regulatory and advisory agencies), mentions in relevant documents (e.g., minutes of meetings, regulatory applications), and their presence at relevant events (e.g., from list of participants to stakeholder meetings and workshops). Introductions and referrals by existing contacts and key stakeholder (snowballing) formed a key element in the individuation and recruitment of research participants.

Initial contact was made either by email or in person at relevant events and conferences, and interviews were arranged either in person or through teleconferencing (e.g., Skype), depending on the availability and location of the participant. In person interviews were conducted during three field visits to EU institutions in Brussels (Belgium) between June and November 2019, and a field visit to the European Food Safety Authority in Parma (Italy) in July 2019.

Interview length varied between 30 and 90 minutes based on the availability of the participant and the degree of their involvement with the case study, with an average of under one hour to maintain the focus and facilitate later analysis. The interview where semi-structured, and the specific questions varied depending on the role of the participant in the scientific advisory or policy process (for example policy officers, scientific officers, external expert). Key topics covered included the participant's:

- experience of the decision-making process around the cloning file
- experience of the commissioning and/or reception of expert advice on cloning
- experience of the framing and production of expert advice on cloning
- experience of the relationship between internal and/or external stakeholders in the case
- views on the specificities related to the cloning case study
- views on similar policy issues
- views on the broader system of expert advice and use of evidence in EU policymaking more generally
- views on scientific advice and political values in the EU policymaking system more generally
- suggestions of other potential interviewees

(see Annex 4 for a comprehensive overview of the interview guiding questions)

The interviewing process presented a number of challenges common to this type of research. Identifying the most appropriate interviewees and obtaining access to them was not always straightforward. Some individuals, especially the members of secretariats at the core of the case study, are made invisible in the process of policymaking and scientific advice, and the involvement of specific individual often cannot be reconstructed from the paper trail alone. This required using indirect approaches, such as snowballing from other interviews, and cross-referencing with attendance lists for relevant meetings, to identify some of the concerned officials. Some of the identified research subjects were no longer reachable at their institutional contacts, either because they had

changed jobs or had retired, and up-to-date contacts had to be identified through internet searchers and professional networking platforms such as LinkedIn.

After the gathering of interviews data and their analysis, the focus of the thesis shifted from a comparison between the role of EFSA's advice in the governance of animal cloning for food purposes in the EU, to a study of the internal dynamics of the ESFA advisory process. For this reason, a subset of the original interviews is used directly to build the case study. However, the other interviews played an important role in contextualising the role of EFSA's advice in the broader processes of EU policymaking and provided valuable insights for the analysis of the construction of policy relevance.

Interviews for case study 2 – SAM

For the second case study on the Scientific Advice Mechanism (SAM) I conducted 8 semi-structured interviews with current and former members of the SAM. The interviews were conducted during the course of 2023 over videoconferencing (Teams) in English, and recorded after obtaining informed consent in accordance with UCL protocols (see below). Recruitment of the participants was done through personal contacts built during my period working as part of the SAM secretariat (see 4.4). Both the participants' recruitment and the interviewees themselves were conducted only after I stopped working as part of the SAM secretariat, thus ensuring a separation from my participation in the SAM's work while capitalizing on the contacts made during that period.

These interviews were conducted after the development and analysis of the ESFA case studies, when the specific role of secretariats in the scientific advisory process had already emerged as an important topic for analysis. For this reason, participants selection for the SAM case study focused mostly on members of its secretariat. Some of the approached participants could not be interviewed because of scheduling conflicts and time constraints, but no participants expressed reservations once the purpose, scope and

confidentiality of the interviews was explained. The full list of approached and interviewed participants is presented in the table below:

Table 7: Participants interviewed for the SAM case study

	Approached	Interviewed
Members of the SAM Secretariat	10	6
Members of the Group of Chief Scientific Advisors	2	1
Members of the SAPEA Secretariat	2	1

Source: Own elaboration.

Interview length varied between 20 and 45 minutes based on the availability of the participant. The interview where semi-structured, and the interviewees were asked to describe their role and function within the SAM, and specifically about their role in the various phases of production of scientific advice. Further details were elicited as necessary about specific phases of practices, or about significant episodes identified through my own experience of working in the SAM (see Annex 4 for a comprehensive overview of the interview guiding questions).

Ethical considerations

The interviews have been planned and conducted in accordance with the UCL research ethics framework. Ethics approval for the project was obtained in September 2017 (reference number: STSEth121, see ethics approval certificate in Annex 2), with the proposed approach falling under the “minimal risk” category.

The research involved mainly participants currently or previously involved with policymaking and scientific advice in EU institutions. These include officials working in policymaking and advisory institutions, and researchers serving in advisory functions and/or studying the process of advice. All participants took part in a personal capacity. Participants were all adults, and the interviews covered their normal working activities. No special health and safety

considerations are required for the project. The interviews have taken place in safe places (mostly the participants' offices), or over the phone/teleconferencing. The place and time of the interviews has been communicated to a trusted person to always ensure the personal safety of the researcher.

Informed consent has been obtained prior to the interview. Participants have been made aware of the scope of the project, and consent was obtained through a designated form (see Annex 1), along with specific consent to record the interview were needed. Consent was obtained to archive the data for the duration of the project and for further use in the immediate aftermath (for example to produce research papers). Participants have the option to withdraw at any stage before, during, and after the interview. Where appropriate, participants have been offered to review directly attributed outputs before these are published. Data has been partially anonymised, so to protect the identity of the interviewees. Interviewee has been classified per the type of organisation they belong to, and/or the type of role they have. Consent was obtained to archive the data for the duration of the project and for further use in the immediate aftermath (for example to produce research papers). Data was stored and safeguarded as detailed below.

Table 8: Data storage and safeguarding

Person(s) Responsible for Data	Personal Data to be Registered	Type of Data Subjects	Data Format	Method of Securing Data
Alessandro Allegra	Interviews	Research participants	Audio recording and/or interview notes and/or transcripts (electronic files)	Password protected encrypted PC and/or secure cloud storage. Recording will be deleted at the end of the project.
Alessandro Allegra	Participants contacts	Research participants	Electronic files	Password protected email files.
Alessandro Allegra	Observation notes	Research participants	Notes (electronic files)	Password protected encrypted PC and/or secure cloud storage.

Source: Own elaboration.

4.4. Autoethnographic observation

Building on my own professional experience as a science policy practitioner working on scientific advice, this thesis uses an autoethnographic approach to complement interviews for its case study on the EU Scientific Advice Mechanism. Taking part in the activities of the research participants is key to fully understand how they attribute meaning (Guest, Namey, and Mitchell 2013), and ethnography and specifically participatory observation are key methods for organisational studies (Jones 2014). Ethnographic methods have a long tradition in the social studies of science and technology (Latour and Woolgar 1979; Knorr-Cetina 1981), as they allow the exploration of scientific knowledge in the making, shedding light on the decision-making process and practices and the importance of contingencies and local context. In a similar way, the study of the practice of science advice can benefit from the use of ethnographic methods, as applied for example by Bijker, Bal, and Hendriks (2009) in their extensive study of the Dutch Health Council.

Autoethnography is a qualitative research method that uses the researcher's personal experience ("auto") to describe and interpret cultural experiences and practices. The defining features of analytic autoethnography are that the researcher is a full member in the research setting under consideration; is visible as such a member in writing about the research setting; and is committed to augmenting theoretical understanding of social phenomena (Anderson 2006). In the context of the study of scientific and expert advice, autoethnographic approaches have been used by practitioners involved in advisory processes to describe and analyse episodes from their professional experience, the significance of which might not have been not immediately clear at the time of their involvement. Autoethnographic approaches have been used to study scientific advisory committee and processes, for example in the context of the UK Royal Society advice on geoengineering (Stilgoe 2016), of social sciences advice in the UK government (Cooper 2016), and of UK advisory committees on drug policy (Stevens 2021).

The main advantage of using an autoethnographic approaches in the study of scientific advice is that it allows to capitalize on the researchers pre-existing experience of relevant events, even when participation was as not originally planned for research purposes. In my case, it allows to explore what it means to be involved in scientific advisory process, from the specific perspective of a member of the secretariat.

However, such approaches present a number of limitations, both methodological and ethical. From the methodological point of view, reliance on the researchers own experience poses the risk of confirmation bias and missing disconfirmatory evidence (Klayman and Ha, 1987). This can be mitigated by triangulating with other sources and comparing with established conceptual frameworks. For this case study, I have mitigated the risk of bias by complementing the autoethnographic approach with data from interviews and documentary evidence (see previous sections), and with comparison with the other case study. The other risk regards the representativeness of the researcher's experience in relation to the broader phenomenon under analysis. In my case, given the very small size of the organization under study and my involvement in it for an extended period of time and on several projects, it is reasonable to assume that my experience is representative of the practices and cultures of the SAM, at least over the period of time under study, as also confirmed by the subsequent interviews.

Moreover, personal professional experience of working in scientific advice in some of the institutions covered in the case study (European Commission) is used to indirectly inform the research and its interpretation in two key way: upstream it informs the selection and framing of the research problem and guides the design of the research approach and the individuation and recruitment of research participants, downstream it informs the interpretation of the data collected from the interviews and documents, and the generalization and contextualization of the conclusions.

SAM autoethnography

For the purpose of the research presented in this thesis, autoethnographic observations are used alongside other sources (documents and interviews) in the SAM case study analysing the advisory process of the European Commission's Scientific Advice Mechanism (SAM).

This builds on my professional experience as full-time member of the SAM secretariat for a cumulative period of 26 months, first as intern between March and July 2018 and again as Policy Officer between October 2020 and June 2022. In this role I have not only contributed to the production of several scientific advisory reports (see below), but also had the opportunity to lead the development of the SAM's own reflection on the role of scientific advice in light of the Covid-19 pandemic, and of its own role in the broader EU scientific advice ecosystem. During my time in the SAM I was directly involved in the various phases (scoping, evidence gathering, drafting, dissemination) of the SAM scientific advisory process (see 6.1) on several topics, as detailed in the table below:

Table 9: Author's involvement in the SAM scientific advisory process

Topic	**Scoping**	**Evidence gathering**	**Drafting**	**Dissemination**
Scientific advice to European Policy in a complex world (September 2019)		X		X
Towards a sustainable food system (published March 2020)	X			X
Biodegradable plastics (published December 2020)			X	X
Strategic crisis management (published November 2022)	X	X		X
Statement on Energy Transition (published September 2022)		X	X	X
Cancer screening (published March 2022)				X

Source: Own elaboration.

I also indirectly have knowledge of the other projects and phases I was not directly involved in through regular interactions with colleagues and participation in weekly team meeting. This experience gave me access to the entire process of production and dissemination of the SAM's advice on a broad range of scientific and policy topics. In my role, I had daily interactions with other members of the SAM secretariat, both online and in person, and regular exchanges with members of the Group of Chief Scientific Advisors (GCSA), members of the SAPEA secretariat, SAPEA experts, policy clients from other Directorate-Generals of the European Commission, and a broad range of stakeholders involved in the scientific advisory process (MEPs, civil society organizations). I took part in regular team and project meetings with colleagues from the secretariat and the expert group, took part in and contributed to organizing several meetings of the GCSA, as well as expert and stakeholders meetings (see 6.4.4 and 6.5). Overall, my professional experience in the SAM gave me access to its entire work during that period, and with all the actors involved in it.

This experience is used to complement documents and interviews to develop the SAM case study presented in Chapter 6. In particular, direct experience of the SAM's work is used to reconstruct its advisory process and backstage practices, to identify the most salient topics and documents for analysis, and to contextualize and interpret data from the other sources. As the participation in the SAM was not designed at the outset as a systematic ethnography or participatory observation, data derived from a combination of recollected illustrative episodes, reconstructions of key moments, and non-systematic contemporary notes.

Ethical considerations

The autoethnographic observations used in this thesis are based on my professional experience working as a member of the SAM secretariat, and are thus not drawn from a planned ethnographic study. For this reason, no ethical approval could be obtained before the observations were conducted, as their future use was not known at the time. This is an intrinsic challenge of

autoethnographic approaches, as highlighted by both Cooper (2016) and Stevens (2021) in the studies mentioned above. The British Sociological Association Statement of Ethical Practice (BSA 2017) states that research without previous informed consent of participants (covert research) can be considered ethically acceptable under specific circumstances, in particular when research participants would change their behaviour because they know they are being studied.

To mitigate these concerns, in the description and analysis of the case study I make no reference to specific individuals nor provide information that would identify them to anyone who was not already directly present and involved in the advisory process being described. Moreover, documents used as sources for this case study are all in the public domain, and no private or confidential materials have been used to inform it beside my own contemporary notes about my experience of being part of the SAM advisory process. The risk of breaching confidentiality or causing harm to any of the individuals involved in the advisory processes described here is therefore minimal.

Retrospective consent for observation was obtained verbally from the colleagues directly interviewed for the case study (see 4.3.2) and from their immediate management. Informed consent has been sought as normal for those members of the SAM secretariat who have been interviewed for the thesis (see 4.3.2), and they have been informed that interviews would be complemented by my own experience. The research involved no intervention other than my normal work as a member of the SAM secretariat.

4.5. Data analysis

Data from all sources has been analysed using a common analytical framework in order to make them comparable and build a complete picture of each case study from these multiple sources. Collected documents, reading notes, interviews transcripts, and interviews notes have been archived and analysed using the NVivo qualitative data analysis software. This data has been subject to thematic coding to identify common themes for analysis (Lune and Berg,

2017, 90–93), using both coding categories informed by the theoretical concepts derived deductively from theoretical framework discussed in Chapter 2 (e.g., hybridization, demarcation, boundary work) and inductive codes emerging form the analysis. In particular, a first round of coding was used to categorize both emerging themes in the case studies (such as independence), and specific tasks and actions undertaken by the advisors and the secretariat, to reconstruct a detailed account of the advisory process. This was done in an iterative manner, with new and refined codes being introduced as the analysis progressed. A theoretically-informed analytical framework derived from the main theoretical concepts, namely the CRELE framework and the notions of coordination and demarcation in boundary management, was then applied to interpret these initial themes. The key concepts of the analytical framework used are the following:

CRELE attributes (Cash et al 2002)

- Credibility (authoritative, believable, and trusted, meeting standards of scientific adequacy and quality)
- Relevance (policy context, Timeliness, appropriateness of scale and scope)
- Legitimacy (fairness, unbiased, inclusiveness)
- Tensions and complementarities among CRELE attributes

Practical trade-offs between CRELE attributes (Sarki et al. 2014)

- use of actors' time (interfacing VS other activities)
- clarity-complexity (simple message vs communicating uncertainty)
- Speed-quality (timely outputs VS in-depth quality assessment and consensus building)
- push-pull (supply VS demand-driven).

Organizational features of boundary organizations (Guston 2001)

- Dual participation
- Dual accountability

- Use and construction of boundary objects

Boundary management strategies contributing to CRELE (Cash et al 2002)

- Communication
- Translation
- Mediation
- Coordination

Hybrid management strategies (Miller 2001)

- hybridization
- deconstruction
- boundary work (creating and maintaining boundaries)
- cross-domain orchestration

Boundary management (Gieryn 1983)

- Coordination
- Demarcation

5. Case study 1: Scientific advice at the European Food Safety Authority (EFSA)

To understand how Credibility, Relevance and Legitimacy (CRELE) are constructed the practice of scientific advice to policymaking in the EU, this chapters explores in detail the scientific advisory process at the European Food Safety Authority (EFSA), as the main provider of scientific advice on food safety policy to EU institutions. This case study is based on the analysis of documents governing the advisory process or being produced through it, and of interviews with key actors involved in its production and reception.

In particular, the ESFA advisory process is described here through the specific example of the production of advice on the regulation on animal cloning for food purposes in the EU in the years 2007-2010. In the cloning case the work of EFSA was supplemented by other forms of expert advice, most prominently from the European Group of ethics in Science and New Technologies (EGE), an expert body that sits outside the traditional distinction between risk assessment and risk management (see 3.3). The institutional structure and mandate of an advisory body shape its remit, work practices (e.g., its networks of expertise), and its overall epistemology, and the two advisory bodies differ widely in such regards, with ESFA having a much more rigid and well-defined role in the EU advisory ecosystem than the EGE. These differences play an important role in shaping their advisory outputs, and the uptake of such outputs in the policy process. The backstage work of the EGE is therefore discussed in this chapter where relevant to provide a useful contrast to better understand the scientific advisory work of EFSA.

5.1. Commissioning advice to EFSA

Before scientific advisors begin working, the questions being asked need to be defined. Requests for EFSA advisory opinions come from its "parent" directorate in the European Commission, at the time the Directorate-General (DG) for Health and Consumers (SANCO)[20], which is responsible for food

[20] The Directorate-General for Health and Consumers (DG SANCO) changed name in 2014 to Directorate-General for Health and Food Safety (DG SANTE).

safety policy and consumer protection. The process begins with the SANCO Unit responsible for a specific policy file requiring EFSA's input drafting a mandate letter, outlining what the opinion should cover. This initial draft takes into account what "is already on the table" [EFSA staff 1], i.e. pre-existing knowledge and the policy context, and involves consultation with colleagues from other Units and DGs as needed. A separate, dedicated Unit in SANCO has responsibility for liaising with EFSA and manages the advice commissioning process and ensures coordination and harmonization between different requests.

The mandate is expected to cover not just the terms of reference and the specific question for EFSA to address, but also "the background of why there is a need for asking a question to EFSA" [EFSA staff 3]. This is important because it allows those preparing the advice to understand the context and rationale for a request, which in turn informs their own decision of how to approach it in their work. Knowing *why* certain questions are being asked, and the context and considerations that shaped them, is important for the secretariat of the advisory committee to ensure that the answers provided are relevant and useful to policymakers.

As shown in the interviews, a clear definition of the specific mandate for any advisory request was seen as important by both the Commission's and EFSA's side: from the Commission's side, a clear mandate "limits the scope of the problem, otherwise the Scientific Committee from EFSA could decide 'but I want to put this and I want to say this, and I want to investigate another line', […] [a clear mandate] saves the needs of the Commission" [SANCO staff 1]. On the hand, from EFSA's point of view "We [EFSA] draw the line [between risk assessment and risk management] already from the start of any assessment, which is the problem formulation […] there was always a grey area where we have to consider 'is this not something which is more for the risk manager to decide?" [EFSA staff 3]. From the Commission side, a clear definition of the mandate is seen as focusing and limiting the scope of the advice, thus enhancing its Relevance to the Commission's policymaking

needs. From EFSA's side, the framing of the request for advice is seen as a key step in establishing the boundary between science and policy, and thus EFSA's epistemic authority over the subject and the Credibility of its advice. Specifically, EFSA staff saw a clear boundary around the issue of "acceptability" of a given food safety risk: "What is acceptable is not an issue for the scientist, it is an issue for the risk manager. The risk assessor should provide all the information on the basis of which the risk manager is going to say 'yeah but if it is beyond 90% then in that case I would find it not acceptable', but that is a decision which is not taken by the risk assessor [EFSA staff 3].

Given the importance for both sides of establishing a clear mandate, a significant amount of work was put into ensuring coordination to "try to make more concrete what and how these questions should be formulated" [EFSA staff 3]. Before a formal mandate letter is issued from SANCO to EFSA, interactions and dialogue between counterparts in the two institutions were common [EFSA staff 1 and 3]. These exchanges took place both at the level of senior management and at the more operational level between scientific officers at EFSA and policy officers at SANCO, in a what is described as a "fluent [fluid]" process [EFSA staff 1], a "drafting phase [consisting] mostly of exchanges of emails about what could be the ingredients that we would see back in the terms of reference" [EFSA staff 3], ensuring a mediation between the different policy and scientific considerations. In the cloning case: "there was an initial draft from the Unit dealing with novel foods, but then the final letter was a different one, because it was harmonized with other sectors, with the priorities of the EFSA mandate, for formal issues but also for substantive issues" [EFSA staff 1].

This initial informal coordination, before a formal request from SANCO is sent to EFSA, is managed entirely at staff level without involvement of the advisors. The EFSA secretariat effectively manages the advice-framing process on behalf of the expert committees, on the basis of what it imagines their needs could be: "Although the scientific committee is not involved in this initial negotiation, there will be consideration within EFSA of what is really the

questions that we can address by the scientific committee" [EFSA staff 3]. The secretariat works to ensure that EFSA is not asked to address questions that fall outside its scientific remit, and thus risk drawing it into the policy domain that could undermine its epistemic authority and Credibility.

Once an initial draft mandate has been negotiated between SANCO and EFSA, an official letter of request is issued by the SANCO Director General to the EFSA Director General. The formal procedure for EFSA to accept the mandate requires a reply to the mandate letter, outlining the timeline and process EFSA expects to put in place to prepare its opinion [EFSA staff 1]. In its reply, EFSA has the opportunity to further refine the mandate, to ensure the request is framed in a way that EFSA is well placed to handle, and that expectations are managed. In this phase of preparing its reply, EFSA considered the sub-questions that need to be formulated in order to address the request for advice, and whether it possesses the adequate expertise to address them credibly. These sub-questions eventually ended up forming the backbone of the Opinion itself, so that the results of this coordination process taking place before the mandate is even accepted are eventually reflected in the final output [EFSA staff 1].

This shows how the backstage coordination work carried out ahead of the formal issuing of the advisory request played a very important role in shaping the structure and content of the scientific advice that is produced downstream by the advisory committee. In this process, the secretariat lays the groundworks to ensure the Credibility of the advice to be produced by negotiating a clear scope and framing of the request in scientific terms, and its Relevance by discussing clear expectations and timelines. This upstream coordination is important because once the mandate has been formalized in the request letter, the advisors have limited scope to challenge its framing without challenging the whole process.

A second coordination mechanism was in place within the agency to prepare such a reply in a way that ensures EFSA's different perspectives are taken into

account, and to mediate between them. The mandate letter arrives “centrally to EFSA and then it's discussed at usually directors’ level and then it's being diverted to a specific unit, and in this case, it came to the Scientific Committee unit” [EFSA staff 1]. Internal consultation within EFSA takes place before a mandate is formally accepted, including staff members at managerial levels and members of the Scientific Committee (SC), EFSA’s overarching advisory committee [EFSA staff 1]. A number of considerations were taken into account in this phase, and shaped the framing of the questions that were eventually agreed upon between the EC and EFSA and enshrined in the final terms of reference. Consideration of which of EFSA’s specific advisory panels was best placed to be responsible for the opinion, and therefore which Unit should receive the mandate, started before the mandate was formally accepted: “once [the mandate letter] was received there will certainly also be a consideration of ‘okay how are we going to handle it in EFSA?’ It will be allocated to the unit which is dealing with that, and we will discuss it and with the scientific committee in a plenary meeting “listen we have received a new question, it's related to animal cloning, and we have to agree on how we're going to address the questions” [EFSA staff 3].

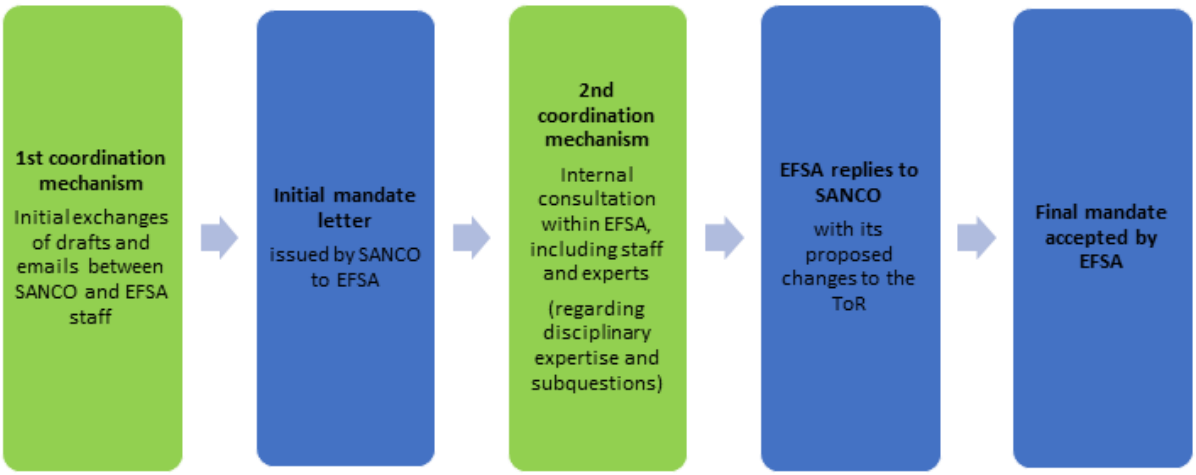
Eventually, given the overarching nature of the cloning topic, the case was addressed by the SC committee itself, as it represents the perspectives of all of EFSA’s panels (see 5.4). After this internal deliberation process, EFSA responded to the request providing “feedback to the Commission: ‘we accept it in the following way’’ [EFSA staff 3]. In the cloning case specifically, EFSA proposed to restrict the scope of its opinion so to exclude an in-depth analysis of the environmental consequences, knowing that the time and data available would not allow for a thorough analysis. In this case, the potential Relevance of the advice for a broader set of policy interests is traded for increased scientific accuracy, contributing to its Credibility.

During this whole process, EFSA staff maintained close contacts with their counterparts in SANCO responsible for the specific policy file (rather than staff from the interinstitutional liaison Unit), who remained closely involved in the

process: “they will be available for particular questions or whatever at least during the meeting of the Scientific Committee, so there was an interaction there, and of course then the Commission representative can also explain or at least give some commands on directions to be taken by the Scientific Committee” [EFSA staff 3].

Multiple levels of coordination therefore existed both between SANCO and EFSA and within the latter to ensure that requests for scientific advice met both the needs of the policy client and those of the advising body, and to ensure that the boundary between the two domains could be upheld. While both members of the SC and members of the secretariat are involved in these coordination mechanisms, the experts who will eventually carry out the risk assessment as part of the dedicated working group are not necessarily involved in the process, and have to accept the framing of the questions contained in the terms of reference. A schematic representation of the process is presented below:

Figure 8 - EFSA frontstage (blue) and backstage (green) coordination mechanisms



Source: Own elaboration.

5.2. Coordination and division of labour between the advisory bodies

The parallel commissioning of advice to both EFSA and the EGE was a unique feature of the cloning case and raises the question of how the boundary between their respective roles was drawn. A frontstage level, the different roles

of the two committees are clearly demarcated: EFSA looks only at the scientific facts, while EGE has competence over the moral, legal and societal implications of science and technology. This is reflected both in the institutional mandate of the two groups, and the specific mandate they received to provide advice on animal cloning. This division of labour is also clearly present in the narrative around the role of the two groups, as emerged from the interviews conducted for this project. The domains over which each of the groups has competence, and the expertise they embody, are presented as naturally distinct.

This demarcation however rests on the assumption that a separation between considerations of facts and values is both desirable and possible, which as discussed in Chapter 2 has been shown not to be the case in both science and policymaking. Indeed from a symmetrical analytic point of view (Bloor 1976), each of the committees should be understood as dealing with both facts and values, and the distinction between these two domains as the product of the committees' boundary work, rather than as their starting point (see 2.2.2). To understand how this distinction was drawn in practice, and its implications, it is therefore useful to look at the degree of coordination happening in the backstage. According to an official working on the issue, in the case of cloning: "the two Cabinets [the private offices of the EC President and the Commissioner responsible for SANCO and EFSA] have surely coordinated the structure of the language of the two requests, so that they would be as clear as possible in their complementarity" [EGE secretariat 1].

Moreover, the key official in the President's Cabinet responsible for liaising with the EGE was his Chief of Staff, who had previously worked at SANCO and had "very good knowledge of its mechanisms, also in relation to EFSA" [EGE secretariat 1]. Although the EGE staff had no direct interactions with their counterparts in SANCO liaising with the EFSA mandate, SANCO appears to have had an input into the definition of the request to the EGE: "The request comes from the DG [SANCO] and is discussed with the EGE secretary, we prepare a draft, it is a work of the services [departments], a joint effort. We [the

DG] present a proposal, then it is finalized together. It is a team effort, it happens at the level of the services, at the level of the officials, of the head of unit" [SANCO staff 3].

Communication and coordination between the two advisory bodies therefore happened at two levels. The President's Cabinet liaised directly with the EGE secretariat, but communicated with DG SANCO and EFSA through the Cabinet of the relevant Commissioner [BEPA staff 1]. At the operational level, staff in SANCO and EFSA interacted directly with the secretariat of the EGE, but not with the President cabinet or the Group members [SANCO staff 4]. Direct interaction between members of the EGE and staff and experts from EFSA took place through the mechanism of hearings and stakeholders' workshops, thus treating them at the same level as other external stakeholders. Effectively, the two groups treated each other as stakeholders, but without any privileged status despite being both directly advising the EC. An important role in the coordination between the two groups was played by Prof Diana Banati, a member of both the EFSA management board and the EGE. Although in the first role she was not involved with the scientific content of EFSA's work, she had profound insight into its logic and mode of working and played an important role in clarifying those to the EGE. In the words of a fellow EGE member, Prof Banati provided "a shortcut to EFSA" [EGE member 2].

These interactions point to the fact that the institutional hierarchy existing in the Commission was reflected in the commissioning of expert advice, with coordination only happening at the level of high-level officials, rather than political decision makers or expert committees themselves. This reflects some key aspects of the Commission's institutional culture, where Cabinet officials are considered gatekeepers between the Commissioners (the political leadership) and their own DGs (departments). However, it also reflects a degree of collegiality in EU policymaking, where all decisions are taken in consultation with colleagues from other departments.

The division of labour between the Groups was not perceived as creating any conflict, as they were seen as each having their own specific responsibilities [EGE member 2], indicating a successful management of the boundary between matters of facts and matters of values. For example, "for the EGE it was very clear that [EFSA's] was a complementary point of view", "essential for the EGE's opinion", and "it was very clear from our side that there was no overlapping" [EGE rapporteur 1]. However, while the EGE took fully into account the output of EFSA's work and used it as the basis for its own assessment, EFSA appears to only pay a passing acknowledgement of the EGE's conclusions, reflecting its structural inability to consider non-scientific viewpoints (see 5.5). This asymmetry reflects the different roles of the two groups, and its well captured in the observation of one of the EGE's rapporteur that "I don't know if people doing risk assessment understand completely the role of an ethics group" [EGE rapporteur 1].

5.3. Coordination and division of labour within EFSA

EFSA is an expert agency structured around multiple levels of expertise. Its scientific core is formed by ten standing advisory committees (panels) composed of external scientific experts with a three-year mandate. They provide subject matter expertise on the various areas relevant to the agency's work, such as plant protection products (pesticides), animal health and welfare, plant health, GMOs, nutrition, allergens, etc. Above it sits the overarching EFSA Scientific Committee (SC), formed by the chairpersons of each of these panels plus 6 external experts. Working Groups (WG) consisting of 8-10 experts, including EFSA panel members and other external experts, are assembled to work on specific scientific opinions.

Coordination among these different levels is essential to produce a scientific opinion which is Credible, Relevant and Legitimate, and several mechanisms are in place to ensure such coordination. The Scientific Committee (SC) plays a central role in this, as it was created to look at emerging overarching topics that span the competence of several panels, and to provide a coordination mechanism between the different disciplinary viewpoints represented in the

panels, thus managing the multiple boundaries internal to the scientific domain. According to the EFSA website, the SC has responsibility for developing "harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit where EU-wide approaches are not already defined" and providing "general co-ordination to ensure consistency in the scientific opinions prepared by EFSA's Scientific Panels.[21]

According to members of the EFSA secretariat, the SC played a key coordination and quality control role: "the role of the Scientific Committee is to ensure that all aspects related to other panels are fully represented in this type of opinions" [EFSA staff 2]. "At the end of the process of developing an opinion all the members of the Scientific Committee, including the chairs of the different panels, are reviewing the draft document" [EFSA staff 3]. The SC therefore contributes to the Credibility of the scientific advice both by providing a quality control and peer review function, and by ensuring that a broad range of different scientific perspective are taken into account.

Normally, once a specific request for advice is received by EFSA, its management assigns it to a specific panel based on the relevant thematic area. Animal cloning however was seen a "very specific and ad hoc topic" [EFSA staff 2], spanning the specific competence of several of EFSA's panels, such as that on novel foods and that on animal health and welfare. For this reason, it was decided that cloning would be dealt with by the SC directly, so to ensure representation of the different disciplinary viewpoints represented by the various panels. This decision was considered "a straightforward matter" [EFSA staff 1], and in line with the *raison d'être* of the Scientific Committee: "our job is to make sure that we have represented all possible divergences of views or critical issues. We cannot permit in EFSA to focus only on food safety aspect, we have to have the animal health and welfare, and the role of the Scientific Committee is to help ensure that together the

[21] https://www.efsa.europa.eu/en/panels/scientific-committee (visited on 24/05/2020).

Scientific Committee goes from farm to fork, everything that you can imagine can pose a burden on the consumer" [EFSA staff 2].

The process of producing the cloning opinion was therefore "like a two-stage process: the working group with dedicated expertise comes up with a draft opinion" which is then discussed at the level of the SC, "where all the panel members provide their expertise and input" [EFSA staff 1]. To ensure coordination between the two stages, as a "rule" the WG is always chaired by a member of the Scientific Committee [EFSA staff 1]. Moreover, in cases where the specific disciplinary perspective of a panel was deemed particularly necessary, as in the case of animal welfare in cloning, members of the relevant panel would be included in the WG as coordination "mechanism" [EFSA staff 3].

Effectively, this setup created a further division of labour within EFSA between two layers of scientific expertise. The SC was characterized by a broad range of scientific competences relative to the whole remit of EFSA, and by experience in regulatory science and scientific advice. The SC played a double role: it received and negotiated the mandate with the policymakers in DG SANCO, and acted as quality control mechanism for the WG, choosing its composition, establishing quality guidelines, and reviewing its work. It thus worked on two fronts performing both a coordination function to ensure the policy Relevance of the advisory process, and a demarcation function by acting as a buffer between the expert advisors and the policy clients, further safeguarding the independence and thus the Credibility of the advisory process. The expert WG on the other hand possessed the specific subject matter knowledge and expertise to carry out the technical risk assessment, as well as the scientific credentials in the relevant fields, thus providing the foundation for the content and lending scientific Credibility to the advice produced.

5.4. Assembling expertise

Understanding who is considered to possess the expertise relevant to the issue at stake, and why, is a key element to understand the dynamics of the advisory process. Relevant questions include how experts are selected and by whom, what forms of expertise are considered relevant and why, and what legitimises the process and the outcome of expert selection. The background of the members of the secretariat, and the criteria according to which they are hired and then chosen for a specific project, are also revealing of how expertise is conceived and embodied in the advisory process. The creation of the EFSA WG is an exercise in balancing the trade-off between depth of subject matter knowledge on the one hand with breath of disciplinary perspectives and representativeness of multiple scientific viewpoints on the other. Both elements are important in ensuring the buy-in of scientific stakeholders, and therefore the Credibility of the advice they produce.

This work of identifying and recruiting experts and creating the WG is carried out by the secretariat in consultation with the relevant panel. To recruit experts for a WG, EFSA relies on the professional and scientific networks of its panel members, on its own institutional networks (such as with similar agencies in Member States and abroad), and on the identification of experts through literature searches. SC members themselves were also asked "if they had a personal interest being part of the working group" [EFSA staff 1].

While the selection and appointment of the WG members is made by the SC, the identification is mostly carried out by the secretariat. The secretariat conducted an initial literature search of published studies to see "who has published what in the field" and "who has the relevant expertise" [EFSA staff 2], to identify experts to invite to join the WG [EFSA staff 1]. This literature search was guided by a pre-existing idea of the range of expertise needed: "what we start always off with is to address this question 'what would be our ideal A team' and that means which type of expertise we need, and then you go and look into literature" [EFSA staff 2].

The secretariat views on what constitutes useful and relevant expertise therefore played an important role in the selection of the experts that will form the WG. While in normal circumstances the secretariat would use scientific publications in a given subject area as a proxy to identify experts with knowledge relevant to the topic, thus relying on the judgement of the potential expert's scientific peer, the relative novelty of cloning as a technique applied to farm animals meant that finding relevant expertise through literature searchers was not always straightforward [EFSA staff 1]. The secretariat therefore had to make a judgement call of what areas of research were to be considered as similar enough, and therefore relevant to cloning.

Members of the WG were chosen either because of their competence in the subject concerned, or because of their expertise in risk assessment. In the case of cloning, a deliberate effort was made to ensure an adequate representation of a range of scientific perspectives, which included technical knowledge of cloning techniques (including genetics and molecular biology), familiarity with the main species being considered (chiefly cows and pigs), expertise in animal health and welfare, and "global inputs" [EFSA staff 2]. The inclusion of "global inputs" is particularly interesting because it reveals the experts' selection process as an instance of hybridization(see 2.5.3), involving considerations beyond the purely scientific ones. In particular, it can be interpreted as a way to involve key international stakeholders upstream in the policymaking process, to defuse potential challenges further downstream and strengthen the Legitimacy of the advice.

This was supplemented by tapping into EFSA's institutional international networks, asking the agencies they regularly collaborate with for suggestions of experts to invite: "we also looked at what other countries have done so in the US they had basically looked at animal cloning already and longer, so one of the experts we invited was from the US FDA" [EFSA staff 1]. The same Unit supports both the Scientific Committee and the EFSA advisory forum, made up of representatives of national member states food safety agencies, so this network was extensively utilized in the cloning case. Although in theory the

sourcing of experts is global, reflecting an ideal of science as transcending national boundaries, in practice all of the experts recruited in the cloning WG were European, except for the one coming from the US FDA. This recruitment of experts through such channels can also be interpreted as a way to involve institutional stakeholders upstream in the process, thus strengthening its Legitimacy and that of its advisory products.

As this selection process is conducted by the secretariat, over time they developed their own personal network with experts in the field and counterparts in other agencies to call upon: “you build up a knowledge base of who are the experts in this field, therefore you do not need always to repeat this search for new peop*le”* [EFSA staff 2]. Moreover, as the secretariat own knowledge of the topic increases, it becomes less reliant on a wide breadth of external inputs, and the size of the expert groups decreases as seen between the 2008 cloning opinion and its later follow ups [EFSA staff 2].

As recognised by Joly (2016), the risk assessment process at EFSA is constructed around a committee of laboratory scientist drawn mostly from the academic sector. This is markedly different from other contexts such as for example the US FDA, where the bulk of the advisory work is done by in house staff, with external peer review. While EFSA committee members had “another day job” and were assisted in the evidence collection and analysis by the EFSA staff, FDA work was done in-house by fully dedicated regulatory science experts, with external peer review of the outputs. The Credibility of EFSA’s experts was therefore based on drawing a rigid boundary between the scientific and regulatory domains, relying on the experts scientific (mostly academic) credentials and their research expertise in a laboratory setting, rather than on the in-depth expertise on the topic at stake or regulatory science more broadly.

“Independence” is a key criterion in the selection of EFSA’s experts. In this context, independence is understood chiefly as not having a financial stake in the issue, for example through ties with industries that could profit from the technology being regulated. All experts have to complete a public declaration

of interests (DOI) before they can be cleared to sit on a panel or WG, and any interest has to be declared so that it can be recorded. As recognised by the interviewees this can create a tension, as industry-based experts are often effectively excluded from the advisory process, despite being the one with the required expertise. In their words: "EFSA may not actually get the best scientific experts, but EFSA is getting the best scientific experts available [spoken emphasis], meaning that there are experts that could be working at an industry that have more expertise and have published more, but because of a possible conflict we cannot always use them" [EFSA staff 1]. The trade-off between depth of expertise on the specific subject at stake and independence from private interests, is in this case resolved in favour of the latter.

Such policy, which has been constantly revised by EFSA, does not however recognise other possible forms of conflict of interest, such as ideological commitments, professional investment in a specific area, and national interest. The latter is particularly prominent in the case of experts employed by national food safety agencies [EFSA staff 1] who officially serve on advisory panels in their personal capacity as experts, rather than as representatives of the country (contrary to their role in other advisory bodies such as the so-called "comitology committees" in the European Commission and the EFSA Advisory Forum).

By comparison, the EGE operates at a different scale than EFSA, being composed of a single expert group, and it can best be compared to the EFSA Scientific Committee rather than the agency as a whole. The group is composed of up to 15 members appointed by the President of the European Commission to include a "triangle of competences" (EGE secretariat 1), encompassing science, legal scholarship, and moral philosophy and theology. Members are drawn from academic and scholarly backgrounds, leading to the perception of the Group as "a very hybrid group, they are not scientists but of course there are people from the research" [SANCO staff 1]. The main competence of the EGE members was not subject matter

expertise, but rather their ability to clearly articulate scientific, legal, and moral reasoning in a dialogical manner [EGE member 2].

5.5. Assembling the evidence base

After the definition of the advisory mandate and the establishment of the WG the scientific advisory process enters its central phase. This involves the collection and analysis of scientific evidence, the deliberation over its implications and relevance to the question, and the writing of the advisory report and recommendations.

The work of the newly formed WG begins with the collection, synthesis and analysis of the relevant scientific evidence and data. According to its mandate established in the EU General Food Law,[22] EFSA's role is to "provide scientific advice […] in all fields which have a direct or indirect impact on food and feed safety". This advice is based on risk assessment, defined in the mandate as "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation" (Art 3.11), "based on the available scientific evidence and undertaken in an independent, objective and transparent manner" (Art 5.6). EFSA is therefore expected to only take into consideration scientific evidence, understood as data and results from the natural sciences. This was reflected in the cloning case, where the opinion was "based upon published peer reviewed scientific papers, data and other information deemed reliable" (EFSA 2008:6). Specifically, given the paucity of published literature on the subject the Opinion relied on both published and unpublished data, largely made available to EFSA by the US FDA [EFSA expert 1].

Animal health and welfare considerations took a prominent role in EFSA's assessment of cloning. In its request to EFSA, the Commission asks it to "advise on food safety, animal health, animal welfare and environmental

[22] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32002R0178

implications of live animal clones, obtained through SCNT technique, their offspring and of the products obtained from those animals" (EFSA 2008:5). The unit of analysis of EFSA's work was therefore animals derived from cloning and their offspring, and more specifically cattle and pigs, due to the paucity of data available on other species (EFSA 2008). Specifically, the main issue at stake in EFSA's analysis was to establish the health and welfare of such animals, as it assumed that food derived from healthy cloned animals would pose no novel risk compared to their conventionally bred counterparts. The focus of the advice is therefore not on cloning as a process or a technique, but rather on the products of such techniques, namely clones and their offspring.

Animal welfare in particular was a key problematic issue in the cloning case, as concerns existed about the suffering caused by the technique to both the mothers and the offspring. However, animal suffering and welfare was a complex issue that raised ethical questions and, given its mandate, EFSA was limited to consider the issue from a strictly objective and scientific perspective. Moreover, according to EFSA's mandate, animal health and welfare is not its main topic of concern, but rather subordinate one EFSA can "take into account" to "contribute to a high level of protection of human life and health" and "in the context of the operation of the internal market" (GFL Art 22.3). To maintain the boundary between facts and values on which EFSA's authority was predicated, in the cloning case animal welfare was conflated with animal health, thus disregarding aspects of animal welfare that could not be immediately translated into physiological indicators. Moreover, this was benchmarked against other reproductive techniques, such as assisted and in vitro fertilization, which were taken as the baseline for comparison (EFSA expert 1). In EFSA's assessment therefore, the indicator of animal welfare (or lack thereof) was the additional physical suffering associated with cloning above the baseline of other reproductive techniques.

Given that WG members were involved only part-time in the advisory process, the initial review and synthesis of the scientific literature and evidence was carried out by the secretariat, which went through hundreds of potentially

relevant publications identified on the basis of keyword searches and referrals [EFSA staff 1] to identify what to bring to the attention of the expert WG. This sifting process required members of the secretariat to make judgements calls about the relevance to the topic at stake of each specific study or piece of evidence encountered. Beside the explicit criteria outlined in the general mandate of EFSA and the specific terms of reference for the cloning request, a number of other considerations were taken into account to inform the selection. In particular, relevance to the risk assessment process was a key criterion informing the secretariat's decision to select what should be included for presentation to the scientific experts in the WG [EFSA staff 1]. In this context therefore, consideration of use (relevance to the downstream risk management process) is a key criterion to judge the importance of a scientific publication, and this judgement is carried out by the secretariat. In turn, this requires knowledge of the risk management process itself. After this initial selection by the secretariat, the WG would make its own judgement over the relevance and quality of the data, effectively carrying out its own "peer review" of the evidence for the purpose of the Opinion.

International networks of expertise, involving research scientists and regulatory agencies worldwide, were widely used to keep abreast of the latest scientific developments in the field, and to ensure consistency in how research results and data are interpreted [EFSA staff 3]. This points to the existence of a global regulatory science epistemic community (Haas 1992) against which the work of EFSA is constantly benchmarked.

Unlike EFSA, the EGE doesn't have limitations to what it can consider as evidence in its enquiry. The Group incorporates a wide range of inputs into its work, including legal documents, scientific evidence published in the literature, and stakeholders' views in an open hybridization process. The process is described by one of the rapporteurs as first trying to understand the state of the questions, then collecting the views and position of different stakeholders "trying to understand the position of different people on the question" [EGE rapporteur 1]. Finally, the Group discussed and weighed

these elements to arrive at consensus on a report. Although all these forms of evidence are given equal status and weight in the EGE reasoning process, this process shows a separation between establishing scientific matters of facts and collecting value-based stakeholder perspectives.

The safety of foods derived from cloned animals was one of the key scientific issues at stake in the cloning case, but the EGE opinion did not address it directly, instead deferring to EFSA's (epistemic) authority to assess such matters [EGE rapporteur 1]. Although its members recognised that it was "essential for any ethical opinion to consider any risk of a new technology", establishing the existence of such risk "was a job that EGE could not do" and the Group did not consider its task "a question of data related to toxicity and safety for consumers" [EGE rapporteur 1]. The Group therefore didn't look directly into the scientific evidence concerning food safety, instead it waited "for the opinion from EFSA, and considered opinion from FDA", which were "clear in this matter that there were no food safety concerns"[EGE rapporteur 1]. In the published Opinion, the FDA's conclusions about food safety are summarised without much discussion (EGE 2008, 21-23). In accepting without challenge the EFSA and FDA conclusions on the safety of food derived from animals, the Group recognised that "if there were food safety concerns, our opinion would have been different" [EGE rapporteur 1]. This deferral to EFSA's role in assessing food safety risk was consistent with how the Group's role was perceived by others: "in this case [cloning] they [the EGE] based themselves in other's scientific base already in existence, and they went a little bit further" [SANCO staff 1].

5.6. Consulting the public

As part of producing its opinion on cloning, EFSA engaged in a public consultation process. This was seen mostly as a (scientific) fact-finding exercise, as in the words of an EFSA official the process was set in motion: because obviously there could be issues that we have missed, indeed with a group of 10 cloning experts [the WG] and 15 experts of Scientific Committee there could still be issues that we would have missed [EFSA staff 1]. Although

another aim of the consultation was “to show open transparency and what EFSA at the time was working on” [EFSA staff 1], the consultation was mostly distributed through the same networks used to identify experts [EFSA staff 1], which highlights how this was intended largely as an exercise internal to the relevant research community.

Comments received were reviewed by the EFSA scientific officer in charge of the file, who did “a preliminary check” to assess whether they are “valid or not” [EFSA staff 1]. Validity was assessed by the secretariat on the basis of the comments’ relevance to EFSA’s role in scientific risk assessment: “A comment that says ‘I don't like cloning’ it's not relevant for EFSA to look at from a risk assessment point of view, that's more policy point of view” [EFSA staff 1]. The secretariat thus had to engage win demarcation to draw a boundary between scientific and value-based comments, allowing only the former to be included in EFSA’s work. Unexpectedly, in the case of cloning, the consultation exercise returned what was perceived as an unusually high number of comments, revealing a high degree of interest in the topic [EFSA staff 1]. However, as EFSA had only been operational for a few years at the time, a number of its processes, including public consultations, were still being developed, so an accurate benchmarking is not possible [EFSA staff 1]. A large part of the comments received in the cloning case were indeed of such more political nature, leaving the members of the secretariat in the position of having to manage the boundary between risk assessment and risk management by deciding what to take into consideration. Such judgements were informed by their perception of the appropriate role for EFSA in the risk governance process, as discussed in section 5.8.

Although the secretariat recognised the potential value of the comments received for the risk management process, no mechanism was in place for such comments to be meaningfully conveyed to the risk managers alongside the scientific advice, thus making the consultation exercise of limited substantial value in enhancing the effectiveness of the advisory process or of the policymaking towards which it was aimed. While the public consultation

exercise could be interpreted as a way to enhance both the scientific Credibility of the advice and its Legitimacy by involving a broad range of both scientific and societal stakeholders, the rigidity of the boundary and the lack of a meaningful way for non-factual inputs to be taken into consideration or passed on to the policymakers limits the legitimating function to a performance of openness. The primary function of this consultation is therefore the further strengthening of the Credibility of the advice by ensuring the completeness of the scientific basis, rather than meaningfully allowing for considerations of values and interests to be taken into account. Although the public nature of the consultation contributes to Legitimacy, it does so only as a secondary goal through transparency rather than meaningful inclusion.

5.7. Deliberating and writing the EFSA report

The aim of EFSA's work in providing a scientific opinion is to establish the state of the scientific knowledge on a specific topic, by achieving a consensus that is robust both scientifically and politically (i.e. producing advice that is Credible and Legitimate). To achieve this, the WG reviewed the evidence discussed above and prepared a draft report for the SC to review, assisted by the secretariat. As customary at the time in EFSA, authorship of the cloning scientific opinion was attributed to the SC, which ensures the quality of the output and takes responsibility for adopting the scientific advice, with acknowledgement to the WG for preparing it. No explicit mention of the role of the secretariat is made in the published opinion, and when mentioned in interviews their contribution is always referred to as "drafting".

Despite this characterization however, the role of the secretariat in the writing of the scientific opinion is not a mechanical execution of the advisors' will. Instead, they contribute to substantially shaping the text, for example by working to "get an opinion flow more nicely" and "write things to make it more understandable from a more layman's point of view" (ESAF staff 1). This work is not purely editorial either, but rather substantial to the Relevance to policymakers of the scientific opinion, by translating from the domain of research science, in which both the scientific evidence and the members of the

WG are largely rooted, to the hybrid domain of “regulatory science”: “making sure that sentences are re-worded into a way that is reflective of a risk assessment opinion. We're not writing a scientific paper per se, but it's a scientific risk assessment opinion” [EFSA staff 1].

Both the scientific experts involved in the WG and SC and the secretariat were well aware of the policy and political context in which they operated, and therefore of the weight carried by each of the words in the opinion. Wordsmithing therefore plays a particularly important role is the report drafting process, to both ensure consensus among the experts and to prevent unintended interpretations: “because we are realizing the political dimension in which we are working […] lots of efforts is invested in how we were wording it in our opinion so that it is not wrongly interpreted by people who are using the information” [EFSA staff 3]. “We operate by consensus yes, but the consensus sometimes is immediate sometimes just a matter of wording or fine-tuning, or put a nuance in in the texts, that's everybody with his own background and expertise can agree with how the sentence reads and it may often take one word” [EFSA staff 2].

The reasoning process of the EFSA committees involved the establishment of thresholds to assess whether something posed a concern: “[the panels] are trying to have a sort of benchmarking of what they consider: ‘well this is really where we consider that, at this phase, if the figures and the data are in this and in this area of concentrations or effects, in that case we don't consider it of a health concern’. But in order to come there you really need to have a weighing of the information, and then you have to explain it” [EFSA staff 2].

Discussion of uncertainties and knowledge gaps was a key part of the EFSA mode of reasoning. In the case where knowledge gaps prevented the group to reach an agreement on a position, the potential for disagreement was defused by bringing the uncertainty to the surface and including recommendation for further studies in the opinion: “If you have knowledge gaps you have to interpret what that means and how you can come to a conclusion in that, sometimes it's

not possible to come to a conclusion because there are too many uncertainties. But of course, the way that experts are looking at these uncertainties can always lead to discussions but not necessarily divergence" [EFSA staff 3].

This is particularly relevant in the cloning case, as the lack of sufficient data led to a cautious approach in drawing firm conclusions, and to the recommendations to continue monitoring the issue. Transparency of the reasoning leading to the conclusions taken in a specific opinion was seen as a core element of EFSA's methodology and Legitimacy. Indeed, shortly after the publication of its first scientific opinion on cloning in 2008, the EFSA SC released an opinion specifically on how to ensure transparency in scientific opinions stating that: "if you are drawing conclusions you should be able in every opinion [to tell] how the experts came to that conclusion, what they considered as of importance and what they considered as of less importance" [EFSA staff 3]. The aim of such transparent approach was both "valuing of the process that has taken place in EFSA" and to make it clear how certain conclusions, for example "a particular threshold or a particularly maximum amount that someone can be exposed to" [EFSA staff 2] have been reached. However, although this commitment to transparency of reasoning was seen as a step-change compared to the past, it is still covering mostly quantifiable uncertainties, rather than more fundamental ambiguities (c.f. Stirling 2007).

5.8. Constructing policy Relevance

As discussed, ensuring policy Relevance requires that the actors involved in the production of scientific advice actively coordinate across the science-policy boundary. In turn, doing so requires them to have an understanding of the policy process they intend to inform and of who is responsible for such policy processes, i.e., who are "the policymakers" being advised. In the cloning case, the risk assessment (RA) function is clearly identified by all involved as being the remit scientific advisory body (EFSA). However, risk management (RM) (the policy and political process towards which the advice is aimed) involves a whole chain of actors. DG SANCO, who is the main policy client of EFSA's

advice, prepares a RM proposal on the basis of the RA from EFSA and a range of other considerations. This needs to be approved by the political leadership of the European Commission before a legislative proposal is put forward by the Commission. This is then discussed by the co-legislators (European Parliament and Councils), who make their own amendments and are ultimately responsible for its adoption. It is therefore not immediately clear who the relevant policymakers are whose needs are to be taken into account by the scientific advisors to ensure Relevance, as different actors locate the risk management function in different “places” in the process.

European Commission staff in DG SANCO for example, who are the ones formally receiving the advice produced by EFSA, describe their role as “only collecting evidence” (SANCO staff 2) to be passed on to the decision-makers, rather than making (value-based) decisions themselves, thus further replicating the facts-values boundary already drawn by ESFA in its advisory process. This is consistent with what identified by Maybin (Maybin 2015) about the reluctance of civil servants to identify themselves as “policymakers”. In this context, RM is still considered a technical rather than explicitly political function, with the locus for political decisions being identified further downstream in the Commissioners Cabinets [SANCO staff 2].

The experts conducting the risk assessment in the EFSA WG are by design removed and insulated from the policymakers towards whom their advice is directed, to protect their independence from undue pressure as had happened in the past (see 3.3). Instead, members of the secretariat were in constant contact with the policy colleagues who will receive the advice, spanning the science-policy boundary to act as both buffer and coordination mechanism between the (independent) advisors and the policymakers. For EFSA staff, the policymakers towards which the scientific advice was aimed (risk managers), and whose needs and interests had to be taken into account upstream into its production, were broadly understood as including the Commission, the Council, the Parliament, as well as individual EU countries: “the risk managers are the Commission and members states, because the Commission is coordinating on

behalf of member states what kind of questions we receive, on the basis of which we have to do the risk assessments. […] aside from those we have also the Parliament, and we have Member States themselves. It could also be that Germany or France is asking us to take something on board [in terms of scientific evidence]" [EFSA staff 3].

Although formally the request for scientific advice to EFSA comes from the Commission, which was the "policy client" for the risk assessment, the secretariat at EFSA was keenly aware of the complexity of the downstream policy process in which it fed: "there was a quite a hard discussion Parliament of course. Parliament was dealing with it [cloning], there were lots of discussions taking place. Sometimes EFSA experts were invited to [46:02] come there" [EFSA staff 3].

A key task of the secretariat was therefore to follow and take into account the latest policy and political development surrounding the cloning case, and closely liaise with the risk managers in DG SANCO: "it was very important that that we could follow what was happening because those discussions in the parliament, those questions that were in the risk management area, were of course very important for us to know" [EFSA staff 3].

Although on the frontstage the process is presented as a strict separation between the risk assessment and the risk management, relying on a rigid boundary between science and policy to assert its independence and Credibility, in the backstage there was constant coordination between the secretariats and the risk managers in the Commission to ensure Relevance. Crucially, these interactions were managed entirely at the level of the secretariat, to preserve the independence of the WG experts. Moreover, while the WG was dissolved after the publication of the cloning opinion in 2008, the members of the secretariat continued regular engagement with policymakers in the Commission and with the broader policy process, allowing them to be ready when a new request came.

In this regard, it is important to trace back the historical origins of EFSA and its evolving relationship with its main advisee and “policy client”, DG SANCO. As mentioned above, up until the establishment of EFSA in 2000 the risk assessment and the risk management functions in EU food safety policy were competence of the same organization, DG SANCO. The scientific advisory committees informing EU food policy where managed directly by DG SANCO. When the separation of the RA and RM roles was institutionalized by creating EFSA as a separate entity, staff from the units previously responsible for the scientific committees in DG SANCO was detached to the newly formed agency, forming its core staff. EFSA was thus created by spinning out one of DG SANCO’s functions and the responsible teams into a new entity, geographically and administratively separated. For this reason, staff at DG SANCO and EFSA share the same institutional culture, and therefore the same professional values and goal.

The role off the EFSA secretariat evolved over time. At the beginning the role was more that of “interface” between scientific experts and risk managers in the European Commission, passively “passing the mandate to the committee” [EFSA staff 3]. However, with the growth and expansion of the Agency the staff supporting each committee has grown from 2-3 to 15-20, allowing them to carry out much of the preparatory work. To perform this role, the secretariat has to possess both scientific policy skills, inhabit both social domains, and be fluent in both “languages”. For this reason, it was composed of both technical specialists with a specific scientific background and “generalist that understand the context and can go to Brussels” [EFSA staff 3].

Many members of the secretariat of scientific advisory bodies have a scientific background, having PhD qualifications and sometimes even further research experience. However, they are also part of the professional community of civil servants and have been socialized in the norms and practices of policymaking. This allows them to be considered credible by active members of the scientific community like the expert advisors, while at the same time possessing the networks and language to effectively interact with and understand the needs of

the policymaking meant to receive the advice. In the case study analysed here, and in my own professional experience, the key concern of the secretariat is to contribute to the policymaking process by delivering a timely and usable piece of work, thus prioritizing Relevance. While scientific accuracy is valued in the process, and recognized as fundamental to the Credibility of the advice, it is not usually considered an end in itself.

5.9. Conclusions of the chapter

As shown in this chapter, the Credibility, Relevance and Legitimacy of EFSA's advice are constructed throughout its advisory process through both structural features and working practices. However, while appeal to the scientific credentials of the advisors and their independence from policymaking contribute to the Credibility of the process, these features of the mechanism are in tension with ensuring policy Relevance. Considerations of use are fundamental to inform the judgements made throughout the advisory process so that it incorporates upstream the political and societal dimensions it is directed to (Bijker, Bal, and Hendriks 2009). Yet the expert advisors are only involved part-time in the process, have no direct line of communication with or detailed knowledge of the policy domain they are aiming to inform, in order to preserve their independence. Legitimacy understood as inclusiveness and consideration of societal perspectives is not a prominent attribute of the process, which instead relies on the legitimizing function of its Credibility and independence from political and private interests.

This chapter has shown how at all key junctures of the advisory process (mandate definition, selection of the experts, selection of the evidence, reasoning, writing of the report, formulation of the recommendations) secretariat members engage in coordination, demarcation, translation and mediation and make crucial decisions that affect the Credibility, Legitimacy and Relevance of the advisory process. From the case study presented above it is clear that the experts serving on advisory committees are not the only important actors in this process, as secretariats play a substantial role in carrying out the boundary work that is necessary to ensure the effectiveness of the scientific

advisory process. In particular, it shows how the work of secretariats is crucial to ensure the policy Relevance of the scientific advice.

While scientific advisory bodies such as EFSA have been conceptualized as boundary organizations (Guston 2001) bridging between the domains of science and policymaking, and having lines of communication and accountability to both, the same dynamics are replicated inside the advisory body itself. Once the black box of EFSA is pried open to scrutinize the practices of scientific advice, it becomes clear that the secretariat acts as the main boundary spanner between the scientific experts and the policy client. Overall, the EFSA secretariat was well aware of this role: "we (EFSA STAFF) are in the grey area between risk assessment and risk management" [EFSA staff 3].

6. Case study 2 - the Scientific Advice Mechanism (SAM)

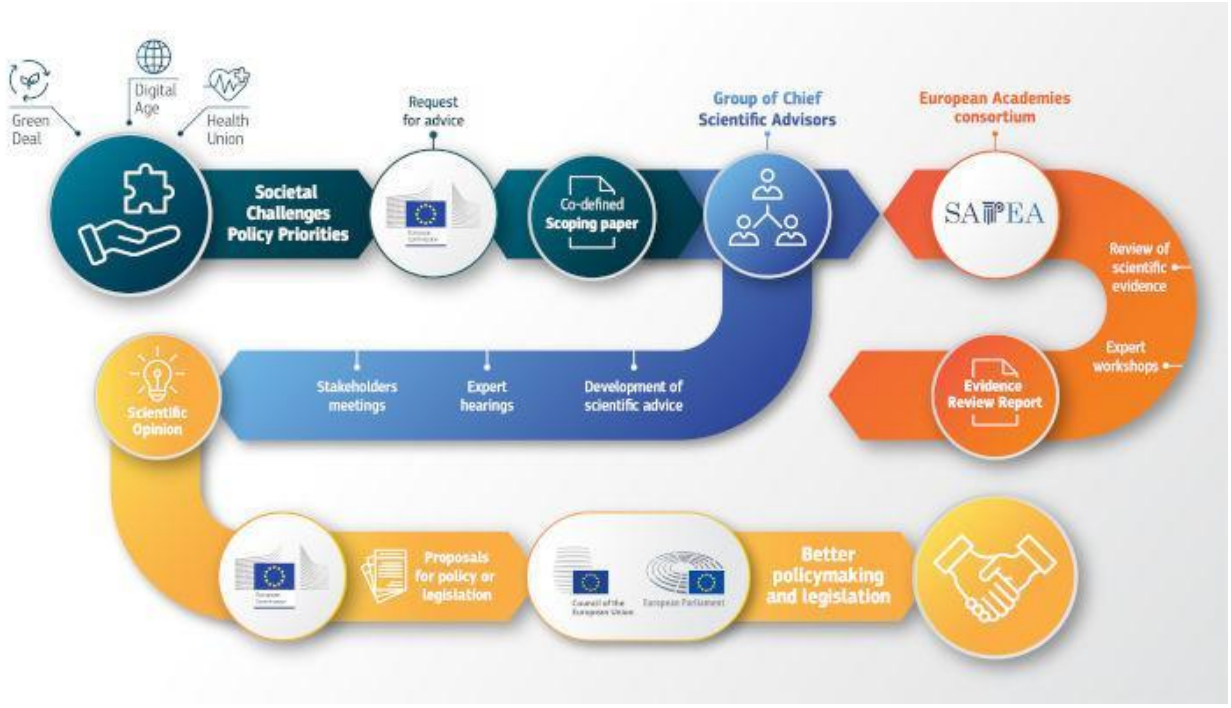
The second case study presented in this chapter discusses the functioning of the European Commission's Scientific Advice Mechanism (SAM) to explore how CRELE attributes (Credibility, Relevance and Legitimacy) are constructed in its work. The case study draws on documents, interviews, and auto-ethnographic observations to present a detailed account of the processes and practices through which the SAM produces its advice, and of how the different actors contribute to the construction of CRELE and the management of boundaries and trade-offs. These are interpreted through the lenses of the theoretical concepts presented in chapter 2, before drawing in the next chapter a comparison with the analysis of EFSA presented above.

6.1. The SAM advisory process

As mentioned, the SAM has its legal basis in the "Commission decision on the setting up of the High Level Group of Scientific Advisors"[23] (henceforth referred to as "Commission decision"), and the process through which it produces its advice is described in the "Rules of Procedure of the Group of Chief Scientific Advisors" and its annex "From questions to answers - How the European Commission's Scientific Advice Mechanism produces scientific advice to support policy making", collectively referred to as the SAM guidelines.[24] These guidelines describe five steps in the production of the SAM's scientific advice: 1) identification of a subject for scientific advice; 2) defining the question (in the form of a "co-defined scoping paper"); 3) gathering evidence; 4) drafting the GCSA advice; and 5) adopting and communicating the advice. The SAM guidelines are complemented by SAPEA's own "Guidelines on advising policymakers and society" and its "Procedures for quality assurance of scientific advice".[25] The process is also illustrated in an infographic flowchart titled "How the Group of Chief Scientific Advisors works", published on the SAM website and reproduced below:

[23] Commission decision on the setting up of the High Level Group of Scientific Advisors (2015, amended in 2023) - Commission decision on the setting up of the High Level Group of Scientific Advisors (europa.eu) (accessed on 13/11/2023)
[24] European Commission (2020) - https://research-and-innovation.ec.europa.eu/system/files/2020-10/rules_of_procedure_group_of_chief_scientific_advisors_sep2020.pdf (accessed on 13/11/2023).
[25] SAPEA (2019) - https://www.sapea.info/wp-content/uploads/qa-guidelines-2020.pdf (accessed on 13/11/2023)

Figure 9: How the Group of Chief Scientific Advisors works



Source: SAM website[26]

In most cases, scientific advice provided to the European Commission by the SAM takes the form of two complementary documents: a longer Evidence Review Report (ERR) produced by SAPEA, which presents a synthesis of the state of knowledge on the topic and provides the main scientific underpinning of the advice, and a shorter Scientific Opinion produced by the GCSA, which provides policy recommendations. While the process is presented in a linear order, with the production of the ERR preceding logically and chronologically that of the Scientific Opinion, in practice it is largely iterative with many steps taking place in parallel, as described in this chapter.

6.2. Commissioning advice

The legal basis of the SAM stipulates that requests for scientific advice to the GCSA are formulated by the Commissioner responsible for Research, Science and Innovation “after consultation of the thematically responsible member of the College” [Commission decision], i.e. the Commissioner in charge of the

[26] https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en (retrieved 15/09/2023)

relevant policy area. The SAM guidelines further detail the commissioning process, stating that thematic Commissioners can initiate it through a request to the Research Commissioner, who is responsible for "informing" the Advisors and "for the formulation of the request for advice following a consultation request originating in the Commission".

Such request takes the form of a scoping paper, the purpose of which is to "provide greater detail on the request for consultation and the question(s) on which advice is to be provided" [SAM guidelines]. It normally contains the context and background on the policy issue at stake, the rationale for the request (for example, an upcoming policy decision that requires scientific input and advice), and the main question(s) and sub-questions being asked. It also defines the deadline by which the advice is expected. As discussed below, these elements are important to ensure the SAM's advice can meet the needs of its policy clients, thus contributing to its Relevance.

The adoption and publication of the scoping paper are preceded by the identification of potential topics for advice, and the formulation of the specific questions contained in the request. Although not explicitly mentioned in the SAM guidelines, the term "scoping phase" is often used by the SAM secretariat and the GCSA to refer to this preparatory work until the adoption and publication of the scoping paper [interviews and personal observation], which normally lasts between 12 and 18 months. This phase is seen as playing a critical role in ensuring the buy-in of the policy clients.

Figure 10 - Commissioning of SAM advice

Source: Own elaboration.

6.2.1. Identifying a topic

The procedure outlined in SAM guidelines begins with the request from the Commissioner responsible for a policy area to the Research Commissioner, who is responsible for the SAM. Before such a formal step, an iterative process takes place to identify suitable topics for the SAM to work on. Policy DGs and Cabinets can spontaneously approach the SAM to discuss potential requests for advice, especially those who have worked with it in the past (e.g., the microplastics (2019) and biodegradable plastics (2020) Opinions were requested by DG Environment as a follow up on previous work on “Foods from the Oceans” in 2017).

Although the Advisors can also identify and propose so-called “bottom-up” topics to work on at their own initiative, and part of their mandate is to “support the Commission in identifying specific policy issues where independent scientific advice is needed” [Commission decision], they cannot autonomously decide to produce advice on a topic without a formal request from the Commission. SAPEA can also identify and propose possible topics for advice, but this is handled through a two-step process mediated by the Advisors and the SAM secretariat. As discussed below (see 6.4.4), direct contacts between SAPEA and the Commission are tightly controlled, with all interactions to be channelled exclusively through the SAM secretariat. This tightly managed commissioning mechanism makes the SAM’s advice strongly demand-driven, managing the push-pull trade off and serving a double function. On the one hand it ensures that the work of SAM remains focused on actual policy needs of the Commission, thus avoiding the mismatch common with advice proactively provided by academies before the creation of the SAM. On the other hand, it allows the Commission to control the topics on which the SAM can express views, thus avoiding potential conflicts or embarrassment.

In most cases however it is the SAM secretariat that plays a proactive role in scouting possible topics for the SAM to work on, and in inviting policy DGs to approach them for a request [personal observation]. As Commission staff, members of the SAM secretariat have access to internal information about the

Commission's ongoing and upcoming policy work and take part in internal networks and knowledge sharing activities that allow them to identify possible topics to explore. One of the mechanisms is the "SAM Inter-Service Group" (ISG), an ad hoc semi-formal network of correspondents from other policy Directorate-Generals (DGs) that is regularly mobilized by the SAM secretariat to share updates on ongoing work and identify possible topics for future advice [SAM staff 6, personal observation]. ISGs are standard mechanism used within the Commission to coordinate work across different DGs. The ISG is "the first line of communication with other DGs, allowing them to intervene in the process of discussions during the scoping phase" [SAM staff 6], and is used both during the exploratory identification of topics and during the later refinement of the scoping paper.

Other mechanisms include informal contacts with colleagues, attendance to internal seminars and presentations, and the scanning of internal planning documents which are regularly circulated within the Commission to seek input and coordinate across DGs. Having both the same professional culture and formal access to information as their colleagues in the "client" policy DGs, members of the SAM secretariat participate in both social worlds and can more easily engage in these interactions. Knowledge about upcoming policy or regulatory activities can be shared with them through informal and confidential exploratory exchanges that would not be possible with externals [personal observation] (see also section 6.6).

In the identification of possible topics for the SAM to work on, an important concern of the Advisors and the secretariat is to ensure a good fit with the specific remit and competences of the SAM. This means identifying topics which are neither too broad or overlapping with the work of other advisory bodies such as the International Panel on Climate Change (IPCC), or too technical or regulatory, for which specialized EU agencies like EFSA could be better placed [SAM Staff 2]. A too broad focus would make the Scientific Opinion not actionable, not "so effective in suggesting what line of policies should be taken" [SAM staff 2], thus undermining Relevance. On the other

hand, a too specific focus would risk duplicating existing efforts, and not add value from the SAM perspective. A good topic for the SAM is seen as having a "substantive" scientific dimension "in the sense that it can be based on evidence rather than just on views of people [CSA 1]" and is complex, systemic and requires a multidisciplinary approach [SAM staff 2]. Most importantly, it needs to address a clear policy need of the Commission, i.e., have a defined policy process or decision to target and the necessary buy-in from those in charge of developing the policy and potentially receiving the advice [personal observation].

Following these initial interactions and assessment, potential topics identified by the secretariat are "discussed both with the Advisors and to certain extent also with SAPEA to see whether the question is amenable to scientific advice and what form the advice could take" [SAM staff 6]. The Advisors "evaluate whether it is possible to address the question using their approaches and their type of processes. And generally to see if the question is important enough to put that much energy into it" [SAM staff 6]. These considerations of scientific adequacy and feasibility are important, as meeting them is a prerequisite for producing Credible advice. Based on these considerations from the SAM, on the interest of the requesting policy DG, and on practical considerations about resources and time available, some topics are selected for further scoping.

6.2.2. Defining the question

Once a suitable potential topic is identified, the work begins to formulate a specific request in the form of a scoping paper and obtain the necessary buy-in and approval from all actors involved. This is a "very long and iterative" process [SAM staff 2] in which the SAM secretariat is responsible for "coordinating the development of the scoping paper with the service(s) under the Commissioner who initiated the subject, involving also other relevant services" [SAM guidelines]. In practice, this involves members of the SAM secretariat performing desk research to identify the key references for the policy and scientific context and prepare a first draft in consultation with colleagues from the requesting DG [personal observation]. Drafts of the

scoping paper are distributed internally for feedback via the SAM Inter-Service Group (ISG), with DGs closer to the policy area at stake more closely engaged in the drafting process, as well as with the Advisors [SAM Staff 6]. Due to the high number of ISG and the sometimes low level of engagement when requests are sent to a large internal mailing list, informal networks and contacts between staff members are often leveraged to secure engagement and feedback [personal observation]. Involvement of policy officers from several DGs in shaping the specific questions and sub-questions is seen as instrumental to ensuring their buy-in for the advice provided, as "everyone finds one aspect, one sub- sub- sub-recommendation that talks to them, and this is the objective, to be relevant for the different DGs" [SAM staff 2]. In this phase, they key concern is to ensure a clear and adequate framing of the request, a comprehensive mapping of the policy context and the identification of clear policy targets, and a realistic timeframe.

Although most initial interactions take place at the more technical level of policy DGs, Commissioners' Cabinets are sometimes also involved to bring in a more political perspective. Active involvement of a Commissioner's Cabinet in the scoping of a request can be positive, as it demonstrates political buy-in and the "almost guarantee" that the advice "is going to be used in one way or another" and "actively considered in the policy making process" [SAM staff 4], contributing to its Relevance. However, there is also a risk that direct requests from a Cabinet are too specific and narrowly framed in policy terms, and therefore not a good fit for the SAM [SAM staff 4]. A too specific and detailed scoping paper for example risks "to pre-empt what would be the final Scientific Opinion, because by the question you ask you are also guiding the type of response that you may get" [SAM staff 2]. The SAM secretariat needs to carefully and selectively manage inputs and requests from policy clients, and is only obliged to take them into account "to ensure factual correctness and relevance regarding the policy and regulatory context" [SAM guidelines].

The secretariat takes an active role in shaping the questions with the policy DGs, using their judgment to assess "what they need more than what they

want. Because maybe they don't exactly know what they need, maybe they want something that they don't necessarily need and vice versa" [SAM staff 4]. The SAM secretariat often has to reframe purely "practical" policy questions into broader and more general ones that are better suited to be addressed by the SAM on scientific grounds [SAM staff 2], while at the same time ensuring that the question remains relevant in a policy context, thus bridging the boundary between the policy and scientific domains by performing a translation. Through its work, the secretariat makes the boundary selectively porous to ensure both a clear demarcation between the policy and scientific framing of the issue, and thus contributing to its Credibility, and sufficient cross-domain orchestration (Miller 2001) to ensure Relevance.

The Advisors are consulted through the secretariat, and "may suggest that the request is (re-)focused, that timing or precise questions are modified, or that a scoping paper is sent back to the Commission for further clarification" [SAM guidelines]. It is important that these clarifications happen early on during the scoping phase, because once the scoping paper is finalized and published any discrepancy between the request and the advice provided become obvious, risking undermining the process [SAM staff 4].

Negotiations over the timeframe of the production and provision of the advice are a key part of the scoping phase. On the one hand, it is important that the timeframes of the policymaking processes towards which the advice is aimed are taken into account, to ensure its timeliness and therefore Relevance. On the other hand, producing comprehensive and scientifically robust (and therefore Credible) advice requires a lengthy process. Diverging demands over deadlines are a common feature of the SAM scoping phase, and the secretariat is well aware of the trade-off between speed and quality [personal observation]. The secretariat actively works to mediate between the often-competing demands of the policy clients and the Advisors and SAPEA to negotiate a mutually agreeable timeframe. This is achieved in practice by attempting to understand the needs of the two sides (for example, is the deadline proposed by the policy client due to an unmoveable legislative timeline, or to a

consideration of political opportunity such as a scheduled public event at which the advice could be announced? Is the proposed timeline clashing with the academic calendar most of the experts are tied to?) and proposing solutions (can the scope be narrowed to something more manageable in the time available? Can the advice take the form of a shorter statement rather than a full scientific opinion, or broken down into intermediary deliverables? Can some steps of the advice production process be compressed or parallelized?).

6.2.3. Co-creating the mandate

Once a draft scoping paper is agreed between the requesting policy DGs, the SAM secretariat, and the Advisors, it is transmitted to the Cabinet of the requesting Commissioner for political validation. The requesting Commissioner then transmits the scoping paper to the Commissioner responsible for Research and Innovation and for the SAM, who takes the final decision on its adoption “in cooperation with the Advisors” [SAM guidelines], before formally issuing the request and publishing it on the SAM website.

The scoping paper provides the main public link between the policy needs of the Commission and the scientific advisory work of the SAM. By identifying the specific knowledge needs of the Commission and a clear policy target towards which to direct the advice, it contributes to defining its exact scope to enhance its usefulness for policymakers. Moreover, by setting a deadline for the delivery of the SAM’s work, it ensures that the timeframe of the advisory process is aligned with that of policymaking. The scoping paper is a hybrid: scientific, policy and political considerations all contribute to its shaping, and although it is published as a document issued by the Commission, the decision to adopt it is taken by the Research Commissioner “in cooperation with the Advisors” [SAM guidelines], so that both parties have ownership of it.

The SAM scoping paper exhibits some of the features of boundary objects (Star and Griesemer 1989; Guston 2001). By focusing the scope of the advice to be provided, it also outlines its limits, determining which issues are to be considered as open and which as fixed/settled, and thus not within the remit of

the Advisors. It therefore provides a demarcation function, separating the domains of science and policy and reinforcing the respective autonomy of the policy clients and of the scientific Advisors, thus contributing to the independence and Credibility of the advice. At the same time, it also serves a coordination function by framing the question in policy terms, providing a clear timeline to produce the advice, and outlining the policy processes it aims to inform. This provides the framework conditions to enhance the policy Relevance of the advice.

Overall, the scoping phase is seen as an intrinsic although sometimes "underestimated" [SAM staff 2] part of the SAM advisory process, and one which is central in ensuring its effectiveness. The involvement of both the demand and supply sides in the definition of the mandate is seen as a unique feature of the SAM advisory process [CSA 1], and this dual participation in the co-production (Jasanoff 2004) of the request distinguishes it from previous models of scientific advice in the EU. Although the formal process outlined in the SAM guidelines allows for the Advisors to reject or send back for clarifications a request after the scoping paper has been finalized by the Cabinets, in practice the coordination happens beforehand, thus avoiding public deconstruction of the request. However, the scientific Advisors themselves are only involved indirectly, and the larger scientific community represented by SAPEA, which carries out the bulk of the evidence assessment and synthesis, is largely absent from the process. Instead, the SAM secretariat carries out most of the coordination, translation and mediation work, and plays a central role in this phase: they are "very strongly involved" and "usually quite instrumental in putting [the scoping questions] in the correct words" [CSA 1].

Moreover, this active participation in the scoping phase enables the SAM secretariat to have a better understanding of the wants and needs of the requesting policy Directorate-General (DG) beyond what expressed in the final scoping paper [SAM staff 4]. It allows them to understand "the many tensions between different DG and how they see differently the same topic" and "the different nuances and the different perspectives that need to be taken on board"

[SAM staff 2] in the formulation of the scientific advice. While the final published scoping paper will reflect a compromise position between these different perspective, knowledge of the full context of a request, and access to these internal discussions and negotiations, allows the secretariat to see beyond the black-box of the scoping paper and have the relevant background to better coordinate the production of the scientific advice downstream from the scoping phase, for example when giving direction to SAPEA for their evidence gathering [SAM staff 2, personal observation]. As remarked by a member of the SAM secretariat [SAM staff 4], keeping "the people who were closely associated with the preparation and the review of the scoping paper in the loop" of the evidence gathering process is important, as it allows for the considerations of policy needs beyond those that can be publicly expressed in the scoping paper, thus strengthening the Relevance of the advice.

6.3. Assembling expertise

The SAM advisory process involves a large number of actors, each contributing with their unique expertise. While the core structure and composition of the SAM is fixed over the medium term, the specific sub-configuration working on a specific piece of scientific advice is determined ad-hoc for each project. In particular, while members of the GCSA are appointed for a multi-year mandate and thus work on several topics, for each specific topic 1-2 are selected as leads based on individual interests and availability, supported by 2-3 members of the SAM secretariat and by an ad-hoc Working Group (WG) of subject matter experts created by SAPEA.

6.3.1. Selection of the GCSA

Members of the GCSA are appointed by the European Commissioner for Research and Innovation for a 3-year mandate (renewable up to 5 years) following an initial screening by an identification committee and a preselection by the SAM secretariat. Following an open call for nominations, an "independent identification committee" assist the Commission in selecting potential Advisors "on the basis of objective criteria" [Commission decision] outlined in the legal document establishing the Group. These criteria include

scientific excellence, experience in providing scientific advice to policymakers, scientific leadership, as well as considerations of diversity and inclusion.

While scientific excellence is a prerequisite for being selected as part of the GCSA, experience of working at the science-policy interface at the national or international level is also a key factor: “Members of the group shall individually have an undisputed reputation as research leaders and for their independence and commitment to research. […] Beyond their proven reputation as scientists and researchers, the membership shall collectively bring experience in providing scientific advice to policy makers, acquired across a broad range of Member States, and at European and international levels” [Commission decision]. While disciplinary diversity is an important consideration in the composition of the Group, a strong emphasis is put on interdisciplinary, and individual Advisors “shall not perceive themselves as representatives of a discipline or of a particular line of research” [Commission decision].

Gender, age, and geographical provenance are also among the criteria used in the appointment of GCSA members, and the balance of these characteristics is central to ensure the representativeness of the Group, which contributes to both its Credibility and Legitimacy: “the credibility[27] of the group shall be built on the balance of qualities amongst the women and men who make it up, and they shall collectively reflect the breadth of the research community across Europe. Consideration shall also be given to younger next-generation leaders” [Commission decision].

However, the identification committee only assesses individual nominees, and it is therefore the responsibility of the SAM secretariat to assemble a proposal for the Commissioner’s consideration that takes into account the Group as a whole, and the balance between disciplines, genders, geography and career stages. In doing so, the secretariat needs to take into account and mediate between the values and norms of both domains: those of the scientific community, from which the group is drawn and the association with which lends

[27] The term is reported here as used in the original document

it scientific Credibility, and those of the EU policy community, in which the Group will operate and in the eyes of which it has to be perceived as Legitimate. Criteria like multidisciplinarity, disciplinary diversity and involvement of early career researchers are of great importance to the scientific community, and reflect debates about scientific practice itself. On the other hand, attention to the geographical distribution of members (large vs small countries, old vs new member states, north/south and eastern/western Europe, low R&I performing "widening" countries[28]) reflects political criteria and mirrors the broader norms of committee formation in EU policymaking. Given the small size of the Group, the balance between these sometimes competing criteria is often found by identifying individuals who fit as many criteria as possible, for example by working between different countries and scientific disciplines, and thus enable for a flexible interpretation of which criteria they "tick" depending on context (for example, expertise in psychology and behavioural sciences is interpreted as falling under both the social sciences and health categories, allowing a degree of flexibility in constructing disciplinary balance).

Beside the criteria explicitly set out in the legal base, the secretariat also takes into account pragmatic considerations such as the nominees communication and English language skills, and their attitude towards cooperation and teamwork. This is done to ensure a smooth working dynamic within the Group and is achieved through a combination of desk research and discreet enquiries among the scientific community [personal observation]. As detailed in section 6.3.3, an extensive screening for possible conflicts of interest is also put in place to guarantee the independence from private interests that might bias the Advisors, thus contributing to the Legitimacy of their advice. Based on the proposal put forward by the secretariat, the decision to appoint a specific group and/or member rests in the hands of the responsible Commissioner, and is ultimately a political decision. The boundary between science and politics is maintained through this division of labour in the selection and appointment: the

[28] In the context of EU policy "Widening countries" are defined as those with low participation rates in EU funded Research and Innovation programmes, mostly from Eastern and Southern Europe (Bulgaria, Croatia, Cyprus, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia) – see https://rea.ec.europa.eu/horizon-europe-widening-who-should-apply_en

identification committee makes the first filtering based mostly on scientific criteria, ensuring that each potential candidate individually meets criteria of scientific Credibility. The secretariat assesses the Group as a whole and mediates between scientific and policy considerations to propose options of configurations which are both Credible and Legitimate. On this basis, the Commissioner's Cabinet can make the final (political) decision, without however being able to impose candidates who have not been selected in the previous stages.

Unlike Chief Scientific Advisors in other countries, and the single CSA model previously implemented by the Commission, in the SAM model Advisors are not directly employed by the Commission. Although they receive payment for serving as part of the GCSA, this is meant to "cover the direct cost of the time that's used" and entails "no contractual commitment" [CSA 1]. Advisors remain employed by their home institution, usually a university, and thus their independence is further guaranteed by their academic freedom: "they are independent scientific researchers, usually from academic institutions, so they don't have the at-home direct pressure from the ministries and so on" [CSA 1]. This can be interpreted as a form of dual accountability: in their role as Advisors they are appointed and funded by the Commission, but as scientists they remain attached to their scientific institution, and responding chiefly to its norms and dynamic, which provides them a degree of insulation from political pressures.

A full list of GCSA members with their affiliation and discipline can be found in Annex 3. Out of 16 members who have served since the establishment of the GCSA is 2015, the gender split is equal, and the disciplinary distribution is balanced between physical and mathematical sciences, life sciences, and social sciences. All GCSA members were affiliated either to universities of public research institutes, which together with their personal scholarly credentials (signalled for examples by accolades such as Nobel prizes, Field medals, ERC grants) contributes to the scientific Credibility of the GCSA.

6.3.2. Establishing the SAPEA WG

While the GCSA provide a semi-permanent group of high-level experts, for each specific request for scientific advice SAPEA establishes a dedicated working group (WG) of subject-matter experts to provide the specific evidence base in the form of the Evidence Review Report that informs the Advisors' Scientific Opinion.

The first step once a request is received by SAPEA is to identify a Chair for the WG [SAPEA staff 1], who "leads the whole process of evidence gathering and assessment which results in the preparation of an Evidence Review Report [SAPEA guidelines]. Criteria for selecting the Chair include "experience in leadership and the science policy interface, knowledge of the subject and track record of scientific excellence" [SAPEA guidelines]. The potential Chair is identified by the SAPEA academies network leading on the specific topic through a "very informal" process [SAPEA 1], based on the scientific contacts and networks of the academies, and appointed by the SAPEA Board, which takes the final decision [SAPEA guidelines].

Contrary to the informal process of selecting the Chair the process to nominate members for the WG is "very formal" [SAPEA staff 1]. A call for nominations is drafted by the SAPEA secretariat with the help of the Chair, outlining the areas of expertise that are being sought for the WG [SAPEA guidelines]. The call is not public, but instead is distributed through the academies networks to all the academies across Europe, which can decide to nominate experts "if they want and through the whatever system they want" [SAPEA staff 1]. Experts nominated by academies do not have to be members of the academies themselves [SAPEA guidelines]. Although the experts selection and the evidence gathering process is run independently by SAPEA, the GCSA and the SAM secretariat can suggest experts to be considered. This is usually done to ensure that all areas of expertise deemed relevant to inform the production of "meaningful recommendations" [SAM 4] are covered in the WG. However, SAPEA retains the autonomy to decide whether to accept these suggestions

[SAM staff 6], and the final decision rests with the SAPEA Board, which is responsible for the scientific quality of the WG and its outputs.

Nominations are pre-screened by the SAPEA secretariat, which assesses their fit to the topic based on CVs, and submitted to a selection committee composed by the WG Chair, two SAPEA Board members, and a second independent topic expert "to counterbalance the expertise" [SAPEA staff 1] of the WG Chair, which chooses the WG members based on a range of criteria. Expertise in the specific areas outlined in the request is "the first and most important criteria" [SAPEA staff 1] alongside scientific excellence [SAPEA guidelines], thus forefronting scientific criteria which contribute to Credibility. But other criteria such as gender balance, representation of early- and mid-career researchers, inclusion of "widening countries" and geographical balance in general are also considered, as outlined in the SAPEA strategy of diversity and inclusiveness.[29] Explicit efforts are put in ensuring that a broad range of disciplinary perspectives, including from the social sciences, are taken into account for any specific topic. Based on a long list prepared by the selection committee, the SAPEA Board decides the final composition.

6.3.3. Assessing conflicts of interests

All experts involved throughout the SAM Advisory process are thoroughly screened for potential conflicts of interest (COI) to ensure they act "in the public interest" [SAM guidelines]. This includes the Advisors, members of the SAPEA WG, participant in SAPEA and GCSA expert workshops (see 6.4.1 and 6.5.3), and any other expert who provides input in the production of the SAM's advice [SAM guidelines, SAM rules of procedure, SAPEA guidelines]. As the independence of the experts involved in the SAM process is a central element of its Legitimacy (see 6.6), the assessment of potential COIs is a key step in the selection process.

[29] See https://scientificadvice.eu/about-us/scientific-advice-mechanism/diversity-and-inclusiveness/ (retrieved 13/11/23)

According to the definition provided in the European Commission's rules on expert groups, which is used by the SAM, a COI is "any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest when providing advice to the Commission in relation to the subject' of the advice in question".[30] In this context, interests are defined as including relationships of employment, consultancy, or advice; receiving research funding; ownership of shares, stock or patents; as well as "involvement in public statements or positions"; and extend to the interests of immediate family members [SAPEA guidelines]. In practice, interests are often narrowly interpreted as those of economic or financial nature such as employment in, or research funding from, private sector entities [SAM staff 6, personal observation]. "If an expert is being paid by an organization that has an interest in the policies that can favour them […] this would be a red flag, because it could be seen as someone trying to benefit directly from the advice they would give an orientation" [SAPEA staff 1].

Experts are requested to fill in a standard Declaration of Interest (DOI) form, requiring them to declare interests "that are relevant to the field of the activity in question from the past five years" [SAPEA guidelines]. This is then assessed by either the SAM secretariat (in the case of members of the GCSA and experts interacting directly with them) or by the SAPEA secretariat and selection panel (for WG members and other experts involved in the SAPEA process). SAPEA uses the same DOI form and definitions as the Commission, so an expert participating in separate events organized by SAPEA and the Commission only needs to fill one form. However, the assessment of potential COIs is dynamic and specific to each activity. In the case of the GCSA, potential COIs are assessed both at the moment of appointment and dynamically throughout their mandate for each new topic and activity.

[30] Article 2(4) of Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups, C(2016) 3301 final.

Assessment of the information reported in the DOI is “supplemented” by desk research: “[we] try to see if there was maybe something that hasn't been declared, or if they're if some interest has been declared to try to find out if the extent to which the interest was declared is correct” [SAM staff 1]. Web searches play a particularly important role, as perceived COI are as important as substantial ones, and the secretariat scan for what someone looking to challenge the independence and Legitimacy of the SAM process could find out in the public domain [personal observation]. DOIs of selected experts are public: only after publication of the report, for six months, in the case of SAPEA experts; for the whole duration of their mandate in the case of the GCSA.

Having a declared interest does not necessarily mean having a COI and “does not automatically disqualify experts” [SAPEA guidelines]. For example, a potential expert being considered for contributing to SAM’s advice on sustainable food consumption was considered has having a potential COI for having previously received funding from a large player in the food industry. However, because “enough time had passed since [they] had received these grants and because [they] was employed by the French government, we judged that the interest was not important enough to constitute an actual conflict of interest” [SAM staff 1]. In this case, government affiliation not only is not seen as an interest of concern, but instead is considered a positive element that mitigates previous industry contacts.

If SAPEA establishes the existence of a conflict of interest, the expert can be excluded from some or all activities, for example being excluded from the main WG but still invited to participate in expert workshops [SAPEA guidelines], and their contribution carefully managed: “if the conflict of interest is not so big, but it's a risk, then you can also monitor very closely the contributions and also make sure that the experts stays clear from the sections of the report that would be in direct potential conflicts with them, and then you would put them in other sections [SAPEA staff 1]. Making interests transparent to the rest of the WG, and the public (after publication), is also a way to reduce the risk of biases. Independence from external interests is also ensured by holding WG meetings

“closed to the public in order to attempt to reach a consensus free from outside influence” and not making public the names of the WG members until after the publication of the ERR [SAPEA guidelines]

In the case of the GCSA potential COIs are also managed through total or partial exclusion of the expert from a given meeting or activity, or by deciding “that the expert shall abstain from discussing an item on the agenda, depending on the magnitude and nature of the COI”. Such instances are recorded in the public minutes of the GSCA meetings [SAM rules of procedure]. This flexible management “gives better control of conflicts of interest issues whilst allowing access to the full range of scientific evidence necessary for good scientific advice for better policy development” [SAM report], allowing for a dynamic balance between Credibility and Legitimacy based on case-by-case considerations of the specific context.

The assessment and management of COIs is central to the SAM’s narrative of independence, and is seen by some members of the SAM secretariat as one of their main tasks [personal observations]. The SAM secretariat even double-checks the DOIs of SAPEA experts to confirm the assessment performed by SAPEA. The process is “not pro forma” [CSA 1] and is taken very seriously by the secretariat [SAM staff 2], with a number of cases in which experts have been partially or totally excluded [CSA 1, personal observation]. However, in practice the main reason for exclusion are economic interests, and the process effectively screens out most experts with private sector affiliations, so that it's mostly the academic world represented in the evidence gathering process [SAM staff 6, personal observation]. Overall, independence and Credibility are given prominence over a broader representativeness of societal perspectives and interests, which would contribute to Legitimacy (as defined by Cash et al, see 2.6).

6.3.4. Expertise of the SAM secretariat

The SAM secretariat is presented as a purely ancillary structure whose role is to provide administrative and operational support to the GCSA and to manage

the SAM [SAM guidelines], and it is therefore not necessarily considered a source of expertise. However, as shown in the rest of the chapter, members of the secretariat actually play an active role in the production of the SAM's advice, bringing in both scientific and policy expertise (c.f. Page 2010). The majority of the members of the secretariat dealing directly with the production of the scientific advice (thus excluding those with purely management or administrative responsibilities) come from a scientific research background, holding a PhD and having (at least some) research experience. For example, of the 15 members of the secretariat who worked in the SAM during my time there (March to July 2018 and October 2020 to June 2022) all had a PhD and many had further post-doctoral research experience, in fields varying from mathematics to engineering to linguistics.

This scientific training serves both a practical and a symbolic purpose. On a practical level, members of the secretariat are expected to engage with scientific content at various stages of the process, both to conduct evidence gathering themselves and to assess the evidence gathering done by SAPEA (see 6.5.1). To this end, their scientific background comes useful, providing them with the knowledge of how to search and navigate scientific literature, assess its quality and reliability, and extract and synthesize relevant information [SAM staff 1, 4, 5 and 6], as well as more generally exercising "critical thinking" [SAM staff 5 and 6]. Moreover, their background in scientific research enables members of the secretariat to discuss scientific content with the Advisors and scientific stakeholders with "credibility"[31] [SAM staff 1], and to be perceived as helpfully contributing on the content [SAM staff 1 and 4], rather than simply on process.

At the same time, given their role in coordinating the production of scientific advice with policy colleagues and in supporting the drafting of the Scientific Opinion (see 6.5) they need to be able to "communicate [scientific] complexity [to policymakers] without being too technical" [SAM staff 5], performing a translation function between the scientific and the policy domains. Moreover,

[31] The term is reported here as used by the interviewee

being civil servants working within the European Commission, members of the SAM secretariat have access to internal knowledge and processes not available to external experts and can interact as peers with the policy officers in other Directorate-Generals requesting the scientific advice, being perceived as “trusted colleagues” [SAM staff 4]. They effectively belong to both the social worlds of scientific research and that of EU policymaking, being fluent in both languages and having unfettered access to both.

6.4. Producing the SAPEA Evidence Review Report (ERR)

Once the request for scientific advice has been issued by the Commission in the form of a scoping paper, the process of producing the advice begins with evidence gathering. As stated in the SAM guidelines: “The collection and presentation of the relevant scientific evidence (evidence review), which often includes consultation with experts in the field through expert workshops, is by default undertaken by the SAPEA consortium, unless agreed otherwise with the Advisors and SAM secretariat” [SAM guidelines]. The process of producing the SAPEA Evidence Review Report (ERR) involves several steps to identify and gather the relevant expertise and evidence, systematize it in a coherent narrative, develop possible scenarios and assess their consequences, and review its overall quality and soundness. As the ERR provides the main scientific foundation of the SAM’s advice, and its anchor in the scientific literature and the research community, it plays an important role in establishing its scientific Credibility. Its production requires close coordination with the rest of the SAM and the Commission to ensure its usefulness and thus Relevance, while also maintaining the independence of the process (demarcation) to avoid bias and ensure Credibility.

In order to ensure communication and coordination between the different parts of the SAM, and that SAPEA’s work meets the expectations of the Commission, the scoping paper outlining the request from the Commission to the GCSA and the questions on which advice is sought is translated into a more detailed “specification of work” for SAPEA [SAM staff 6], outlining “the kinds of expertise and specific topics that we want to see represented in the working group” [SAM

staff 4]. These specifications are prepared by the SAM secretariat “in discussion with SAPEA and with the Advisors” [SAM staff 6], and “help [SAPEA] to identify the disciplinary backgrounds that are relevant to an opinion, as understood by the requesting DG, but also as understood by us” [SAM staff 2]. The specifications represent a formal request from the Commission to SAPEA in the context of its grant agreement, and enable SAPEA to formally commit resources to work on the specific topic [SAM staff 6], thus serving multiple purposes as a boundary object: they are used by the Commission to instruct and guide the work of SAPEA, to outline and align expectations, and to contractually bind SAPEA to follow them. At the same time, they are used by the SAPEA WG to draw the limits of their involvement, allowing them to defend their independence and push back on requests for evidence that they consider outside the scope of their mandate.

6.4.1. Gathering evidence

The ERR should “provide a comprehensive overview of current knowledge on a scientific topic […], describe, summarise, evaluate, and clarify the evidence, as well as the uncertainties and knowledge gaps in a systematic manner” and include “a critical appraisal of the evidence, evidence-based conclusions, and evidence-based policy options” [SAPEA guidelines]. Once the SAPEA WG is established, the evidence gathering process begins. This normally involves a review of the relevant published scientific literature conducted by SAPEA scientific staff under the instructions of the expert WG, conducted in an iterative manner.

Through a contract with the University of Cardiff, SAPEA has access to a dedicated “Review Team of methodologists (who are expert in designing and conducting systematic reviews), information specialists (who carry out the literature searches) and topic experts (who analyse the results and write up a synthesis)” who work with the SAPEA secretariat and the WG to prepare “in depth and extensive literature reviews” “using an established and transparent procedure” [SAPEA guidelines]. These include scoping reviews, “providing an overview of the available body of literature and indicating where most evidence

has been published and where possible gaps are", systematic reviews of the published evidence, and ad-hoc literature searches on specific aspects of a topic [SAPEA guidelines]. Only scientific evidence "which is publicly accessible at the time of publication of its scientific advice" is admissible in the SAM process [SAM guidelines].

Although systematic literature reviews are considered the gold standard as they "can reduce the risk of bias and uncover possible blind spots" [SAPEA guidelines], these are not always possible depending on the nature of the literature on a given topic or the time constraints, so sometimes a rapid review (a review with systematic elements) or a mapping review (an overview of the peer-reviewed literature within the field) is conducted instead [SAPEA guidelines]. Depending on its length, the literature review(s) may either be incorporated directly in the ERR or form a standalone document published separately by SAPEA as part of the evidence base, after having been synthesised into a publishable narrative and peer-reviewed by at least two independent experts in the field. The search protocol outlining questions, sources and inclusion/exclusion criteria is defined by the WG together with the SAPEA Review Team and is published alongside the ERR to enhance transparency and as an "aid to reproducibility" [SAPEA guidelines].

These reviews are complemented by additional input which can take the form of "expert hearings, workshops, or other forms of expert elicitation and information-gathering such as structured interviews, desk research, meetings with stakeholders, and the involvement of further contributors" [SAPEA guidelines]. The SAPEA evidence gathering process is based on providing a reasoned synthesis of the published data and evidence, and no novel primary research or analysis is conducted.

On the basis of this evidence the WG proceeds with the production of the ERR through an iterative process of writing and discussion, normally over several online and in person meetings. An outline of the key issues to address is prepared by the WG Chair with the support of the SAPEA secretariat, and

individual sections are attributed to WG members based on their specific expertise. These subgroups independently draft their sections on the basis of the literature reviews provided by the SAPEA Review Team and their own scientific knowledge and expertise in the field, and then send it to the SAPEA secretariat for putting them together into a coherent draft. The draft is then discussed collectively by the WG, normally in the presence of observers from the GCSA and SAM secretariat [SAPEA staff 1], and the process is repeated a couple of times in an iterative manner. The WG Chair has responsibility for establishing a coherent narrative for the whole document, and for coordinating the input from the point of view of the content. While the SAPEA secretariat manages the practical aspects of process and can "help synthesise some text or clean up some text if required" and "draft executive summary or some first conclusions" [SAPEA staff 1], sometimes with the help of an external scientific writer [SAPEA guidelines], they emphasize that they don't contribute to the scientific content nor "write from a experts point of view" [SAPEA staff 1].

The evidence gathering and synthesis process is framed in the frontstage narrative as a purely scientific one, in which policy considerations play no role beyond defining the initial questions (no coordination), only members of the scientific community participate (no dual participation), and scientific methods and quality standards are applied, to ensure the Credibility of the product. However, as discussed below, close backstage coordination ensures that considerations of use from the policymaking domain can be incorporated in the process to enhance Relevance, while maintaining its independence and Credibility.

6.4.2. Formulating policy options

In addition to a detailed overview of the relevant scientific knowledge the SAPEA ERR also includes an overview of the relevant policy context (usually written by SAPEA staff on the basis of a mapping done by the Review Team) and identifies so-called "policy options" [SAM guidelines]. These are framed as clearly distinct from the policy recommendations that will be presented in the GCSA's Scientific Opinion and are understood as representing "scenarios"

[SAM staff 1 and 2, GCSA 1] of what policy actions could be enacted and what the consequences and implications of the different options would be. Policy options set out different possible courses of actions and the trade-offs involved [SAPEA staff 1], analyse the pros and cons of each [SAM staff 4 and 6, SAPEA staff 1], and outline the rationales for the different possible approaches. [SAM staff 6].

Policy options are meant to be firmly based on the scientific literature [CSA 1] and are usually written by the WG Chair, who has the best overview of all the content [SAPEA 1]. The aim is for the WG "to base their options on all the science that is in this evidence review report and extract from that conclusions that are policy relevant" [SAPEA 1]. These scenarios play an important role in the SAM's advisory process as they are seen as "fram[ing] the evidence" and having an impact on "what may be considered at the end" [SAM staff 2]. The options outline "possibilities" for the Advisors and the SAM secretariat to consider when working on the policy recommendations for the GCSA Scientific Opinion [SAM staff 2]. The Advisers can then use the policy options as the basis to "develop real recommendations, taking also into account a much more thorough knowledge of the policy background in the Commission" [SAM staff 6].

The distinction between policy options and recommendations rests on how broadly or narrow each frames issues, and on the sort of considerations taken into account to formulate them. Policy options are seen as being more general, firmly rooted in the literature, and based mostly on scientific considerations [CSA 1] and on analysis based on "how the world is, without taking into account the policy framework in place" [SAM staff 5]. In writing the policy options, the WG is "supposed to stick to the science because then you can see the inconvenient truths that we would never be able to write as policy recommendations, but we still want to have there" [SAM staff 4]. On the other hand, GCSA policy recommendations "are really actual recommendations for policy to the European Commission" [SAM staff 1]. These are "more precise" [SAM staff 2], take into account "other considerations" [GCSA 1] such as the

specific policy contexts and constraints of the European Commission [SAM staff 6], and “ponderate the feasibility of the policy options” [SAM staff 5]. Both policy options and recommendations are hybrids of scientific and political considerations, but present different degrees of hybridization: SAPEA’s options are more closely rooted in the domain of science, providing a stepping stone for the GCSA’s recommendations to venture further into the domain of policy.

By virtue of being one step further removed from the policy domain, SAPEA has less constraints in exploring and outlining alternative courses of actions and their consequences, including those “that we usually would not put it as a recommendation” [SAM staff 4]. These include what a member of the secretariat refers to as “the inconvenient truth”, i.e. scenarios which might appears as politically appealing but have clearly negative consequences, and “business as usual” or “do nothing” baseline scenarios [SAM staff 4]. Even if the evidence shows that such courses of action have clear negative consequences and should not be considered as a viable option, putting them on the table is important to frame the discussion and show the alternatives to the course of action eventually recommended by the Advisors: “just because you think that the evidence proves that one possible policy options shouldn't be the one to pursue, you shouldn't discard it. You should put it there. You should explicitly mention it. Mention the pros and cons, and if the cons are much more than the pros then the Advisors or whoever will read it will understand this is not the way to go” [SAM staff 4].

While this distinction between options and recommendations is seen as conceptually important to maintain the separation of roles within the SAM between the GCSA and SAPEA, it is also recognized that in scientific advice “nothing is value free” and the distinction is a “grey zone” [GCSA 1] hard to implement in practice, requiring continuous boundary work by both the SAM and SAPEA secretariats to demarcate them. Moreover, it needs to be re-established each time, because while the GCSA and the SAM and SAPEA secretariats are semi-permanent and have the opportunity to develop and retain institutional memory by working on several topics over time, the SAPEA

WG is created anew for each topic and needs to be socialized in the ways of working of the SAM and its distinctions. Each WG therefore interprets this distinction in slightly different ways [SAPEA 1].

To uphold the demarcation between the ERR and the Opinion it is therefore important to set clear expectations for the SAPEA WG, and especially “this very difficult thing to explain as to what they can do and not do, i.e., they can't recommend but put forward options” [SAPEA 1]. Members of the SAM secretariat are often involved in this demarcation process, to explain to the WG that “the evidence review report should identify and assess the validity of possible policy elements and possible policy options, but without explicitly for recommending one” [SAM staff 4]. Nevertheless, the distinction is not always clearly understood by the SAPEA WG members [SAM staff 6, SAPEA staff 1] and “it takes a few iterations to get this [the policy options] chapter right. It usually starts with recommendations where we have to say [to the WG members], “you can't really do that” [SAPEA 1]. As acknowledged by all actors involved, a fundamental tension exists between the concepts of recommendations and policy options. The boundary between the two “is not that rigid” [GCSA 1], but rather it is a “fine line” [SAM staff 4] that needs to be constantly redrawn. This in turn reflects an underlying tension between SAPEA and the GCSA on their respective roles, and the boundary between them (see 6.7).

6.4.3. Reviewing quality

The scientific quality of the SAPEA ERR is central to the construction of the overall Credibility of the SAM’s advice, as it forms the main scientific underpinning for the GCSA’s policy recommendations contained in their Scientific Opinion. The SAPEA ERR is therefore subjected to a stringent quality control procedure before finalization and publication, “following methods developed with SAM to ensure the highest quality standard in order to minimise bias, improve efficiency and ensure transparency” [SAM guidelines]. Although the SAM secretariat and the GCSA have no formal direct involvement in carrying out the quality control, which is managed independently by SAPEA

with external experts, they are indirectly involved by contributing to shaping the procedure itself [SAM staff 6].

This quality control procedure is clearly framed in the language of scientific excellence and peer review. According to the SAPEA guidelines: “The quality of the SAPEA Evidence Review Reports is inherently related to the excellence of scientific experts, as endorsed by the judgement of their peers and manifested in their various careers and research activities, including those beyond traditional forms of scientific output.” This quality control procedure includes expert workshops, double-blind peer review, and approval by the SAPEA board.

An **expert workshop** is organized by SAPEA “to provide a critique” of the draft evidence report by identifying potential blind spots or biases, ensure the comprehensiveness of the evidence, and “discuss the practical applicability of the options proposed in the Evidence Review Reports, to ensure they have practical implications for real world scenarios, on timescales that are relevant for EU policy development.” The workshop takes place before the final peer review process and “does not duplicate it.” [SAPEA guidelines]. The workshop is attended by external scientific experts invited by SAPEA, often identified from the research conducted for the establishment of the WG, and applying the same conflict of interest and diversity and inclusion criteria [SAPEA staff 1]. Members of the SAM secretariat and the GCSA working on the topic are also invited “as observers” [SAPEA staff 1], although they are not “active participants” [SAM staff 6]. The workshop is organized in the style of a scientific seminar, with each chapter of the ERR being assigned for review to two external experts, who provide their feedback in a presentation to the workshop, during which each chapter is discussed. Following the feedback from the expert workshop, the SAPEA WG can rework the draft ERR to address any gaps and criticisms, before finalizing it for peer review. [SAPEA staff 1]

All SAPEA Evidence Review Reports are subject to **double-blind peer review**. This is conducted by sending out the draft report to external scientific experts

who have not so far been involved in the process, who are asked to assess “1. The scientific/technical quality of the work; 2. The completeness of the analysis, ensuring that it includes the full range of information and opinions; 3. Impartiality and objectivity; 4. When appropriate, whether the report addresses the questions of the Scoping Paper” [SAPEA guidelines]. Peer reviewers, normally three, are “selected based on the appropriate expertise” [SAPEA staff 1], thus following mostly a scientific criterion. They are not aware of the identities of the authors throughout the process, and their names and affiliation are only made public with the publication of the report [SAPEA guidelines]. Their comments are then conveyed to the WG, who take them into account “to revise the report if needed. The Working Group responds to, but need not agree with, the reviewers’ comments […] To increase transparency, each report includes an annex which describes the peer review process, the reviewers’ comments and how the report was adapted in response to them” [SAPEA guidelines].

Finally, the **SAPEA Board** receives the revised report alongside the reviewers’ comments and the WG notes on how these have been addressed. On the basis of these, the SAPEA Board “assess if that's satisfactory or not” [SAPEA staff 1] and eventually “endorses” the report and approves its publication [SAPEA guidelines]. The SAPEA board doesn’t necessarily possess any subject matter expertise relevant to the specific report, and thus it cannot fully assess its content. Rather, it acts as a guarantor of its overall scientific quality and of the process through which it has been produced, thus lending it scientific authority and contributing to Credibility. In this context, the SAPEA board plays a role similar to that of a journal editor, assessing whether the peer reviewers’ comments have been adequately addressed and that the report overall satisfies SAPEA’s standards. However, a key difference with the normal scientific publishing process is that the SAPEA board takes ownership of the report, which is issued by SAPEA as organization. The individual members of the WG and the Chair are credited with its production, but they are not attributed authorship in the traditional scholarly sense.

Like the evidence gathering process, the quality review process is also framed and presented as a purely scientific one, responding only to criteria of scientific adequacy and quality and involving no actors from the policy domain. However, as discussed below a parallel backstage process of coordination is in place to ensure that policy considerations and criteria of usefulness and timeliness are also incorporated.

6.4.4. Balancing independence and coordination

Although the evidence gathering process is conducted by SAPEA and presented as fully independent in the frontstage narrative of the SAM, members of the SAM secretariat and the GCSA are involved through several backstage coordination mechanism. Over the years of operation of the SAM, a number of semi-formal and informal practices have been developed to manage the trade-offs between maintaining the independence of SAPEA's work and ensuring it addresses the needs of the SAM and ultimately of the Commission.

Members of the GCSA and of the SAM secretariat are invited to attend most meetings of the SAPEA WG but their role is limited to observers [CSA 1, SAM staff 5], only intervening "in very specific cases if there's a question from the WG regarding, for example, internal procedure of the SAM or stuff that is not directly related to the content" [SAM staff 4]. Members of the SAM and SAPEA secretariats, as well as (less often) the Advisors and the WG chair, also have regular coordination meetings throughout the evidence gathering process to discuss both content and process issues, such as timelines for publication [SAM staff 1]. Work in progress drafts are shared regularly by SAPEA with the SAM secretariat [SAM staff 1 and 5]. This communication and coordination between the SAPEA evidence gathering process and the rest of the SAM serves multiple purposes that contribute to the Relevance of its work. These include both ensuring the timeliness, completeness and focus of the SAPEA ERR, and allowing the GCSA to begin their work in parallel with SAPEA's, thus contributing to addressing the trade-off between speed and quality.

For the SAM secretariat and the Advisors it is important to “start to get the knowledge of what is already the evidence so that then the GCSA could start drafting some of the scientific advice proposals” [SAM staff 5], i.e., to familiarise themselves early on with the scientific evidence base on which the GCSA advice will be based. This is because although the ERR and the Scientific Opinion are presented as logically serial, the process to produce them runs in parallel, with the two documents both being finalized around the same time. If the Advisors or the secretariat identify gaps in the ERR that the WG is unable or unwilling to address (see below), they can also start planning their own additional evidence gathering [SAM Staff 1].

Access to the ongoing evidence gathering process and coordination meetings with the SAPEA staff allow the SAM secretariat to monitor progress and timelines and keep the SAPEA’s work on track, as they have “the full perspective” [SAM staff 5] of the overall SAM process. Communication and coordination are also important to ensure that the independent ERR addresses the actual knowledge needs of the Commission in terms of scope and scale, to “make sure that they don't move away from the scoping paper, that the thing doesn't go too wide or too general, and that some of the points are not missed” [CSA 1]. This is important as the ERR forms the main scientific input for the GCSA to develop their Scientific Opinion: SAPEA is “collecting and analysing the evidence shaping what will be the field and what will be the basis on which the Opinion will develop” [SAM staff 2].

Throughout the SAPEA evidence gathering process, the SAM secretariat monitors its completeness from the point of view of the GCSA, and its alignment with the terms of reference: “we report to the Advisors, of course, on how the WG is debating and how the evidence collection is going, which direction it is taking” [SAM staff 4]. They can identify gaps “or if extra things could be considered to make it more complete or to understand if it was within the scope” [SAM staff 5]. This is important to ensure that the ERR remains focused on, and therefore relevant to, the request set out in the scoping paper. Closely

following and monitoring the work of SAPEA is seen by the SAM secretariat as a central part of their role in the Advisory process [SAM staff 4].

The SAM secretariat's understanding and experience of the scientific process and of the process of collecting and synthetizing evidence [SAM staff 4 and 5], combined with their access to the Commission's internal policymaking processes, allows them to monitor the SAPEA WG "to see what are the possible shortcomings of this [evidence synthesis work] from the point of view of somebody who's interested in feeding the policy rather than just writing an essay on the more academic side of things" [SAM staff 4]. Although they "do not directly intervene in this process" and it is "not really present in the official job description" it's seen as one of their most important duties because "you have to be aware of what they're doing, and start to flag if you think that something is not going well" [SAM staff 4]. Likewise, the Advisors consider that their "primary responsibility is that the assessment that SAPEA does is in line with the terms of reference, with the scoping paper" [CSA 1]. SAPEA staff agrees that regular coordination is important not only for operational coordination on timeline and deliverables, but also "to make sure that we're all on the same page with the content that we have a similar understanding so we can convey to our different experts" [SAPEA staff 1]. In particular, members of the SAM secretariat can answer "questions regarding the scope that the SAPEA [secretariat] can't always answer because they don't always have all the discussions and background that happened leading to a topic" [SAPEA staff 1].

Despite these efforts to coordinate, however, caution is used to ensure the SAPEA evidence gathering remains sufficiently independent: "we coordinate between the evidence gathering and the Advisors. But that being understood in principle SAPEA does the evidence gathering independently" [SAM staff 6]. Interactions and contacts mostly happen between the SAM and SAPEA secretariats [SAM staff 1], with the GSCA and the SAPEA WG two steps removed from each other. When concerns from the GCSA about the content or direction of the evidence gathering process are to be raised, the SAM

secretariat “takes the very long road” [SAM staff 4] by conveying them to the SAPEA secretariat, who in turn informs the WG Chair.

Effectively, the work of SAPEA undergoes two parallel layers of quality control. On the frontstage, peer review looks at scientific adequacy and caters to the Credibility of the process. On the backstage, monitoring by SAM staff and Advisors looks at timeliness, completeness in regard to the knowledge needs of policymakers, and adequacy of scope and scale, catering to Relevance. The separation of the two processes allows to maintain the public narrative of independence while at the same time remaining anchored to both the scientific and policy domains.

While SAPEA receives funding from the Commission to provide its evidence gathering services, the funding is tied solely to the fulfilment of the requested deliverables, i.e., the Evidence Review Reports, and the Commission has no influence over their content beside what requested in the specifications of work [SAM staff 1]. Although the SAM secretariat, and through them the GCSA, can point to perceived gaps in the expertise or evidence being considered by the WG and express their concerns, they cannot directly instruct them: “we can make a request but we have no way of telling SAPEA to do something or not do something related to the content, which is very important to make sure that these experts are independent” [SAM staff 1]. “We were always playing a role of observer, not being able to contact them and saying you shouldn't use this and that reference or this and that article” [SAM staff 5].

The GCSA and the secretariat can “comment” and “advise” [SAM staff 6] on the SAPEA expert selection and evidence gathering, but SAPEA retains the autonomy to decide what to take on board and “should be able to act independently and should not need to change their thinking or processes upon comments from either us [the SAM secretariat] or the GCSA” [SAM staff 6]. The SAPEA WG Chair retains the independence to decide if and how to act on them [SAM staff 4], and can refuse to add additional experts or sections [personal observation].In such cases, the SAM secretariat has to integrate the work of

the SAPEA WG by gathering further evidence [SAM staff 4]: “ we can ask if the WG would like to address this, but they don't have to of course. And if they say no, this is not relevant or this is not the question that we have been asked or whatever, then it's up to us to fill that gap [SAM staff1].

In its evidence gathering work, SAPEA is thus formally accountable to the European Commission and the rest of the SAM only in terms of deliverables and processes, but not in terms of the content, for which it remains accountable solely to the scientific community through the peer review and quality control processes discussed above. This distinction serves the frontstage narrative of separation between science and policymaking (independence of the advisory process from political pressures), and caters to the Credibility of the process. However, backstage coordination ensures accountability towards the policy domain and enhances Relevance, and is valued by both parties.

6.5. Producing the GCSA Scientific Opinion

The GSCA Scientific Opinions all follow a similar structure including: an executive summary; a description of the issue; the policy context; the methodology used; and a set of policy recommendations [SAM guidelines]. Its production involves the gathering and assessment of scientific evidence; the formulation of policy recommendations, which form the core; and a number of validation steps with scientific, external and policy stakeholders.

Normally only one or two Advisors are directly involved in the drafting of the Opinion throughout the entire process (referred to as “lead Advisors”), with the rest of the GCSA being consulted occasionally at certain stages, mostly in regard to the direction and wording of the recommendations, and for the final adoption. The process of formulating the policy recommendations and writing the Scientific Opinion involves a back-and-forth between the Advisors and the SAM secretariat [SAM staff 6]. It is a process of grouping ideas, synthesis, and abstraction where points are brought together under headings and subheadings [SAM staff 4]. These iterations happen both during dedicated meetings and through written exchanges between the lead Advisors and the

secretariat, before a wider discussion with the whole GCSA: “at some point eventually all of these becomes a draft that can go out for everybody's review.” [SAM staff 4].

As discussed above, the production of the Opinion is informed by, and largely based on, the SAPEA ERR. Accessing the SAPEA evidence gathering process is thus crucial to enable the Advisors and the SAM secretariat to get familiar with the evidence base and start identifying possible areas for recommendations without having to wait for the SAPEA evidence review to be completed [SAM staff 5 and 6]. Effectively, although they are presented as distinct phases of a linear process, the evidence gathering and formulation of the advice run in parallel [SAM staff 5], with the advice being finalized just after the ERR to ensure that “the evidence base is still solid” [SAM staff 6]. This requires a balancing of coordination and demarcation.

6.5.1. Assessing the evidence base

According to the SAM guidelines, the collection and review of evidence is by default carried out by the SAPEA consortium [SAM guidelines], with the ERR forming the main scientific input and “the evidence base” [SAM staff 6]” for the production of the Advisors’ Scientific Opinion. However, the Advisors can complement the SAPEA ERR with additional evidence gathering, especially when gaps or blind spots identified during the SAPEA evidence gathering have not been fully addressed by the WG in the ERR. Beside directly performing their own literature searchers, the Advisors can request members of the SAM secretariat to collect “extra input or data” [SAM Staff 4] and perform “quick” literature searchers and summaries of papers [SAM Staff 1]. The Advisors can also ask the SAM secretariat to request additional literature searches and review from SAPEA [SAM staff 1 and 6], which are performed directly by specialized SAPEA scientific staff, and do not involve the WG which produced the ERR, or to organize additional evidence gathering workshops, referred to as “expert hearings”, in which external experts identified by the secretariat or SAPEA are invited to take part in an “expert elicitation” process [SAM staff 6].

While the Advisors “cannot be experts on everything” [CSA 1] and most of the time do not possess deep subject matter knowledge in the specific area being considered, the lead Advisors working on a specific topic are often (but not always) from a broadly adjacent scientific field, such for example material sciences in the case of biodegradable plastics and biology in the case of cancer screening [personal observation]. They can thus draw on their own scientific experience and standing to assess the overall validity of SAPEA’s work, as in science “there are lots of analogies among the fields, there are lots of analogies how to deal with challenging issues” [CSA 1].

In this phase, the focus is on assessing both the overall scientific quality of the evidence provided by SAPEA and its relevance to the policy question, to decide what to include in the Scientific Opinion and inform the formulation of the policy recommendations. In contrast with the SAPEA evidence gathering process, which is framed as following exclusively a scientific logic, this phase is more explicitly recognized as a process of hybridization in which both scientific and policy considerations are taken into account. Normally the Opinion only contains the main scientific elements necessary to explain and support its recommendations, while referring to the SAPEA ERR for the full summary of the relevant evidence. Over the years, Opinions have become shorter and sharper, focusing more on the recommendations and leaving more of the scientific background to the SAPEA ERR [personal observation], thus reinforcing the demarcation between the purely scientific evidence gathering work carried out by SAPEA and the hybrid work of the GCSA.

The scientific Credibility of the Opinion is therefore constructed mainly on the foundation of the ERR, and if policymakers “want to have much more detail they can go into the options presented by SAPEA in their in their ERR” [CSA1]. Nevertheless, the Opinion always contains a list of references to cited papers and policy documents, aligning it with normal practice in the scientific world, to show that “everything we do should be based on the evidence” [CSA 1]. This construction of the scientific underpinning of the Opinion, and the independent SAPEA process and peer review that produce and validate it, are often invoked

defensively to counter deconstruction attempts by external stakeholders who challenge the content of the SAM's advice by questioning the lack of relevant specialist knowledge among the GCSA, and thus their authority and Credibility to provide advice on a given matter, as in the case of the 2023 advice on sustainable food consumption [personal observation].

In fact, the GCSA distance from the specific topic is seen by the SAM as a strength of its advisory process, as it allows the Advisors to assess the evidence in a dispassionate way from a critical distance, unlike the subject matter experts involved in the production of the ERR, who are invested in their given scientific field: "because the chief scientific advisers are not necessarily topic experts, they have a kind of more distanced, I would say, almost objective view of that evidence as it is presented in the ERR. And so they can discuss it without maybe having been involved in the discussions on this topic for let's say decades and does not being influenced by this" [SAM staff 1]. A boundary is thus drawn within scientific expertise between the topical scientific knowledge of SAPEA experts, which is important for Credibility, and a more general scientific wisdom of the Advisors, which can act as further layer of independence of the SAM process and mitigate biases and interests, enhancing the impartiality and Legitimacy of the process.

6.5.2. Formulating policy recommendations

Alongside the scientific evidence base, the other key element underpinning the Scientific Opinion is the policy landscape chapter, which is prepared by the SAM secretariat and provides the Advisors with the relevant policy context and background to take into account when formulating policy recommendations [SAM staff 6]. The recommendations form the central part of the GCSA Scientific Opinion and anchor the whole document and its production. The process of writing the Opinion starts with the identification of headline recommendations emerging from the evidence review, and once these have been identified, details and supporting evidence are added through an "iterative process" [SAM staff 4]. The formulation of recommendations begins with an analysis of work-in-progress drafts of the SAPEA ERR to identify those parts

“that could be transformed into recommendations knowing what are the different policy instruments available within the European Commission” [SAM staff 6]. In particular, the policy options presented in the SAPEA report often “are being transformed into full recommendations” [SAM staff 6], although the recommendations don’t necessarily have to be based on them [SAM staff 1].

While the Advisors are ultimately responsible for the “actual policy recommendation”, “they need a lot of help and a lot of time to put it together” [SAM staff 4], and the SAM secretariat is “heavily involved in their development” [SAM staff 2]. Members of the secretariat read through the draft ERR and any additional evidence being considered and “scan the points where you have a feeling that the recommendation could arise from” [SAM staff 4], using their judgement to identify “things that we should keep an eye on in in terms of regulation” [SAM staff 4]. The initial points are discussed with the lead Advisors as part of “a sort of more or less collective brainstorming” [SAM staff 4], in which the secretariat can use its knowledge of the policy context to explain to the Advisors the policy implications of possible recommendations being considered [SAM staff 6]. This process is “iterative” and “not linear”, and the thinking develops while developing their recommendations [SAM staff 6].

The secretariat and the Advisors take into account several considerations to ensure that the SAM’s advice meets the needs of EU policymakers, in particular regarding the specificity, actionability, timeliness and clarity of the recommendations. The production of relevant recommendations requires “being aware of all of the policies and constraints that are actually surrounding Commission decisions” and take them into account to ensure “we don't have a blue-eyed opinion completely disentangled from reality, what the Commission could do or not do” [CSA 1]. As remarked by a member of the secretariat, formulating the advice goes beyond a simple work of “synthesis” and “translation” of the evidence: “you need to distil what is really important for decision and policy making”, “what can be acted upon”, because “not every action can be taken” and “it's useless to provide the entire spectrum of knowledge” [SAM staff 2]. This identification of useful and actionable

knowledge and formulation of relevant advice requires considerations of use and a deep knowledge of existing and previous polices (the so-called policy landscape), and an “understanding the policy needs in very concrete terms, and also where are the leverages on which Europe can actually act” [SAM staff 2].

While the scoping paper provides some of these elements, the long time passing between its production and the formulation of the policy recommendation (often over a year) means that the policy landscape might have evolved. To remain up to date, throughout the SAM advisory process the secretariat regularly reaches across to the policy domain to actively map policy developments within the Commission, especially for policy areas involving multiple DGs like food policy, “liaising with colleagues from policy DGs” “to learn what was the update, what was the discussion ongoing and to ask for their feedback” [SAM staff 5], leveraging networks and contacts are built during the scoping phase [SAM staff 5]. By maintaining contacts with the policy officers in the requesting DG, members of the SAM secretariat can be timely informed of [SAM staff 1] and “follow to a certain extent more in real time” [SAM staff 2] internal policy developments, especially those due to unforeseen events such as the COVID pandemic or the energy crisis due to the Ukraine war. The secretariat can thus inform the Advisors of such developments and incorporate them in the development of the scientific advice [SAM staff 1] to “adapt consequently to policy needs” [SAM staff 2], thus maintaining its Relevance in the face of changing policy landscape beyond what foreseen in the scoping paper. Moreover, some of the relevant knowledge about ongoing policy development is internal to the Commission and not yet in the public domain, yet it can be shared with the secretariat: “colleagues from other DGs will be more open to us knowing that we are Commission colleagues, and we are basically internal” [SAM staff 1]. The secretariat can then use this knowledge to steer the process and inform their decisions without sharing or revealing to the Advisors more than strictly necessary [personal observation].

An important consideration to ensure the Relevance of the SAM's advice is to target its recommendations to the specific policy competences of the European Commission, especially in regard to "subsidiarity" [SAM staff 2], i.e. the division of competences between the EU and its member states, and take into account "all the caveats and the constraints that policymakers have" [SAM staff 2]. While some of the experts involved in the SAM advisory process, both among the Advisors and the SAPEA experts, have a clear understanding "of how the EU works and what is the role of the different [EU] institution" [SAM staff 2], and of the interplay between them and the respective responsibilities of the EU and the Member States, others have "a very blurred understanding, very similar to the one of the general public in Europe, which is not a good thing" [SAM staff 2]. By virtue of being "embedded in the Commission" the SAM secretariat has both access to, and "a much better understanding" of, the broad range of policy tools and documents at the Commission disposal, their differences and functioning, and the different levels of maturity of a certain policy [SAM staff 2]. This knowledge and understanding allows them "to put [these documents and policies] in context", "characterise" them, and "understand therefore what can be the contribution of the opinion in this regard" [SAM staff 2], thus better tailoring the advice to the specific tools and needs. The process of producing policy recommendations represents a further level of hybridization of scientific and policy considerations, which builds on what done by the SAPEA in producing the policy options. Specifically, the secretariat's access to and participation in the social world of EU policymaking allows them to incorporate context-specific policy considerations that are not available to outside experts.

Framing recommendations and advice in clear policy terms and getting the language right for a policy audience also contributes to enhance its Relevance by translating across the two domains: "we hear more and more that the policy officers appreciate the fact that the recommendations are let down in very clear, concrete language that is understandable" [SAM staff 6]. Thanks to frequent interactions with policy officers and familiarity with policy language and writing style, the secretariat plays an important role in adapting the message for a

policy audience, pointing out to the Advisors what might not be easily understandable [SAM staff 6].

While this coordination with policy demand plays and important role in aligning the advice with policymakers' needs and contributing to its Relevance, it needs to be carefully managed with demarcation to safeguard its independence (see 6.6), and mostly takes place through "indirect channels" [CSA 1] mediated by the secretariat. As employees of the Commission, members of the secretariat can freely interact with policy colleagues from other DGs and report "insights into the internal discussions in the Commission" back to the Advisors "to make sure that their recommendations are as relevant as possible" [SAM staff 1]. Ultimately, the Advisors maintain the autonomy to "decide what to do with this" input [SAM staff 1] and "the advice still remains independent in the sense that if something that is suggested that doesn't resonate with the Advisors, they don't agree or they don't deem it relevant, it will not become part of the Scientific Opinion" [SAM staff 2]. Coordination with policy DGs was "like a check that we were going in the right direction. Not in terms of the content of course, but in terms of the focus that we were we're keeping" [SAM staff 3].

6.5.3. Validating and adopting the Opinion

The process of producing the GCSA's scientific advice involves a number of "review steps" [SAM staff 6] to "validate" [SAM staff 5] it with other parties and ensure its quality. These steps involve validation by scientific experts external to the evidence gathering process, external stakeholders representing private interests (NGOs, civil society, industry organizations), and internal policy stakeholders (policy officers from other DGs). Although the drafting and quality control phases are presented as distinct, a substantial degree of overlap between the two exists, with the text being reworked sometimes radically until the very final adoption [personal observation]. Each step involves a different range of actors and stakeholders external to the SAM and contributes distinctively to the CRELE of the advice.

Sounding board with external experts

Once the draft of the Scientific Opinion is sufficiently mature, normally "towards the very end of drafting […] a so-called sounding board" [SAM staff 1] meeting with external scientific experts is organized to review it. The purpose of the sounding board is to introduce another "level" [SAM staff 6] of independent scientific expertise in the SAM process, by inviting "experts in that field that have not been involved in a process so far" [SAM staff 1] to review the draft opinion, looking both at the underlying evidence and the recommendations [SAM staff 6]. The aim of this additional level of expert review is to avoid "group think" and "reduce bias as much as possible" [SAM staff 6].

Invited experts receive a draft of the Scientific Opinion [SAM staff 1 and 4] and are asked to "peer review it similarly to how they would peer review scientific papers." [SAM staff 1] This review is based on scientific quality criteria such as the soundness of the arguments put forward, the quality of the underlying evidence and whether it supports the arguments and recommendations, and any gaps in the content or reasoning [SAM staff 1 and 4]. The process is seen as mirroring the SAPEA expert workshop and peer review of the ERR, as both processes involve external experts [SAM staff 5]. A list of all the scientific experts consulted by the GCSA throughout the process is also annexed to the opinion, alongside the list of stakeholders invited to the stakeholders meeting (see next section). This contributes both to the transparency of the process, and thus its Legitimacy, and to its Credibility, by publicly associating the experts to it. In parallel to this formal process of scientific validation, the Chief Scientific Advisors involved in the specific opinion might also informally share the draft with "some trusted people, professors" [SAM staff 4], without "direct involvement" of the SAM secretariat, thus tapping into their own scientific networks to get an extra validation of the Opinion's content.

By bringing into the process scientific quality criteria and scientific expertise external to the GCSA and the SAPEA WG, the sounding board and the informal consultation of external experts contribute to strengthening the scientific Credibility of the Advisors' Opinion by providing both external validation of its

scientific base, and by involving a broader range of scientific stakeholders. The language of peer review is borrowed from the scientific domain, and makes a link with the process through which scientific results and publications receive validation from the community. However, the hybrid nature of the Opinion is also recognized: while being “scientific” and “based on evidence”, it remains “an opinion [which] goes beyond what can be peer reviewed because it provides policy recommendations” [CSA 1]. For this reason, a broader set of stakeholders is also involved in the other validation steps.

External stakeholders meeting

Once the policy recommendations are sufficiently developed, a meeting with external stakeholders is organized “close to the publication” [SAM guidelines] to “present the draft recommendations” [SAM staff 1]. In this context, stakeholders are understood as representatives of private interests likely to be impacted by the policy being advised, i.e. representatives of industry associations, NGOs and civil society organizations, normally at the level of European umbrella organizations [SAM staff 1 and 6]. Policy stakeholders from within the EU policymaking process and scientific organizations are not consulted in this stage.

In this phase, information flow is carefully managed by the secretariat, and only the headline draft recommendations are presented to the stakeholders, rather than the full draft of the Opinion and/or its scientific underpinning. Unlike the sounding board, no draft is circulated in advance, with stakeholders seeing the draft recommendation for the first time during the meeting itself [personal observation]. The aim is to “elicit some first reactions” and “identify gaps or inconsistencies” [SAM staff 1], “make sure that we didn't miss anything important in drafting the opinion” [CSA 1] and check whether the draft recommendations are “incompatible with existing laws or with industry practices” [SAM staff 1] or have “unintended consequences” [SAM staff 5]. However, “the goal is not to rewrite the Scientific Opinion” [SAM staff 1], and it is unlikely that substantial modifications to the recommendations will take place at this stage. Stakeholders “can say what they like and what they don't like, but

at this point you have already gone through several steps of review with experts. So it's not like they [the Advisors] are going to change their recommendations very much" [SAM staff 4].

A clear demarcation is thus made between the scientific input sought in the earlier phases of the advisory process and in the sounding board, which informs and shape the content of the advice, and the interest-based views of stakeholders elicited in this phase, with a rigid boundary being drawn between the two. Stakeholders' concerns "will be taken into consideration, but they cannot necessarily impact the content of the Scientific Opinion" [SAM staff 6]. More than informing the advice, the stakeholders' meeting serves "for us to be aware of what are the worries of the stakeholders" [CSA 1], "to see what the reactions might be once the opinion is published" [SAM staff 1], and to identify where stakeholders are "going to put their fingers" and "prepare defensives" [SAM staff 4].

In this context, stakeholders are identified as bearers of interest that need to be kept at safe distance from the formulation of scientific advice, rather than as a potential source of scientific input or evidence to be considered: "Many of them are actually lobbying the Commission so, you know, they have certain purpose behind their feedback. So we have to take that with [hesitation] a little bit of reflection" [CSA 1]. This distinction is important to maintain the unique status of scientific advice: "At the end of the day it's advice to policy, but it's scientific advice. So you don't want the lobbies to come up with their, I don't know, tobacco [industry] sponsored scientific studies, etcetera, etcetera" [SAM staff 4].

Importantly, these meetings do not represent "stakeholders' consultations" [SAM staff 1 and 6], a formal process through which the Commission elicits and considers stakeholders' views in its policymaking processes, which have to follows a specific process to ensure broad and meaningful participation.[32]

[32] See Chapter II of European Commission "Better Regulation Guidelines" (2021) - https://commission.europa.eu/system/files/2021-11/swd2021_305_en.pdf (retrieved 13/11/23)

Rather, these are framed as “information events” [SAM guidelines] convened by the independent Advisors and entail no obligations to consider the stakeholders’ views and reflect them in their advice. Despite this distinction however, stakeholders are still requested to be registered in the Commission’s “transparency register” and “as such they are known to be lobbyists within the European Commission context” [SAM staff 6]. While the SAM secretariat takes care of organizing these meetings in practice, including identifying and inviting participants [SAM staff 1] and writing up a report, they do so “behalf of the Advisor” who “chair and lead” the workshop [SAM guidelines], rather than on behalf of the Commission. The SAM’s stakeholders meeting is therefore clearly distinguished from the Commission’s own stakeholders’ engagement processes, thus further demarcating policymaking by the Commission (which requires stakeholders’ input) from scientific advice (which doesn’t). This is an important distinction, which is invoked defensively when stakeholders criticize the SAM’s work by saying they have not been given the opportunity to feed their views and evidence into the process [personal observation].

While this insulation of the SAM advisory process from any private interests is perceived as important to ensure the independence the advice produced, on which its Legitimacy is constructed (see 6.6), it also risks alienating any group outside the academic scientific community and the internal policy stakeholders. While coordination and demarcation mechanisms are in place to make the science-policy boundary selectively porous and ensure that the interests of policymakers are considered in the process without being seen as unduly influencing it, a much more rigid boundary is drawn between the advisory process and the interests of external stakeholders. The latter are effectively excluded from meaningful participation in the co-production of the advice and are cast as passive receivers, which could eventually undermine its Legitimacy: “I do understand why [the stakeholder meeting] it's important for us. I don't understand why it's important for them [the stakeholders]. Because at the end of the day, they cannot influence the recommendation much” [SAM staff 4].

Validation with policy stakeholders

A final validation step in the production of the Advisors' Opinion is the presentation of the policy recommendations to policy officers from relevant DGs, i.e., a consultation with internal policy stakeholders aimed at ensuring that the advice provided responds to, and is aligned with, the needs of the policy clients. As stated in the SAM guidelines "the draft advice shall be presented to the relevant Commission services prior to its adoption by the Advisors. The purpose of this presentation is to ensure that the report answers the questions asked, to ensure factual correctness regarding the policy and regulatory background and that any necessary clarification can be sought from the Advisors."

This consultation takes the form of a meeting organized by the SAM secretariat, to which colleagues form the relevant policy DGs are invited to provide feedback on the Advisors draft recommendation. In parallel, and sometimes before this more formal validation step, the secretariat also shares early drafts of the recommendations and policy context chapter with the relevant colleagues they most closely liaise with in an informal, "confidential" manner [SAM staff 4]. These consultations allow the secretariat and Advisors to gather feedback on and calibrate their work in progress, identify gaps in the policy context, fine-tune the wording of the recommendations, and sound out initial reactions, providing an important coordination channel to enhance the Relevance of the advice.

One goal is to "see whether we have indeed identified all relevant policies that already exist, and whether the colleagues might know about policy that is currently being developed that is also relevant for the topic" [SAM staff 1], and avoid embarrassments such as somebody publicly coming up with "Why are you suggesting a policy in this area where we already have one or we are writing one? I was busy writing this 5 minutes ago and I had no idea you were doing this" [SAM staff 4]. Another goal is to identify in advance possible areas where the Advisors' recommendations could be in tension with existing or upcoming policies. While the Advisors are free to provide recommendations

that “go explicitly against” Commission policies if “there is good scientific justification for that”, advance knowledge of potential “clashes” allows them to better consider “how something needs to be argued and how it needs to be justified” [SAM staff 1]. This allows them to put in place defensive strategies in advance and mitigate the risk of future attempts at deconstruction.

Adoption and authorship

Following these validation steps, the draft Opinion is finalized and shared with the entire GCSA for adoption. Although in practice only a small subgroup is actively involved in the process of gathering evidence, drafting the text of the Opinion and formulating the recommendations, Opinions are adopted collectively by the GCSA by consensus. Dissenting opinions can be included [SAM rules of procedure, SAM guidelines]. This collegiality is an important element of the work of the GCSA and is seen as a way to mitigate individual idiosyncrasies and biases, thus distinguishing the SAM from the previous individual CSA model. However, the low level of engagement by the Advisors who are not directly leading on an Opinion, who often fail to adequately prepare for discussion meetings and do not closely follow the process, can undermine this collegiality leading to a split in the sense of collective authorship, with in at least one case the lead Advisor referring to the GCSA Opinion as “my Opinion” [personal observation].

Although responsibility and authorship of the Scientific Opinion formally rests with the Advisors, members of the SAM secretariat are heavily involved in the various stages of the drafting process. However, while they contribute heavily to the writing of the actual text of the Opinion, they make a clear distinction between “writing the content” and “writing physically the document” [SAM staff 3], with the secretariat “holding the pen when the actual Opinion is being written by the Advisors” [SAM staff 4]. Their contribution is referred to as “drafting”, “editing” [SAM staff 3] or “assist[ing] in the preparation and in the writing of the opinion [SAM staff 4]”. This is consistent with the institutional culture of policy organizations such as the Commission, in which any writing activity by staff

members is referred to as “drafting”, with the responsibility for taking decisions left to the political layer [personal observation].

Members of the secretariat don’t see their role as producing knowledge, but rather “a linkage between the knowledge production coming from academia and practitioners and the knowledge consumption” by policy users and decision makers [SAM staff 3], facilitating collection and synthesis of evidence and knowledge [SAM staff 3]. In particular, it is seen as important that the content comes from the Advisors, who are responsible to decide what is included in the Opinion and how it’s framed: “My role [as member of the secretariat] included reading that literature review and helping to determine whether it was important to add this or not. But it is the Advisers who then decide what goes into an Opinion, what doesn't, and how it is phrased” [SAM staff 1]. As employees of the European Commission, the secretariat’s involvement in writing the content of the scientific advice would be perceived as compromising its independence by “biasing the opinion” [SAM staff 3]. For this reason, their role is relegated to the backstage of the advisory process and they are presented as purely ancillary in the public narrative of the SAM.

6.6. Constructing and managing independence

Independence is a key feature of the SAM’s self-identity. In the context of the SAM, the concept of independence is operationalized as a combination of autonomy of its various parts from each other, independence from private (mostly economic) interests (see 6.3.3), and from political pressures. Independence is engrained both in the structure of the SAM and in its processes. The SAM features several “layers of independence” [SAM staff 2, SAM staff 6], as shown in the previous sections: SAPEA gathers evidence independently from the Commission and the SAM; its WG experts are independent from SAPEA itself and from private interests; the GCSA are independent from the Commission and from private interests, and are free to take or not into account the work of SAPEA and feedback from external and policy stakeholders when preparing their advice; experts involved throughout the process are screened for interests that might bias their input or judgement

(see 6.3.3). Together, these layers are seen as ensuring the overall independence of the SAM process. This implies a multitude of boundaries, both internal and external to the SAM, that require careful management.

While the CRELE attribute of Credibility captures some of the dynamics observed here, specifically in relation to the demarcation between science and policy and the independence of scientific advisors from policymakers and political pressures, other practices observed are not fully captured by any of the CRELE attributes, despite the clear role that independence is seen as playing in ensuring the effectiveness and broader political legitimacy (in the lay sense) of the SAM. This limitation of the CRLE framework is further discussed in Chapter 7.

Independence is recognized as a central concern for all involved in the SAM's advisory process: "people think a lot about it, and they are very concerned about it", "the willingness [to ensure independence] is genuine", not just "an advertisement" [SAM staff 2]. This independence is prominently displayed as part of the SAM's process: "The effectiveness and credibility of the Group of Chief Scientific Advisors requires that its independence is transparently communicated" [SAM rules of procedures]. This is achieved through the publication of process and quality control guidelines, of the declarations of interests of all the experts involved, of the list of experts and stakeholders consulted, and of interim documents such as workshop reports.

Independence of the advice makes the latter useful to the Commission to legitimize its policies: the Commission "in principle can use the advice also to defend their policy proposals, pointing out that this has been recommended by an independent advice mechanism" [SAM staff 6]. At the same time, the Advisors' independence can be invoked to distance the Commission from their remarks if necessary, as "[GCSA] members should not in any way give the impression that they are employees of, or represent the views of the European Commission" and "any questions about policies or opinions of the Commission should be directed to the Commission, for the Spokesperson to respond" [SAM

rules of procedure]. A successful demarcation of the boundary between advice and policy is therefore instrumental to maintain the social order between science and policy, and to legitimize both the authority of the Advisors and the political decision-making role of the Commission.

Independence is not seen as an intrinsic, static feature of the SAM, but rather as something that needs to be constructed and "managed" [personal observation] through constant work, mostly by the secretariat: the boundaries between the layers of independence are "insured to quite a large extent by the Unit, or policed by the Unit let's say" [SAM staff 6]. This management takes the form of assessing COIs; selectively excluding experts and stakeholders in meetings; controlling the flow of information; and limiting interactions between policy DGs, the GCSA, and SAPEA. At the same time, it is understood that a too rigid boundary would be detrimental, that it would be "not very useful" to think of independence as "working in total isolation, that you are encapsulated and sent to the moon so that you don't have any influence from the outside" [SAM staff 2]. In particular, while the SAM''s independence in formulating its advice is important, it is also recognized that a degree of coordination with policy demand plays an important role in ensuring its Relevance, and that trade-offs exist between these two dimensions: "there's the independence of the independent, and the independence of the relevant" [SAM staff 4]. This requires careful management by the secretariat, which has to reach across into the policy domain to orchestrate with the policy demand side while at the same time buffering the Advisors to protect their independence.

While the Advisors have some "direct channels" [CSA 1] to interact with the requesting policy DGs through the feedback meeting with policy stakeholders and occasional ad-hoc informal meetings (see 6.5.3), these direct interactions are kept to a minimum and "managed very carefully" [SAM staff 6] by the SAM secretariat. Interactions without "filtering barriers" could leave the Advisors "exposed to manipulation" or "lobbying" from policy interests [SAM staff 5], and introduce idiosyncrasies and biases: "the Commission is a very big animal with many people having very strong opinions one way or another, and having the

Advisers talk to the one or the other person in the DGs may give them a wrong idea of what really is being requested by the Commission" [SAM staff 6]. All requests for such interactions are thus conveyed through the secretariat which decides on their appropriateness; controls the agenda, invites, and flow of information; and attends the meetings [SAM staff 6]. The secretariat can use its knowledge of such internal context and dynamics to navigate, balance and mediate these disparate policy interests, and selectively allow permeability of the boundary when judged appropriate.

While the usefulness of coordinating across the science-policy boundary is widely recognized by the members of the SAM, it is seen as particularly problematic for the public narrative of the SAM's independence. While the meetings with external experts and stakeholders are presented as key steps in the flow diagram used for communication purposes (see 6.1) for example, the consultation with policy stakeholders is left out of the public narrative and relegated to the backstage, despite being mentioned in the SAM guidelines. The coordination and informal exchanges of drafts by the secretariat are done "with secrecy" [SAM staff 4]. While the Advisors are aware of these exchanges, see their value in contributing to the advice's Relevance, and sometimes explicitly encourage them [CSA 1], they are not directly involved and have no obligation to take them into account, thus giving them plausible deniability in regard to such coordination. Overall, coordination with policy stakeholders is seen as posing a threat to the narrative of independence of the SAM [personal observation], and is thus relegated to the backstage.

Similarly, a rigid boundary is enforced between SAPEA and the policy DGs in the Commission. Contacts between SAPEA and Commission officials outside the SAM secretariat are strictly forbidden, unless explicitly sanctioned by the latter, and this is enforced by appealing to SAPEA's contractual agreement as an EU-funded project with the Commission, which establishes a designated Project Officer in the SAM secretariat as the sole allowed point of contact [SAM staff 1]. This strict demarcation and the mediating role of the secretariat are seen as important because there may be internal "political sensitivities" "that

maybe SAPEA is not aware of that we may be aware of, because we work on the Commission and hear things internally that are not public knowledge" [SAM staff 1]. Likewise, SAPEA staff or experts are not supposed to contact the GCSA directly without going through the SAM secretariat. "Centralising major communication tasks" between SAPEA and the rest of the SAM and the Commission in the secretariat is seen as a way to both "filter" the interactions to avoid undue influencing, and "maintain the independence" of the parts involved SAM process [SAM staff 5].

Members of the SAM secretariat are reflexively aware of and embrace their role as boundary managers, which they describe as "guarding the border" between "the institution and the two external group, SAPEA and the Advisors" [SAM staff 4]. "It always works best when people in the Unit are taking care of those [relations with the policy DGs] and mediating it with external rather than when the Advisors or SAPEA try to make this sort of connection themselves" [SAM staff 4]. The secretariat has "more experience in approaching colleagues from other DGs and, you know, asking the right questions, dealing with certain topics" [SAM staff 1], and "translates" between "the science people who know the stuff about a certain topic" and "the policy people who have to take the decision", which requires being aware of the respective priorities of the two sides, and "making connections" as necessary [SAM staff 4]. In case of tensions or disagreements between the Advisors and the requesting policy DGs, it helps to have "somebody in between, who could be like a trusted contact for both" explaining to each side the others reason and mediating between the interests of the two: "if you just put the groups together in a room and see what happens, could be dynamite. But you need a sort of soft cushion in between" [SAM staff 4].

6.7. Division of labour within the SAM

According to the SAM guidelines, its overall mandate is to "provide high quality and independent scientific advice to the European Commission on matters of importance to Commission policy making, in as transparent and unbiased a manner as possible." However, from the respective mandates of the GCSA and

SAPEA it is clear that the responsibility for providing advice to policymakers is firmly with the former, with the latter relegated to a support function. As mentioned above, the legal base of the SAM defines the main task of the GCSA as “to provide the Commission with independent scientific advice on specific policy issues” [Commission decision], while the SAPEA grant agreement requests it to provide, at the request of the European Commission “targeted scientific evidence in a timely and transparent manner to inform the production of science advice by the Group of Chief Scientific Advisors” [SAPEA procedures]. This division of responsibilities is reinforced in the 2019 GCSA activities report, which refers to “a ‘dual layer system’: the first layer is SAPEA’s provision of a peer-reviewed comprehensive evidence synthesis […]. The second layer is the development of the scientific advice ourselves [the Advisors] based on the analysis of the Evidence Review Reports by SAPEA” [SAM report]. On the frontstage, the SAM thus presents an orderly separation between policy-relevant scientific knowledge (embodied by SAPEA and its Evidence Reviews Reports) and science-informed policy advice (embodied by the Group of Chief Scientific Advisors and its Scientific Opinions).

This division of labour contributes to addressing some of the practical trade-offs between CRELE attributes identified by Sarki (et al. 2014). The production of two separate documents, with the ERR providing an in-depth overview of the scientific evidence and a range of options and the Scientific Opinion providing more focused policy recommendations and their immediate scientific underpinning, allows to mitigate the clarity-complexity trade-off (simple message vs communicating uncertainty). While the SAPEA options open the scope of choice for policy makers, GCSA recommendations “don't open” and focus “on what are the considered alternatives that are most probable” [SAM staff 2]. In this regard, the SAM model can thus be understood as a combination of Pielke’s (2007) honest broker of policy alternative and issue advocate, presenting policy makers with both a menu of options based on the science (in the form of the ERR), and a recommendation on the preferred one based on policy as well as scientific considerations (in the form of the scientific opinion).

The process of producing the two documents in parallel addresses the speed-quality trade-off (timely outputs VS in-depth quality assessment and consensus building). However, as discussed above, the public narrative of the SAM requires that the two steps are presented as a linear process, with the evidence gathering separated and prior to the formulation of policy recommendations. This separation of roles creates tensions that need to be managed through demarcation and coordination. Despite some clear definition of tasks being hardwired in the institutional architecture of the SAM, the boundary between the scientific work of the SAPEA expert and the policy work of the Advisor needs to be renegotiated each time. This is partially due to the ephemeral nature of SAPEA working groups, which are constituted ad-hoc for each topic and therefore have no institutional memory of the process.

In the characterization of the SAM's work, all of its output constitutes "scientific advice", but only the Advisors can provide "policy recommendations". Throughout the advisory process, a strict separation is enforced between the role of SAPEA and its WG, which are responsible for the synthesis of policy-relevant but not policy-prescriptive scientific knowledge, and the Scientific Advisors, who are solely responsible for the provision of scientific advice and policy recommendations. This separation requires a constant upholding and renegotiation of the science-policy boundary *within* the SAM. While the GCSA have a say in the SAPEA evidence review process, SAPEA has no say in the formulation of the scientific advice and policy recommendations by the Advisors. Effectively, the coordination between the GCSA and SAPEA is one-directional.

The different nature of the ERR and the Scientific Opinion is also reflected in their validation process: while the ERR is treated as mostly scientific document, and thus is validated according to scientific standards through traditional peer review to enhance its Credibility, the hybrid nature of the Opinion is recognized in the SAM process, and its validation is carried out by an "extended peer

community” (cf. Funtowicz and Ravetz 1993) of experts, stakeholders and policymakers, catering to all three CRELE attributes.

6.8. The role of the SAM secretariat

As described in this chapter, throughout the advisory process, the SAM secretariat actively manages several boundaries between the scientific expertise of the GCSA and SAPEA and the policy demand of the Commission DGs requesting their advice, and the advisory roles of the GCSA and SAPEA. Effectively, the SAM secretariat acts as the “hub” of the SAM. It mediates any interaction between experts, SAPEA and GCSA and the Commission services and policy clients, and external stakeholders. By managing and mediating these interactions the secretariat ensures the independence of the advisory process and its Credibility , while at the same time allowing enough permeability of the boundary to ensure the policy Relevance of the advice produced. The secretariat contributes to the selection of experts, source and assesses evidence, decides what is relevant, and coordinates across the science-policy boundary. In this regard, the secretariat plays a clear boundary management function between the scientific Advisors on the one side, and societal and policy stakeholders on the other, providing both coordination and demarcation functions.

A key feature of the SAM’s advisory process is how it coordinates the production of scientific advice with the needs of the policy “demand” side. While this coordination is most visible at the beginning and the end of the advisory process, respectively through the scoping phase and the validation with internal policy stakeholders, it takes place throughout thanks to the interactions of the secretariat. Policy “clients” commissioning the advice are kept at arm’s length from the GCSA to ensure the independence of the advisory process. However, as shown above feedback from policy clients is highly valued as it allows to fine tune policy recommendations to ensure their feasibility and applicability. While the Advisors recognize the importance of incorporating considerations about policy timeframes, political sensitivities and internal dynamics , they normally lack access to such knowledge by virtue of their independence from

both the policymaking institutions and the specific policy and scientific domains involved. All communication between policy directorates at the scientific components of the SAM (GCSA and SAPEA) are handled though the SAM secretariat. The secretariat therefore acts as both a buffer and a communication channel, performing both a coordination and a demarcation role.

As shown above, ensuring Relevance of the advice requires insider knowledge of, and direct access to, the policymaking processes towards which the advice is directed. By virtue of being embedded within the Commission, members of the SAM secretariat not only have a better understanding of these aspects, but also the necessary networks and access. Secretariat staff, while normally also lacking full knowledge because the specific policy domain changes with each piece of scientific advice, have the means to access it. First, they have unrestricted access to non-confidential internal documents. They belong to professional and personal networks, such as interservice groups. Especially longer-serving staff have previous professional experience in other Commission departments, especially those more relying on scientific expertise such as DG SANTE and DG ENV. Personal networks and contacts among colleagues can be activated to gather information about ongoing policy work in other departments, to validate and contextualize knowledge acquired through documents and other sources, and to informally “sound out” ideas before putting them in written. By participating in both social worlds, members of the secretariat can effectively span the boundary between science and policy and balance coordination and demarcation to provide a fundamental contribution to the CRELE of the SAM’s advice.

6.9. Conclusions: Constructing CRELE in the SAM

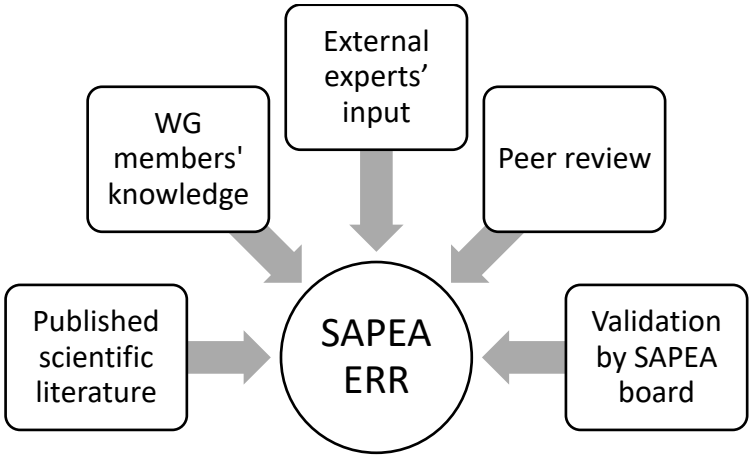
This chapter shows how a division of labour between the different parts of the SAM is essential to construct the Credibility, Relevance and Legitimacy of its advice. In particular, it highlights the crucial role played by the SAM secretariat in ensuring the policy Relevance and counterbalancing the independence of the external of scientific advisor by providing both a linkage and buffering

function. As shown in this chapter, the Credibility, Relevance and Legitimacy of the SAM advice are constructed throughout its advisory process, through both structural features and working practices.

Credibility

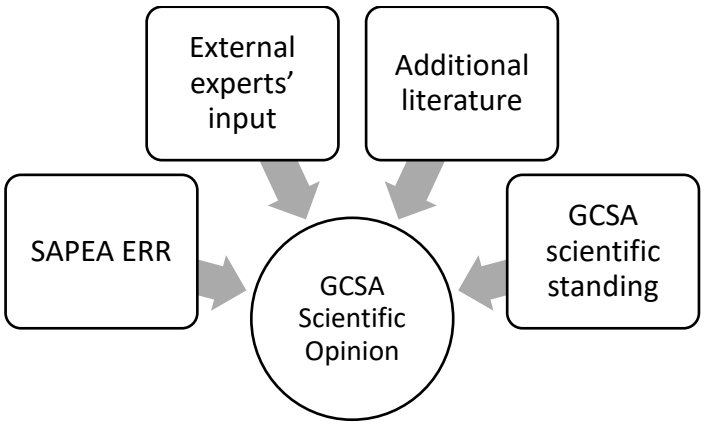
As in the construction of scientific knowledge (see 2.2), the scientific Credibility of the SAM's advice is constructed by creating a network of associations (Latour 1990) between scientific evidence from the scholarly literature, academic experts, prestigious scientists and scientific institutions, the SAPEA ERR, and the GCSA's Scientific Opinion. This is achieved by selecting well-regarded scientists for the GCSA and the WG, synthetizing and referencing peer-reviewed scholarly literature, inviting external experts to workshops and explicitly acknowledging them in the reports, and inviting them to peer review the reports.

Figure 11: Construction of SAPEA ERR Credibility



Source: Own elaboration.

Figure 12: Construction of GCSA Scientific Opinion Credibility



Source: Own elaboration.

Relevance

Policy Relevance is constructed by ensuring meaningful engagement of the policy clients throughout the advisory process, from the identification and formulation of the questions to the gathering of evidence, to the formulation of policy recommendations. This allows the incorporation of considerations of use upstream in the advisory process (Bijker, Bal, and Hendriks 2009): Timeliness, language, actionability, constraints, specificity. This happens directly through the co-definition of the scoping paper and the validation of the recommendations with policy stakeholders, and indirectly through the coordination work of the SAM secretariat.

Legitimacy

In the context of the SAM, Legitimacy is mostly constructed through the involvement of all interested parties in the advisory process (scientific experts, policy clients, private interest groups) while at the same time maintaining the independence of the SAM by carefully managing these interactions. On balance however, independence is given more prominence than inclusion. Independence is prominently displayed and performed (through transparency) through the publication of process guidelines, interests, experts consulted, interim documents. It is also invoked defensively whenever the SAM's advice is questioned.

Experts selection and recruitment include both scientific and diversity and inclusion criteria, such as gender, geography and career stage. Geographical inclusion and balance criteria play an important role in contributing to Legitimacy, at least in the eyes of policy stakeholders. This diversity of experts is seen as important to reduce “potential biases due to the personal values, feelings, political or religious beliefs of Working Group members” [SAPEA guidelines], and contributes to the Legitimacy of the WG and therefore of its output. While experts consulted throughout the SAM process, both to produce and review the SAPEA ERR and to directly provide input to the GCSA, have to complete an extensive screening to ensure they have no conflict of interest, stakeholders are by definition assumed to have and represent interests, so they are not required to declare them.

7. Discussion and conclusions

7.1. Constructing scientific advice in EFSA and SAM: a comparison

Both organizations have at least two layers of scientific expertise in place that contribute to the production of scientific advice. In the case of EFSA, the Scientific Committee (SC), the thematic panels, and the ad-hoc working Groups (WG). In the case of the SAM the Group of Chief Scientific Advisors (GCSA, the SAPEA Board, and the ad-hoc SAPEA WG. The layers are organized hierarchically, with the “bottom” layer closer to the scientific domain and charged with the collection and analysis of evidence, without any interactions with policy or private stakeholders, and the “top” layer engaging in a quality control function, both in terms of scientific Credibility and of policy Relevance. In the case of the SAM the division of labour between the layers is further reinforced by the production of separate but complementary reports, thus further separating the scientific underpinning of the advice from the policy recommendations. In both cases, the coordination between the layers is ensured through formal and informal participation mechanisms, and is largely mediated by the secretariat. The secretariat also mediates interactions with policy stakeholders, to ensure that their needs are taken into account in the policymaking process while at the same time demarcating the boundary between advice and policy and buffering the advisors and protecting their independence.

In both cases, the definition of the request is a key step in the production of scientific advice. Both advisory organizations are directly mandated by the Commission to advise it, and the request takes the form of a public document (mandate letter or scoping paper) co-produced by policymakers, members of the secretariat of the advisory body, and some of the scientific experts involved in the advisory process. This document can be interpreted as a boundary object. For policymakers, it allows the definition of clear temporal and topical limits for the advice, ensuring its timeliness in informing the policy process and bounding the scope of issues that the advisors are given authority to cover. For

the advisors and the advisory organization, it ensures that the request is framed in terms that can be meaningfully addressed from a scientific perspective, and gives them the contextual elements to consider when producing the advice to make it useful to policymakers. The request document and its co-production thus contribute to both the Credibility and the Relevance of the advice. By being public, it also makes the advisory process more transparent, allowing scrutiny of at least some of the framing assumptions. The central role of the secretariat in mediating the co-production of the request gives them extended knowledge of further contextual elements and considerations that can be brought into the advisory process to further enhance its Relevance.

7.2. CRELE in EU scientific advice: findings and limitations

As discussed above (2.6.3), CRELE attributes can be vague and ambiguous, and need to be contextualized in the specific setting in which they are used to reflect its unique features. The analysis presented here shows how, in the context of scientific advice to EU policymaking, Credibility emerges as the attribute most valued by the actors involved in the advisory process, especially in terms its frontstage narrative. In this context, Credibility is operationalised as the establishment of a clear demarcation between science and policy, as scientific quality control, as establishing scientific framing of advisory requests, and as the participation of a broad range of scientific stakeholders representing multiple disciplinary viewpoints. Relevance, operationalised as the incorporation of considerations of use and policymakers needs, constraints, language and timeframes in the advisory process, is also considered important. However, it is often relegated to the backstage of the public narrative, as it is seen as compromising Credibility because of the importance attributed to a strict separation between science and policy to ensure independence.

On the other hand Legitimacy, understood in the CRELE framework (see 2.6) as inclusiveness of societal perspectives in the advisory process, does not appear to be a major concern in the cases analysed beyond the inclusion of a broad range of disciplinary and geographical representations, at least for

policymaking bodies. Instead, independence and transparency clearly emerge as the most valued attributes pertaining to the political sphere. This highlights some limitations of the CRELE framework in fully and adequately capturing some of the strategies and practices observed in the EU policymaking context, in particular regarding the fit between the Legitimacy attribute as defined in the CRELE literature and the strategies and practices put in place to ensure the independence of SPIs and scientific advisory mechanisms in the EU.

As discussed above (2.6.1), in the CRELE framework Legitimacy is normally understood as referring to whether actors perceive the information producing process as "fair", unbiased and inclusive, and considering the values, concerns, and perspectives of different actors. Legitimacy is assessed against standards of political and procedural fairness, and judged based on who gets to participate or not in the information production processes, how choices are made, and how the information is vetted and disseminated. The focus is thus on fairness and unbiasedness, achieved through the inclusion and participation of different societal actors in the process and the consideration of their values and concerns. However, this concept of Legitimacy fails to capture the observation that Legitimacy can be constructed through exclusion as much as through inclusion. The empirical analysis of the case studies of scientific advice in EU policymaking shows that strategies of exclusion and transparency can also be used to establish independence and construct political legitimacy. In the case studies analysed here the exclusion of any interest and the independence of the process are seen as the most important element. Transparency (for example in regard to who has been consulted throughout the process and their absence of conflicts of interest) is thus especially important to show that no private interests have biased the advice. Yet both organizations studied here go to great lengths to include and consult a broad range of policy stakeholders, which contributes not only to the Relevance of the advice, but also to its Legitimacy in the eyes of this community. In this regard, the advisory processes analysed here seem to be oriented more towards EU institutions and policymaking processes, rather than a broader political community. This

could reflect a technocratic policymaking culture which, in the face of a plurality of values and a fragmented political sphere, seeks legitimacy through results. This observation confirms the importance of defining and operationalizing the CRELE framework in a way that reflects the unique features of the specific context of the analysis. In particular, while the norms of the scientific domain on which Credibility is constructed appear to remain stable when moving from the context in which the CRELE framework was originally developed to the specific context of EU policymaking, those of the political domain on which Legitimacy is constructed reflect specific local values. While this doesn't fundamentally undermine the validity or usefulness of the CRELE framework as a heuristic framework, it becomes clear that the attribute of Legitimacy needs to be expanded to account for a broader range of political realities.

7.3. The division of labour in scientific advice and the role of secretariats

Accounts of the role of scientific knowledge and expertise in policymaking, and of scientific advice, have mostly focused on the division of labour between experts possessing the knowledge and the bureaucrats and policymakers making use of it (see 2.1.6). This thesis argued that it is also important to look at the division of labour taking place *inside* scientific advisory mechanisms. Once the black-box of advisory bodies like EFSA and SAM is opened by looking at their backstage practices, it reveals that their different components perform different roles in the construction of scientific advice.

One of the fundamental question in the study of scientific advice is how to balance the inherent tension between neutrality and independence on the one hand, and usefulness and relevance to policymaking on the other (Bijker, Bal, and Hendriks 2009; Pamuk 2021). Doing so requires boundary work to both separate and bridge the domains of science and policy. This thesis argues that, in the context of EU scientific advisory committees analysed here, a division of labour can be observed between the expert advisors themselves, whose scientific credentials and independence from policymaking institutions contribute to the Credibility and Legitimacy of the process, and the members of

the secretariat, who not only support the advisors but also play a key role in ensuring upstream and downstream coordination with policymakers, ensuring policy Relevance while protecting the independence of the advisors. In order to uphold the boundary between science and policy externally, the advisory mechanisms internalize it through this division of labour. This division of labour is not only functional to the management of the boundary, but represent in itself an important boundary management strategy and should thus be regarded as a key organizational feature of effective advisory mechanisms.

7.4. Contribution to knowledge

This thesis provides both an empirical and theoretical contribution to the study of scientific advice. First, it provides the first critical account of the functioning of the European Commission's Scientific Advice Mechanism (SAM), which as argued in section 4 represents a novel and unique development in the EU advisory landscape. Second, it aims to make a theoretical contribution by linking insights from STS and policy studies with the empirical observation of how boundary work is performed in practice in EU advisory bodies, to show how the division of labour between advisors and secretariats is a central boundary management strategy in itself. In this regard, it contributes to opening the black box of boundary organizations (Gustafson 2018) to enhance the explanatory power of the concept by revealing its internal practices.

The analysis conducted in this thesis confirm that the CRELE framework is best regarded as a heuristic tool rather than a strict evaluative framework. By mapping out the effectiveness of scientific advice onto three dimensions of Credibility, Relevance and Legitimacy and spotlighting their inherent synergies and tensions, the CRELE framework allows to better investigate the different contributions of the various actors involved in the advisory process. Moreover, this thesis shows how the heuristic power of the CRELE framework can be expanded beyond institutional features and abstract strategies to include all actors involved in the advisory process (not just experts and policymakers), and the day-to-day practices they employ in their boundary management.

7.5. Limitations and scope for further research

As discussed, boundary management strategies are context specific, so there is limits to how far the findings of this thesis can be generalised. While personal and professional experience in the field indicates that the findings illustrated by the case study are representative of the broader role of secretariats in the scientific advisory process of EU institutions, there are limitations to its generalizability. As discussed, advisory committees are the main scientific advisory structure employed in EU institutions. These committees are mostly made up of academic experts who serve on them on the side to their main research job, and thus are heavily reliant on secretariats to carry out the bulk of the work. This is not necessarily the case in other institutional settings where more of the risk assessment is carried out by directly employed full time regulatory science experts (as in the case of the US FDA (Joly 2016), or where individual Chief Scientific Advisors play a more prominent role. While it is clear from this research that the role and influence of secretariats on the scientific advisory process needs to be taken seriously, their role in ensuring its policy Relevance might be different in different institutional contexts.

Further research in this field could explore this role in a comparative manner and identify other structures or features that might serve the same purpose of balancing independence with Relevance. A full ethnographic study of the working practices of scientific advisory mechanisms in different settings could contribute to further elucidate such dynamics, capturing interactions that might not be fully visible through the document analysis and interviews that inform this research.

7.6. Policy implications

The considerations above have a number of practical implications for policymaking and for the design and institutionalization of scientific advice. A lot of effort and attention is normally put in the selection of scientific advisors and the scientific-quality control procedures, which contribute to scientific Credibility. However, the points illustrated above imply that to design more

effective scientific advisory mechanisms it is necessary to look at their institutional set-up beyond the advisors themselves.

In particular, it is necessary to invest as much effort in building the upstream policy linkage as the scientific Credibility, and doing so requires identifying who will actually do this linkage in practice and how, as it depends on the specific bureaucratic and policymaking culture.

While the specific model of a division of labour between expert advisors and their secretariat works in the context of EFSA and SAM, and possibly of EU policymaking more broadly, each institutional model needs to reflect the policymaking context it serves. In the same way as scientific advisory reports don’t necessarily travel well across different polities and political systems, scientific advisory models do not necessarily travel across policymaking cultures and institutions. What works in one context does not necessarily work well in another.

To ensure policy Relevance of scientific advice, it is necessary that scientific advice mechanisms are designed to adapt themselves to the specific local policy context and to reflect its values, rather than only those of the scientific community. Bringing to the surface and making explicit these values is important to identify potential biases and strengthen the political legitimacy (in the broader sense) of the scientific advisory process.

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ANNEX 1 – Sample information sheet and consent form

Information Sheet – Cultures of science use in policymaking

Interview Information
Thank you for agreeing to participate in an interview investigating your professional experience of working at the science-policy interface. Your comments will be used to investigate how different cultural contexts influence the structure and functioning of scientific advisory mechanisms.

The interviews are being conducted by Alessandro Allegra, PhD student at University College London (UK), and results will feed into his doctoral dissertation and other academic outputs (research articles, conference presentations). Your comments will be partially anonymised in all reporting documents, and only attributed to you by name after explicit approval has been sought from you.

The interview will be audio recorded and you may stop the interview at any time. Recordings will be stored safely and destroyed at the end of the project in accordance with UCL policies. No one except the interviewer will hear the recordings or be able to connect specific participants with any of the reported project findings, except if explicitly approved as discussed above. Participants' names and contact details will be stored securely and in a separate location to any comments made.

Withdrawal
If, following the interview, you decide you would prefer not to participate in the project, or would like to remove specific comments from the data set, please contact me at the address and your comments will be withdrawn from the study.

Email: a.allegra@ucl.ac.uk

If you have any queries or comments about the interview please don't hesitate to get in touch. Many thanks once again for agreeing to be involved.

Best wishes,

Alessandro Allegra
Department of Science and Technology Studies
University College London

Consent Form – Cultures of science use in policymaking

Thank you for agreeing to participate in the interview. Please indicate Yes (Y) or No (N) in the appropriate boxes to signify that you have understood and agree with the relevant following statements:

		Y/N
1.	I have read the interview information sheet and understand the information provided and my role as a participant	
2.	I understand that my participation is entirely voluntary and that any information used for reporting purposes will be partially anonymised	
3.	I agree to participate in the above study	

Name of Participant _____

Signature of Participant _____

Date _____

ANNEX 2 – Ethics approval certificate

DEPARTMENT OF
SCIENCE AND TECHNOLOGY STUDIES

UCL

This document certifies that

Alessandro Allegra

has received ethical approval for their project entitled

Cultures of science use in policy-making

in accordance with the UCL Department of Science and Technology Ethical Research policies and procedures.

Application reference number: STSEth121

[redacted]

Signed: Director of Research

Date of Approval: 23 October 2017

ANNEX 3 - GCSA membership

Updated as of November 2023.

Name	Position and Affiliation	Dates of mandate	Gender	Disciplinary Area	Nationality
Nicole Grobert (Chair)	Professor of Nanomaterials, Department of Materials, University of Oxford	2018 - Present	Female	Physical and Mathematical Sciences	German/British
Éva Kondorosi	Professor, Research Director of the Institute of Plant Biology, Biological Research Centre, Hungarian Academy of Sciences Centre of Excellence, Szeged	2020 - 2023	Female	Life Sciences	Hungarian
Maarja Kruusmaa	Professor of Biorobotics, Vice-rector for Research, Tallinn University of Technology (TalTech) and Visiting professor with Norwegian Institute of Science and Technology (NTNU)	2020 - Present	Female	Physical and Mathematical Sciences	Estonian
Eric F. Lambin	Professor of Geography and Sustainability Science, Université catholique de Louvain and Stanford University	2021 - Present	Male	Social Sciences	Belgian
Alberto Melloni	Professor of History of Christianity, Chair Holder of the UNESCO Chair on Religious Pluralism and Peace, University of Modena/Reggio Emilia, Secretary of the Foundation for Religious Studies	2020 - Present	Male	Humanities	Italian
Nebojsa Nakicenovic	Deputy Chair, Director of The World in 2050 (TWI2050), Former Deputy Director General and Acting Director General of the International Institute for Applied Systems Analysis (IIASA) and a former tenured Professor of Energy Economics at Vienna University of Technology	2018 - Present	Male	Social Sciences, Physical and Mathematical Sciences	Austrian
Eva Zažímalová	Professor of Plant Anatomy and Physiology, President of the Czech Academy of Sciences, Scientist at the Institute of Experimental Botany of the Czech Academy of Sciences	2018 - Present	Female	Life Sciences	Czech
Carina Keskitalo	Professor of Political Science, Department of Geography, Umeå University	2016 - 2021	Female	Social Sciences	Swedish

Name	Position and Affiliation	Dates of mandate	Gender	Disciplinary Area	Nationality
Paul Nurse (Deputy Chair)	Director of the Francis Crick Institute, London	2016 - 2021	Male	Life Sciences	British
Janusz Bujnicki	Professor, Head of the Laboratory of Bioinformatics and Protein Engineering, International Institute of Molecular and Cell Biology, Warsaw	2015 - 2020	Male	Life Sciences	Polish
Pearl Dykstra (Deputy Chair)	Professor of Sociology, Erasmus University Rotterdam	2015 - 2020	Female	Social Sciences	Dutch
Elvira Fortunato	Professor, Materials Science Department of the Faculty of Science and Technology, NOVA University, Lisbon	2015 - 2020	Female	Physical and Mathematical Sciences	Portuguese
Rolf-Dieter Heuer (Chair)	Director-General of the European Organization for Nuclear Research (CERN)	2015 - 2020	Male	Physical and Mathematical Sciences	German
Julia Slingo	Chief Scientist, Met Office, Exeter	2015 - 2016	Female	Physical and Mathematical Sciences	British
Henrik Wegener (Chair)	Executive Vice President, Chief Academic Officer and Provost, Technical University of Denmark	2015 - 2017	Male	Engineering	Danish
Cédric Villani	Director, Henri Poincaré Institute, Paris	2015 - 2017	Male	Physical and Mathematical Sciences	French

ANNEX 4 - Interviews guides

Case study 1 (EFSA) interviews guide

Introduction

- Thank participant
- Explain purpose of the interview
- Explain confidentiality

Role

- What was your role in the animal cloning file?
- When exactly did you work on this file?
- What was your role in the commissioning and/or reception of expert advice on cloning?
- What was your role in the advisory process?

Practices

- How did you ensure the scientific quality of the advice?
- How did you ensure the independence of the advisory process?
- How did you manage the interactions between the various stakeholders involved in the advisory process (EFSA, EC. EGE, industry, experts)?
- How did you manage interactions with policymakers/other advisory bodies?
- What are the unique features of expert advice in the cloning case?

Context and snowballing

- What are similar policy issues on which you have provided/requested advice? What are the key similarities/differences?
- What are your views on the broader system of expert advice and use of evidence in EU policymaking more generally?
- Do you want to suggest someone else I should interview?

Case study 2 (SAM) interviews guides

Introduction

- Thank participant
- Explain purpose of the interview
- Explain confidentiality and consent

Role

- Can you please describe your role within the SAM?
- What is/was your role in the production of the SAM's scientific advice?
- Elicit role in specific phases if needed: Can you tell me more about the scoping/evidence gathering/opinion writing?

Practices

- How do you ensure the scientific quality of the advice produced by SAM?
    - Can you give an example?
- How do you ensure the independence of the advice produced by SAM?
    - Can you give an example?
- How do you ensure the policy relevance of the advice produced by SAM?
    - Can you give an example?
- How do you manage the interactions between the different parts of the SAM (SAPEA, GCSA, EC)?
- Can you give an example of particularly effective advice produced by the SAM?
    - Why do you think it was effective?
- Can you give an example of when the SAM advice was challenged and why?