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EFFECTIVE GOVERNANCE DESIGNS OF FOOD SAFETY
REGULATION:
EVIDENCE FROM 15 EU COUNTRIES

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ABBREVIATIONS

BSE	Bovine Spongiform Encephalopathy
EU	European Union
GMO	Genetically Modified Organism
CAP	Common Agricultural Policy
FAO	Food and Agriculture Organization
WHO	World Health Organization
CAC	Codex Alimentarius Commission
WTO	World Trade Organization
SPS	Sanitary and Phytosanitary measures
DG	Directorate General
GFL	General Food Law
vCJD	Variant Creutzfeldt-Jakob Disease
EC	European Commission
FBO	Food Business Operator
WTP	Willingness to Pay
FSMS	Food Safety Management System
RASFF	Rapid Alert System for Food and Feed
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
IAD	Institutional Analysis and Development
IGT	Institutional Grammar Tool
FVO	Food and Veterinary Office
MS	Member States
UN	United Nations

INTRODUCTION

It has been over 25 years since “doing a Gummer” passed into slang. In 1990, the British Minister of Agriculture John Gummer attempted to reassure the public that British beef was safe – despite growing concerns over the Bovine Spongiform Encephalopathy (BSE) disease - trying to feed his daughter a beef-burger, and taking a large bite himself, saying it was “absolutely delicious”. That episode became emblematic of social and political tensions surrounding the regulation of food safety, particularly between public authority and public opinion, market and consumer protection. Protecting consumers from possible food-related risks and health consequences is today a crucial goal of any developed social statehood, and food safety regulation has become a key factor in modern consumer policies, both at the EU and at the domestic level. Food safety regulation intervenes on a wide range of areas, from animal health to chemical residues in agriculture, genetically modified organisms (GMOs), labelling, traceability of the food chain, thus exerting a remarkable impact on public health as much as on the market and on the productivity of the agri-food sector. Food safety policy is defined as the set of “*goals, rules, and structures that are designed to ensure food quality and address the risk of food contamination in order to promote and protect the health of humans, animals, and plants*” (Thomann, 2018: 5; Ansell and Vogel, 2006; Cafaggi, 2012; Redman, 2007; van der Heijden *et al.*, 1999). To tackle the policy problems related to the safety of the food products, food safety policies must govern the whole production and supply chain for food, including production, processing, storage, transportation, retail, and sale (Robson, 2013;Phillips and Wolfe, 2001; Thomann, 2018). These governance structures comprise a set of normative objectives and standards (standard setting), processes for detecting deviations thereof (monitoring), and mechanisms for correcting non-compliant behaviour (enforcement). They involve public regulators who are responsible for these functions, and *regulatees* whose task is to adopt the rules and comply with them (Verbruggen, 2016; Thomann, 2018).

Since the BSE crisis, a large number of *food scares* dominated media reports across Europe, and recent trends show that alerts have not diminished¹. Unsurprisingly, the issue has compelled a common response at the level of the European Union to reform the procedures and the governance for improving food safety. The reform, introduced since 2002, has not made the common Europe a

¹ 584 alerts in 2013, 725 in 2014, 748 in 2015, 817 in 2016, 923 in 2017 (source: <https://webgate.ec.europa.eu/rasff-window/portal/?event=searchForm&cleanSearch=1>)

zero-risk area. Nevertheless, the European countries display differences in their effectiveness to tackle food safety problems.

Food safety regulation has become a multidisciplinary issue that is worthy of exploration, and in recent years many political scientists have undertaken empirical studies into differences across countries from the perspective of regulatory politics and public policy. Neo-institutionalism, rational choice theory, policy networks, and organizational culture theory are frequently used to study this issue.

This work focuses on the institutional design's approach to success and failures of food safety regulation, modelling the control dimension of regulation (i.e. monitoring and enforcement) and the impact it exerts on the substantial dimension. Contributions on food safety regulation are still missing and this study aims to contribute to the literature that applies configurational analyses of institutional designs making use of the Institutional Analysis and Development framework (IAD: Ostrom 2005, 2011). Specifically, this study investigates differences in effectiveness of food safety regulation across 15 EU countries and explains them by differences in domestic institutional designs. The focus is justified by a pragmatic consideration, inspired by the Institutional Analysis and Development framework developed by Ostrom (2005; 2011): although regulatory effectiveness more directly depends on a wide array of non-institutional factors, the institutional dimension of governance is the one which shapes individual actors' strategies and behaviours (Ostrom, 2005; 2011) and achieves the desired outcome.

One of the main assumption of the IAD is that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20). A simplifying assumption that is frequently made in analytical theories is that individuals will take only those actions that are permitted or required. However, in settings where a high investment is not made in monitoring the actions of participants, considerable difference between predicted and actual behaviour can occur as a result of the lack of congruence between a model of legitimate behaviour and the illegal actions that individuals take (Ostrom, 2011: 22). This is particularly true in the policy area of food safety, where the spreading of new animal and human diseases (e.g. Escherichia Coli infections, Listeriosis, Campylobacter, Salmonella, and other foodborne illnesses), the use and the contamination of some harmful products for the human and animal health as well as for the environment (e.g. the massive use of pesticides in agriculture) and the deliberate adulteration of food products (or substitution with lower value ingredients) shed light

on the crucial role played by food safety regulation for the protection of public health. Within this policy area, monitoring and enforcement of regulation have a central stage, and the Institutional Analysis and Development constitutes the theoretical framework that makes the strongest claims with respect to the impact these activities exert over regulatory effectiveness, by identifying the coercive power of rules as the crucial element for the desired outcomes to occur. Therefore, the assumption that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20), enables me to select those institutional features of regulatory designs of monitoring and enforcement in order to investigate the impact they exert on the effectiveness of governance (i.e. the extent to which they ensure predicted results in actions and, thus, behaviours). Moreover, the assumption that institutions are intentional constructions that structure information (Ostrom, 2009: 5) enables me to identify the quality of regulatory designs as one of those institutional features, being the agencies operating in the collective-choice action-situation those who exert control over information which is circulated in the operational action-situation. Finally, in light of the assumption of the configurational nature of institutions, it is possible to argue that the institutional arrangements of monitoring and enforcement activities and of control of information – jointly given – exert an impact on the effectiveness of operational outcomes.

Regulatory governance and design theories have always been concerned with achieving effectiveness in regulatory instruments, and institutional theories suggest that institutional structures and arrangements significantly shape regulation and its effectiveness. Specifically, the institutional design theory identifies in information asymmetries the main regulatory failure-mechanism: agency drift on one hand and industry drift on the other are particularly contributing to the failure of regulation, and several scholars identify in the quality of regulatory design the response to this effectiveness challenge (Gilardi, 2008; Maggetti, 2007; Levi-Faur, 2010). Debates about quality of regulatory designs bring together discussion of independence and accountability (Gilardi, 2002; 2005; 2008; Hanretty and Koop, 2012; Ennser-Jedenastik, 2016; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Biela and Papadopoulos, 2014; Koop, 2015; Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018), and recent design literature extensively discussed policy (and regulatory) capacity, highlighting their fundamental nature to produce effective outcomes (Peters *et al.*, 2018; Considine, 2012; Ramesh and Howlett, 2015; Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016).

Drawing upon the IAD as general framework of institutional analysis, I aim to test the explanatory power of complementary or competing theories and models (Ostrom, 2006: 26). This way, this research contributes substantially to enriching the debate about quality of regulatory designs on one hand, and of policy capacity on the other.

I undertake empirical work by employing Qualitative Comparative Analysis (QCA) – which provides a range of institutional configurations of causal conditions and explores the links of the institutional configurations to the outcome (i.e. effective governance of food safety regulation) through (combinations of) necessary and sufficient conditions. To emphasize the effects of governance designs, the study narrows on those Member States in which the implementation of the European reform has consolidated (with the Regulation 178/2002). As all the Member States accessing the EU in 2004 and 2007 have this regulatory system still in the making – the Central and Eastern European Countries, but also Malta and Cyprus – this study identifies its scope condition in the EU 15, i.e. the countries that joined the European Union before 2004.

The analysis reveals the prominent role of capacity in producing an effective response, and it unfolds its effect in combination with an integrated model of distribution of the regulatory functions. This explanation provides insights on the complementarity of the institutional design's theory and the policy capacity's theory. As claimed by Howlett (2016), capacity is a factor affecting effectiveness of any single governance mode, and governance is linked to policy success and, therefore, to policy capacity. As to regulatory failure, the conjunctural effects of both institutional design's elements (low accountability or low independence) and of low policy capacity are proved to contribute to ineffective response, in line with the theoretical expectations.

Chapter 1 presents an extensive literature review regarding the central concepts of regulation and its governance, policy designs and regulatory instruments, as well as regulatory designs. The review contains conceptual and theoretical insights about regulatory effectiveness, and how the debate has developed in the literature. It focuses on the institutional and organizational aspects of regulatory policies, by summarizing current debates about quality of regulatory designs. The second part of the chapter extends the discussion to the field of risk regulation and risk governance, introducing the most acknowledged definitions and theoretical approaches. Finally, it focuses on

governance of food safety regulation, by reviewing recent scholarly development in the field and identifying the issues worth of further exploration.

Chapter 2 introduces the Institutional Analysis and Development (IAD) framework as the main theoretical foundation of this study and identifies the institutional elements that are particularly relevant to address the research question, by establishing a connection between the IAD and acknowledged regulation theories. By making use of Ostrom's conceptualization of the action-situation, it models the governance of food safety as a configuration of institutional elements that structure information and create incentives to act or not to act - thereby imposing constraints on the range of possible behaviours (Ostrom, 2009: 5). It identifies the agencies that carry out monitoring and enforcement activities and exert control over the information which is circulated in the operational action-situation as unit of analysis of this research. In light of regulatory governance and design theories, it specifies independence, accountability, and policy capacity as the main institutional elements relevant to address my research questions, that is which institutional features do affect the effectiveness of governance of food safety regulation. Finally, it constructs the explanatory model by involving precise assumptions about a limited set of explanatory conditions and by deriving precise expectations about the result of combining these conditions. The operation yields a model explaining differences in governance effectiveness by:

- (1) institutional separation of risk assessment from risk management,
- (2) independence of actors carrying out risk assessment,
- (3) accountability of actors carrying out risk assessment,
- (4) capacity of actors carrying out monitoring, control, and enforcement of risk management.

Chapter 3 addresses the research design by tackling both methodological and ontological questions. Recent literature on policy design (Capano and Howlett, 2019) shed light on the necessity of adopting a mechanistic perspective to focus on "*realistic causation* and to answer to *one of the most important questions for policy designs: how does a policy design encourage, constrain and otherwise structure policy targets' behaviour to achieve desired outcomes?*" (Capano and Howlett, 2019: 2). Drawing upon this tenet, this study aims to combine systematic cross-case comparison – by identifying regularities – with within-case analysis – by focusing on the underlying mechanisms and the configurations that unfold their effects. The method's choice should be "*guided by the goal of achieving a good fit between theories and research aims on the one hand, and the method-specific*

assumptions on the other” (Schneider and Wagemann, 2012: 12). Drawing upon the IAD assumption about the configurational nature of institutions, the chapter explains the choice of employing Qualitative Comparative Analysis (QCA). This methodological approach provides a range of institutional configurations of causal conditions and explores the links of the institutional configurations to the outcome (i.e. effective governance of food safety regulation) through (combinations of) necessary and sufficient conditions. Good case-based research is built on extensive contextualization and deep understanding of the cases at hand (Rihoux and Ragin, 2009). Here, I argue that the sector of food safety regulation is an illustrative and likely case for assessing the impact the institutional features of monitoring and enforcement exert over operational outcomes and, thus, effectiveness of governance. The chapter also discusses case selection and provides an overview of the food safety regulatory designs of the 15 EU countries under scrutiny.

Chapter 4 tackles the question of how we can think and measure the effectiveness of food safety regulation. Although effectiveness is itself a highly contentious issue, it can be understood as goal achievement (Skjærseth and Wettestad, 2008; Levi-Faur, 2011; Thomann, 2018). Accordingly, the question of effectiveness entails gauges to establish whether the food safety regulation realizes its objectives. Dealing with the concept of food safety, the literature discriminates between “delivered safety” and “perceived safety” and suggests that the effectiveness of its regulation can be measured on both dimensions (Righettini, 2015). My contribution to the existing empirical work consists in developing a measure of delivered food safety. To do so, a systematic literature review of the existing measures of both perceived and delivered food safety is presented. Finally, a new measure is proposed. The gauge is based on the Rapid Alert System for Food and Feed (RASFF) data. As a tool that ensures *“the flow of information to enabling swift reaction when risks to public health are detected in the food chain”*, the RASFF provides notifications about food safety related risks occurring across its members, recording original notifications together with follow-up notifications. As outlined by the European Commission itself, the effectiveness of RASFF can be assessed in terms of achievement of its main objectives – namely, information exchange between members of the network on (a) direct or indirect risks in relation to food or feed, (b) the follow up to notified direct or indirect risks, (c) measures to contain risk. The new metrics understands delivered food safety as the quality of the response of the domestic system to food-related risks about which they get information through the RASFF network – exchanged information, quality of notifications transmitted, and reaction to the risk.

Chapter 5 discusses in detail the operationalization of the causal conditions, presenting data collection sources and detailing the coding. The gauges draw upon European and domestic regulations, statutory provisions of the national agencies involved in the governance of food safety, and official documents and reports. My contribution to the existing empirical literature consists in developing a measure of food safety policy capacity and in gauging formal independence and accountability of the 15 domestic food safety agencies of the EU countries under scrutiny. I have drawn upon the acknowledged indicators developed by Gilardi (2008; 2005; 2002) and Hanretty and Koop (2018; 2009; 2012; 2013) which ensure comparability with existing empirical measures and is in line with the empirical literature that employed Qualitative Comparative Analysis (QCA) (Maggetti, 2009; 2007).

Chapter 6 performs and discusses the so-called calibration process of the explanatory conditions and of the outcome, as well as the analyses of necessity and of sufficiency. QCA models causal complexity, which includes three features: equifinality, asymmetric causation, and conjunctural causation (Rihoux & Ragin 2009, Schneider & Wagemann 2012). Instead of assuming isolated effects of single variables, the assumption of conjunctural causation *“foresees the effect of a single condition unfolding only in combination with other conditions”* (Schneider and Wagemann, 2012:78). The method implies the assumption that appropriate performance (effectiveness) can have a different explanation than deficient performance (causal asymmetry). Finally, the assumption of equifinality allows for different, mutually non-exclusive explanations of the same phenomenon.

CHAPTER ONE

LITERATURE REVIEW:

DEFINITIONS, THEORETICAL APPROACHES AND EMPIRICAL EXTENSIONS

1. INTRODUCTION

This research applies configurational analysis of institutional designs and investigates differences in the food safety regulatory designs accounting for differences in the effectiveness of governance of food safety across the EU-15. To do so, it draws upon the notions of regulation developed by Levi-Faur (2010) – which includes continuous action of monitoring, assessment, and enforcement of rules – and of risk governance developed by Hermans and colleagues (2012) – that entails the entire complex system of actors, rules, procedures, and mechanisms connected with all relevant information that is collected, analysed, and communicated about risks and how management decisions are taken (Hermans *et al.*, 2012).

Regulatory governance and design theories have always been concerned with achieving effectiveness in regulatory instruments, and institutional theories suggest that institutional structures and arrangements significantly shape regulation and its effectiveness. Specifically, the institutional design theory identifies in information asymmetries the main regulatory failure-mechanism: agency drift on one hand and industry drift on the other are particularly contributing to the failure of regulation, and several scholars identify in the quality of regulatory design the response to this effectiveness challenge (Gilardi, 2008; Maggetti, 2007; Levi-Faur, 2010). Debates about quality of regulatory designs bring together discussion of independence and accountability (Gilardi, 2002; 2005; 2008; Hanretty and Koop, 2012; Ennser-Jedenastik, 2016; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Biela and Papadopoulos, 2014; Koop, 2015; Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018), and recent design literature extensively discussed policy (and regulatory) capacity, highlighting their fundamental nature to produce effective outcomes (Peters *et al.*, 2018; Considine, 2012; Ramesh and Howlett, 2015; Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016).

Drawing upon these tenets, this chapter presents an extensive literature review regarding the central concepts of regulation and its governance (section 2), policy designs and regulatory instruments (section 3), as well as regulatory designs (section 4). It focuses on the institutional and

organizational aspects of regulatory policies, by summarizing current debates about quality of regulatory designs (section 5). The review contains conceptual and theoretical insights about regulatory effectiveness, and how the debate has developed in the literature (section 6). The second part of the chapter extends the discussion to the field of risk regulation and risk governance, introducing the most acknowledged definitions and theoretical approaches (section 7). Finally, it focuses on governance of food safety regulation (section 8), by reviewing recent scholarly development in the field and identifying the issues worth of further exploration (section 9).

2. REGULATION AND ITS GOVERNANCE: DEFINITIONS AND THEORETICAL APPROACHES

The area of regulation has experienced a considerable evolution over the past decades. Since the 70s - with the introduction of the economic theory of regulation by Stigler (1971) and the rise of consumer, risk, and environmental regulatory activity (Majone, 1994) - it has developed into an international field of research and practice, expanding in particular in the 80s and 90s. Regulatory institutions have been established around the world, both at the international and at the state level, and the effectiveness of different modes and tools of regulation has come under scrutiny, particularly in the context of the financial crisis, environmental disasters, and the safety of food and medicine (Koop & Lodge, 2017).

Much of the academic debates about regulation nowadays deal with the concept of governance of regulation and identifies effectiveness as one of its major challenges (Levi-Faur, 2010). Regulatory governance as a concept refers to the complex interplay of regulatory actors and involves both tasks of design and implementation of regulatory instruments as well as of control. The idea of governance is indeed associated with multiple logics of control (Lodge & Wegrich, 2011: 90) and with the rise of the regulatory state (Majone, 1994). As to the latter, the development of regulation as fundamental tool of governance led to its emergence and consolidation. The claim that we are living in a regulatory state has become widely accepted, and regulation has risen the academic agenda to become both a field of study in its own and a source of new perspectives on the agendas of established disciplines. The argument about the emergence of a regulatory state remains linked to the development of the European Union, and there is an emerging idea of a regulatory state, especially in the political science literature (Majone, 1994). On the one hand, there is a consolidated strand of literature concerned with the general characteristics of a regulatory state or regulatory capitalism in regard to democratic participation (Levi-Faur, 2005, 2011a; Majone, 1999), while on the other there is the literature that identifies the main characteristics of the regulatory state, in

particular the emergence of independent regulatory authorities and their diffusion (Gilardi, 2005, 2008; Maggetti and Gilardi, 2011).

Contributions to both theoretical and empirical debates on regulation have been made by political scientists, economists, lawyers, sociologists, and others, across a variety of disciplines and scholarships (Baldwin, Cave & Lodge, 2012: 2).

2.1 DEFINITIONS

According to Koop and Lodge (2017), the question of what is meant by *'regulation'* is still contested. Baldwin and colleagues argue that there are three main conceptions: regulation as *"the promulgation of an authoritative set of rules, accompanied by some mechanism [...] for monitoring and promoting compliance with these rules"*, regulation as *"all the efforts of state agencies to steer the economy"*, and regulation as *"all mechanisms of social control – including unintentional and non-state processes"* (Baldwin *et al.*, 2012; Baldwin, Scott, & Hood, 1998: 3–4; Jordana & Levi-Faur, 2004: 2–4). The variation is attributed to differences in disciplinary concerns, with lawyers, political scientists, and economists building mainly on the first two conceptions, while socio-legal scholars emphasize the third (Baldwin, Scott, & Hood, 1998; Levi-Faur, 2011).

Regulation can be intended as a deliberate state influence – where it covers all state actions that are designed to influence behaviour (not only command-based regimes, but also economic incentives, contractual powers, deployment of resources, the supply of information) – and as all forms of social or economic influence – where all mechanisms affecting behaviour are deemed regulatory (Baldwin *et al.*, 2012: 3). According to Baldwin and colleagues (2012: 2), regulation is an identifiable mode of governmental activity, and can be thought as a specific set of commands – where it involves the promulgation of a binding set of rules to be applied by a body devoted to this purpose. Some scholars argue that regulation comprises mostly rule making, while others include also rule monitoring and enforcement (Hood *et al.*, 2001). For some, regulations are about the rules and functions of the administrative agency after the act of delegation, emphasizing workings, characteristics, failures, and merits of regulation by administrative agencies.

Many authors rely on Selznick's definition of regulation as *"sustained and focused control exercised by a public agency over activities that are valued by the community"* (Selznick, 1985: 363). However, as argued by Levi-Faur (2010: 8), his definition does not include non-public forms of regulation.

Black proposes a more detailed definition of regulation as *"the sustained and focused attempt to alter the behaviour of others according to defined standards and purposes with the intention of*

producing a broadly identified outcome or outcomes, which may involve mechanisms of standard setting, information gathering and behaviour modification” (Black, 2002: 26; Parker and Braithwaite, 2003; Morgan and Yeung, 2007; Lodge and Wegrich, 2011; Hood *et al.*, 2011). Scott (2001: 283) provides a definition of regulation which makes use of the notion of regime: *“any process or set of processes by which norms are established, the behaviour of those subject to the norms monitored or fed back into the regime, and for which there are mechanisms for holding the behaviour of regulated actors within the acceptable limits of the regime”*. The notion of a regulatory regime encompasses the norms, the mechanisms of decision-making, and the network of actors that are involved in regulation (Eisner, 2000; Drezener, 2008; Levi-Faur, 2010). Krasner defines a regime as the *“principles, norms, rules, and decision-making procedures round which actors’ expectations converge in a given issue-area”* (Krasner, 1982: 185). This notion has been extensively used in the literature, and Hood, Rothstein, and Baldwin used it to connote the way risk is regulated (2001).

Among the plethora of definitions just described, in this study I draw upon Levi-Faur’s definition of regulation, which includes continuous action of monitoring and enforcement of rules: *“the promulgation of prescriptive rules as well as the monitoring and enforcement of these rules by social, business, and political actors on other social, business, and political actors”* (Levi-Faur, 2010: 9). In fact, this notion entails both commands and controls, and the level of control is acknowledged as *“perhaps the most fundamental determinant of the effectiveness of regulation in meeting policy objectives”* (OECD, 2002: 74).

Authors agree that regulation is about intervention in the behaviour or activities of individuals and/or corporate actors, and some scholars view regulation as a distinct mode of governance (Koop and Lodge, 2017). According to Noll (Noll, 1985: 9), regulation is a method of control where a government agency is assigned the task of *“writing rules constraining certain kinds of [...] decisions”*. Accordingly, the more recent literature on regulatory governance emphasizes the difference between regulation and other modes of governance (Braithwaite, 2000; Levi-Faur, 2005), where regulation is about *“steering the flow of events and behaviour, as opposed to providing and distributing”* (Braithwaite *et al.*, 2007: 3; Braithwaite, 2008). Narrow conceptions think of regulation as constituting a legal mandate backed by the possibility of sanctions (Koop and Lodge, 2017: 99). For Hood and colleagues (2001), regulation involves a control system that requires the existence

and functioning of three components: standard setting, information-gathering, and behaviour modification.

As to this latter, one of the most prominent debates over behavioural modifications in regulation literature concerns the relative merits of compliance and deterrence, as ways of applying regulatory standards (Hawkins and Thomas, 1984; Hood *et al.*, 2001: 27). Indeed, variations in the predispositions to compliance or deterrence have often be observed as a feature of national regulatory cultures. Accordingly, regulation is often seen as an activity that restricts behaviour and prevents the occurrence of certain undesirable activities (Baldwin *et al.*, 2012). Recently, newer theories of problem-centred regulation have moved compliance theory onwards, and more attention has been given to motivation and behaviours (Sustein and Thaler, 2008; Jolls *et al.*, 2008), to interactions of control systems (Baldwin and Black, 2008; Black and Baldwin, 2010), and to risk-based and principle-based approaches to regulatory enforcement (Baldwin *et al.*, 2012).

Here, hence, regulation is understood as a set of normative objectives and prescriptive rules and includes processes for detecting deviations thereof and mechanisms for correcting non-compliant behaviour.

2.2 THEORETICAL APPROACHES

In explaining how regulation arises, develops, and changes a number of broad approaches exist. Some accounts of regulation emphasize exogenous factors, while some others focus on endogenous factors. As to the former, public interest theories assume that those seeking to develop regulation do so in pursuit of public-interest related objectives (rather than group, sector, or individual self-interests) (Levine and Forrence, 1990; Hantke-Domas, 2003; Morgan and Yeung, 2007). A second broad approach is the one of interest group theories, prominently associated with economic theory of regulation – which builds on the assumption that actors are inherently self-regarding and oriented at maximizing their own interest (Baldwin *et al.*, 2012: 43). Further approaches assume that legislators and regulators seek to maximise their personal wealth – i.e. the Chicago school of law and economic – while others see legislators and regulators as pursuers of expected votes or ideological end as well as cash, giving greater prominence to the interplay of pressure groups – i.e. the Virginian school of political economy (Foster, 1992; Crew, 1989). These accounts have been highly influential in shaping the literature on regulation, especially when they moved towards the analysis of constitutional rules and institutional design. Other accounts of regulation have moved

the theory towards wider interest group politics: regulatory developments are seen as the result of relationships between different groups and between such groups and the state, and the regulatory behaviour is seen as a competition for power. A number of different strands of literature on regulation and public policy discussed the impact of ideas, ideologies, and beliefs: one strand points to changing ideologies that shape approaches towards regulation, while a second strand stresses the inherent plurality of rationalities that characterise any debate about regulatory instruments, and a third one emphasizes the importance of deliberation and conversations (Baldwin *et al.*, 2012: 49). In sum, the *power of ideas* approach ranges from a focus on the underlying ideas that drive the designs of regulatory instruments, to a stressing of the importance of the broader intellectual environment that shapes regulatory instruments, to an emphasis on understanding the deliberations and discourses, the interactions and communication patterns that characterise the regulatory domains and structure regulatory actions (Baldwin *et al.*, 2012: 52).

Finally, one of the broadest theoretical approaches is the institutionalism, ranging from emphasizing the importance of formal rules in shaping behaviour, as well as of political rules of the games, and the social context in which all human action is embedded. Institutionalists agree on the notion that the institutional structure and its arrangements significantly shape regulation, and different approaches can be detected: economic (Williamson, 1985; North, 1984; Matthews, 1986; Horn, 1995; Moe, 1990; Calvert, McCubbins and Weingast, 1989; Ostrom, 1986), historical (Hancher and Moran, 1989; Shearing, 1993; Scott, 2001), and sociological (March and Olsen, 1984; Meyer and Rowan, 1977; Powell and Di Maggio, 1991; Black, 1997).

According to Baldwin and colleagues (2012), in the institutionalist literature we can identify three strands, focusing respectively on inter-institutional relations (specifically, on institutional design questions), intra-institutional forces (specifically, the evolution of regulatory regimes over time), and network and regulatory space understandings of regulation. The first strand is interested in designing institutions and institutional relations to avoid specific problems associated with regulatory processes (i.e. capture) and it focuses attention on the rules of the game, being concerned of the question “why delegate?” This question relates to three key issues that have informed most of the literature on institutional design: information asymmetry, credible commitment, and blame avoidance. The second strand sees regulatory change as driven by forces that come from within organisations and emphasizes the self-destructive processes that partly emerge from a process of filtered responses to changes in the wider environment of the regulatory

system (Baldwin *et al.*, 2012: 58). This literature developed into four different lines of inquiry: institutional layering, perversity, self-referential and regulatory space/network approaches. In sum, intra-institutional accounts stress endogenous processes that encourage the regulatory change, and the inherent tensions arising when environmental requirements change and competing demands arise. A third body of work understands regulation as decentred and controlled by networks of regulators, giving rise to the so-called network theories and relating to the established regulatory space account. Here, the space is conceived as a cluster of regulatory issues, decisions, or policies (i.e. a regulatory arena) that involves the interplay and competition between various interests.

New institutionalist theories emerged against the background of *behaviouralism*, opposing that expressed preferences are not necessarily identical to true preferences, that the aggregation of individual preferences can be inefficient and imperfectly translated into decisions, and that the utilitarian standard for the identification of the public interest as the sum of individual interests is inappropriate (Gilardi, 2005: 69). New institutionalism is composed of three distinct strands, including rational choice, sociological, and historical. According to the rational choice approach, actors are rational utility-maximisers and their behaviour is shaped and constrained by institutions, defined as rules of the game. Moreover, institutions are the result of deliberate design, and their shape is determined by the benefits they can provide to the relevant actors. The sociological approach is grounded in organisation theory and conceptualizes institutions not only as formal rules and procedures, but also norms, having a strong symbolic dimension. Finally, the historical approach draws on insights of both theories, adding to them by having a marked historical view of institutions and recognising the influence of institutions over the preferences of actors, by focusing on macro-context and the combined effects of institutions and processes.

Table 1.1 summarizes the theoretical approaches to regulation and their constitutional elements.

Table 1.1 – Theories of regulation

Type of Theory	Main emphasis
Public interest	Regulator acting in pursuit of public, rather than private, interests. Regulator disinterested and expert.
Interest group	Regulation as product of relationships between groups and with the state. Role of private economic interests in driving regulation.

	Incentives of firms to secure benefits and regulatory rents by capturing regulator.
Ideas	Role of ideas in steering regulatory developments.
Institutional	Influence of organizational rule and social setting on regulation. Actors seen not purely as individuals but as shaped in action, knowledge, and preference by organizational rule and social environments. Principal-agent issues and problems of democratic control of implementation. Institutional design as shaped by characteristics of political setting. Institutional processes leading to self-destruction. Regulatory authority diffused between and across public and private organizations.

Source: Baldwin *et al.* (2012: 67)

3. POLICY DESIGNS AND REGULATORY INSTRUMENTS

Policy tools are an identifiable method through which collective action is structured to address a public problem (Salamon, 2002), and their study has generated a large academic literature (Eliadis *et al.*, 2005; Howlett, 2000; Salamon, 2002; Hood, 1983; Hood and Margetts, 2007; McDonnell and Elmore, 1987; Schneider and Ingram, 1990; Bemelmans-Videc *et al.*, 1998; Peters *et al.*, 2018). Several scholars have been analysing policy designs and have sorted policies within typologies, categorized them as governance tool or instruments types, compared across dimensions, among which coerciveness and directness (Salamon 2002), stringency (Lester *et al.*, 1983; Meier, 1987; Rinquist, 1994), and level of prescription (Koski, 2007). Indeed, policy design is an area of study in the field of public policy that gave rise to a large literature in the 1980s and 1990s, aimed at understanding design as both a process and an outcome, with prominent representatives such as Lester Salamon, Helen Ingram and Anne Schneider, B. Guy Peters, Christopher Hood, Evert Vedung,

Peter May, who wrote extensively on policy formulation, policy instruments choice, and the idea of designing policy outcomes.

Policy design has been defined as *“an activity conducted by a number of policy actors in the hope of improving policy making and policy outcomes through the accurate anticipation of the consequences of government actions and the articulation of specific courses of action to be followed”* (Howlett and Lejano, 2013: 358). Within the policy sciences, policy design has been linked to studies of policy instruments and implementation (May, 2003) and of policy ideas and policy formulation (Linder and Peters, 1990). It is grounded in the rational tradition of policy studies, being aimed at improving policy outcomes through the application of policy-relevant knowledge to the crafting of alternative possible courses of action, intended to address specific policy problems (Howlett and Lejano, 2013). As Howlett and Lejano highlighted, policy design contains a substantive component – a set of alternative arrangements potentially capable of resolving or addressing some aspect of a policy problem – as well as a procedural component – a set of activities related to securing some level of agreement among those charged with formulating, deciding on, and administering that alternative. Moreover, policy designs can be thought as ideal configurations of sets of policy elements that can be expected to deliver a specific outcome, and policy designing as the process by which these ideal-types are identified and refined (Howlett and Lejano, 2013: 360).

As Linder and Peters noted, policy instruments are especially significant as *“they are the techniques through which a state’s goal attainment occurs, and they comprise the contents of the toolbox from which governments must choose in building or creating public policies”* (Linder and Peters, 1989; Howlett, 2014: 285). A considerable body of work has been investigating the interaction between policy instruments and implementation, in the attempt of assessing successes and failures of *policy tools* (Carter *et al.*, 2015; Lowi, 1972; Hood, 1983; Sabatier and Mazmanian, 1980; Linder and Peters, 1989; Pierson, 2000; Salamon, 2002; Schneider and Ingram, 1997; Peters *et al.*, 2018; Baldwin *et al.*, 2012). According to Howlett, policy design elevates the analysis and practice of policy instrument choice – specifically tools for policy implementation – to a central focus of study, making their understanding and analysis a key design concern (Salamon, 2002; Linder and Peters, 1990; Howlett, 2014). Several studies have focused on the process of instrument choice, outlining the rationale for choosing between particular instrument types (Howlett, 2000; Hood, 1983; Hood and Margetts, 2007; Schneider and Ingram, 1990; Bemelmans-Videc *et al.*, 1998; Vedung, 2010). Although policy instruments appear in all stages of the policy process, policy design studies have focused on those linked to policy implementation and to policy formulation: as to the former, governing tools such as

regulatory agencies and public enterprises are expected to affect the delivery of goods and services to the public and government (Salamon, 2002), while as to the latter, instruments such as regulatory impact are designed to alter and affect some aspect of policy deliberations and the assessment of alternatives (Howlett, 2014: 287).

In his work, Vedung suggests a parsimonious classification of policy instruments, defining a tripartite configuration: regulation, economic means, and information (Vedung, 2010). Salamon in turn provides a definition of the *“tools of public action as instruments to address public problems”* (Salamon, 2000: 1612) and recognizes that each tool *“has its own operating procedures, its own skill requirements, its own delivery mechanism”* (Salamon, 2000: 1613). This notion entails the behavioural constraints given by the set of commands, or economic means, or information, as well as the control dimension, the delivery mechanism, and the procedures related both to the commands and to the control. Drawing upon this notion, Howlett (2000) advanced the study of policy instruments introducing the distinction between substantial and procedural instruments, the latter intended to *“indirectly affect outcomes through the manipulation of policy processes”* (Howlett, 2000: 413). Indeed, one common category of implementation instrument proposes to alter the actual substance of the kinds of day-to-day production, distribution, and consumption of good and services in society, while another focuses on altering political or policy behaviour in the process of the articulation of implementation goals and means (Howlett, 2014: 287; Ostrom, 1986; Howlett, 2000; 2005). Thus, Howlett defines substantive policy instruments as *“those policy techniques or mechanisms designed to directly or indirectly affect the behaviour of those involved in the production, consumption, and distribution of different kind of goods and services in society”* (Howlett, 2014: 287; Schneider and Ingram, 1990; 1993; 1994). Procedural policy implementation tools, on the other hand, *“affect production, consumption, and distribution processes only indirectly. Rather they instead affect the behaviour of actors involved in policy implementation”* (Howlett, 2014: 289). Substantive tools include licensing, subsidies, quotas, standards, warranties, inspections, legislation, labelling, information release, taxes and bans, monetary policy, etc. Procedural tools can change actor positions, setting down, defining or refining actor positions, adding actors to policy networks (Klijn *et al.*, 1995; Klijn and Koppenjan, 2006), changing access rules for actors to governments and networks, influencing network formation, promoting self-regulation, modifying system-level parameters, influencing the pay-off structure for policy actors, changing evaluative criteria for assessing policy outcomes, influencing codes of conduct affecting policy actor

behaviour, regulating inter-actor policy conflict, changing interaction procedures, certifying or sanctioning certain types of behaviours, etc. (Howlett, 2014: 289-290; Peters *et al.*, 2018).

Design studies have always been concerned with achieving effectiveness and efficiency in policy tools, and regulation studies have always been interested in analysing and improving upon the sets of regulatory tools adopted by governments to solve problems (Peters *et al.*, 2018: 5). Policy instruments are intended to change individual behaviour through the use of some sort of coercion, sanction, incentive, or suasion (Bemelmans-Videc, 1998; Schneider and Ingram, 1997). Specifically, incentives and disincentives contained within policy tools are intended to promote some behaviours and discourage others (Salamon, 2002). Policy instruments, through their influence on individual behaviour, also have an influence on the wider social world (Bemelmans-Videc, 1998). Moreover, the influence on individual behaviour translates to an influence on society which works through specifying and structuring specific relationships, identities, choices, and behaviours, as well as creating structures for continued influence (Hood, 1983; Salamon, 2002). These patterns of structured relationships are intended to produce predicted and predictable changes in individual behaviour to such a degree that the resulting activity and its consequences will produce *“the necessary and sufficient conditions for a valued outcome”* (Bobrow, 2006). According to Lascoumes and Le Gales (2007), the study of policy instruments *“reveals a theorisation of the relationship between the governing and the governed: every instrument constitutes a condensed form of knowledge about social control and ways of exercising it”* (Lascoumes and Le Gales, 2007: 3). Accordingly, Hood defined instruments as *“predominantly a way of controlling society”* (1983: 6), and Stewart argued that they are the *“behavioural link between the nature of the problem and the type of action needed to solve it”* (1993: 324). There is an underlying assumption common to policy instruments studies that social behaviour and processes are controllable or modifiable to some extent (de Bruijn and Hufen, 1998). There are two ways in which policy instruments influence behaviour: the first is intended to directly affect individual behaviour, through incentives or sanctions, and the second is intended to affect the context in which behaviour is manifested, through the implementation of knowledge tools, indirectly affecting behaviour (Lowi, 1972). Policy instruments are generally separated into three categories: inducements (including both incentives and sanctions), regulation, and knowledge or capacity tools (Bemelmans-Videc, 1998; Schneider and Ingram, 1997).

Regulation is an identifiable mode of governmental activity (Baldwin *et al.*, 2012: 2), and as such it has been widely conceptualized as the traditional instrument of government (Vedung, 2010). According to Vedung and colleagues *“the defining property of regulation is that the relationship is authoritative, meaning that the controlled persons or groups are obliged to act in the way stated by the controllers”* (Vedung, 2010: 10). This notion entails both command and control dimensions, i.e. prescriptive rules (command) on one hand, and monitoring and enforcement of these rules (control) on the other. Indeed, Vedung conceptualizes policy instruments as made of a certain action content – which specifies what to do and how to behave – and a certain authoritative force – intended as the constraints on the behavioural alternatives of individuals and organizations (Vedung, 2010: 227). Regulatory tools are intended to change behaviour and often originate in the legislative and administrative spheres of government. In the traditional literature, regulation as a policy tool mostly referred to command and control systems, that mainly were concerned with regulating private firms to correct for certain types of market failures. Regulation as a tool has expanded from that original definition to include other regulatory activities, i.e. social regulation, specifically intended to improve public welfare through regulating behaviours that affect public health and safety (May, 2003).

Regulatory instruments can be understood as both substantial and procedural instruments: substantial regulation is designed to affect the behaviour of those who are regulated, while procedural regulation is the procedure of decision-making for substantial regulation, together with the manner in which substantial regulation unfolds. The procedural dimension of regulation is aimed at setting down, defining or refining actor positions, adding actors to the field of implementation, changing access rules and influencing the pay-off structure for actors, and sanctioning certain types of behaviours. Indeed, regulatory tools usually contain four components: rules that specify the desired behaviour, standards for compliance, sanctions for non-compliance, and an administrative system to enforce the rules and deliver sanctions (May, 2003).

Drawing upon this notion, this study aims to tackle food safety regulation as a regulatory instrument that has both command and control dimensions, prescribing behaviours on one hand, and providing for monitoring and enforcement of these behaviours on the other.

4. REGULATORY DESIGNS

When speaking of regulation, one of the main challenges is choosing the right strategy for regulating, and literature distinguishes between direct state regulation, self-regulation, and other modes of delegating the regulatory function beyond the state.

When focusing on direct state regulation, a number of regulatory strategies are built according to the different resources and capacities that governments have to influence industrial, economic, or social activity: to command (i.e. where legal authority and the command of law is used to pursue policy objectives), to deploy wealth (i.e. where contracts, grants, loans, subsidies, or other incentives are used to influence behaviour), to harness markets (i.e. where governments channel competitive forces to particular ends, for instance by using franchise auctions to achieve benefits for consumers), to inform (i.e. where information is used strategically), to act directly (i.e. where the state takes action itself), to confer protected rights (i.e. where rights and liability rules are structured and allocated so as to create desired incentives and constraints) (see Table 1.2) (Baldwin *et al.*, 2012: 106).

Table 1.2 – Regulatory designs

Strategy	Example
Command and control	Health and safety at work
Incentives	Differential tax on leaded and unleaded petrol
Market-harnessing controls (a) Competition laws (b) Franchising (c) Contracting (d) Tradable permits	(a) Airline industry (b) Rail, television, radio (c) Local authority refuses services (d) Sulphur dioxide emissions (USA)
Disclosure	Mandatory disclosure in food/drink sector
Direct action and design solutions (a) Direct interventions (b) Nudge strategies	(a) State supplied work premises (b) Consent to organ donation is assumed unless positive opt-out is exercised
Rights and liabilities laws	Rules of tort law, right to light or clean water
Public compensation / social insurance	Workplace safety schemes

Source: Baldwin et al. (2012: 134-136)

When focusing on other regulatory strategies, the literature generally distinguishes between self-regulation (i.e. when a group of firms or individuals exerts control over its own membership and behaviour), enforced self-regulation (i.e. when the regulatory functions are subcontracted to regulated firms), and co-regulation (i.e. when the industry-association self-regulates with some oversight and/or ratification by government) (Ayres and Braithwaite, 1992; Baldwin *et al.*, 2012). The term meta-regulation is similarly used to refer to processes in which the regulatory authority oversees a control, rather than carries out regulation directly. Recently, hybrid approaches developed, by recognizing the involvement of government, industry, and civil society actors into the regulatory process (Murray and Scott, 2002; Verbruggen and Havinga, 2017).

Nowadays, much discussion over regulatory strategies focuses on regulatory mixes, and over time different patterns of interaction can be expected: there may be tendencies towards either centralization or decentralization, or hybrid solutions resulting in complex governance structures; actor-wise there may be empowerment of private or public actors, respectively, with trends such as agencification, emergence of network governance or the promotion of voluntary approaches (Eckert, 2011: 515).

The first generation of early instrument studies was concerned largely with the analysis of business-government relations, and with the effects of state regulation on business efficiency, concentrating its focus upon identifying the market failures which would justify government intervention in market exchange and the possible governance techniques which could fix those failures. The second generation of instrument studies attempted to develop more policy-relevant models of instrument selection processes, but focusing on either substantive instruments, or on procedural instruments, and ignored their inter-relationship (Howlett, 2000; 2004). Finally, the third generation of instrument studies, instead, attempted to overcome these limitations and applied the first and second generations models to the study of policy instrument mixes, and to the question of developing optimal policy instrument designs in complex multi-instrument settings (see Table 1.3).

Table 1.3 – A taxonomy of eight basic policy instrument components of a policy mix

Principal governing resource used				
	Nodality	Authority	Treasure	Organization
Substantive	Advice Training	Regulation Self-regulation	Grants User charges	Administration

General purpose of instrument use	Reporting Registration	Licenses Census-taking	Loans Tax credits Polling	Public enterprises Policing Consultants Record keeping
Procedural	Information provision / withdrawal	Treaties Advisory committees / commissions	Interest group funding / creation	Conferences Commissions of inquiry Government re-organizations

Source: Howlett and Rayner (2007: 5), adapted from Hood (1986) and Howlett (2000)

The proponents of *smart regulation* (Gunningham and Grabosky, 1998) emphasize the importance to design the optimal mixes of instruments and institutions to produce the best regulatory outcomes. These scholars seek to identify mixes that are inherently complementary, inherently incompatible, complementary if sequenced, and complementary or otherwise, depending on the specific context. An alternative design strategy is that proposed by Sparrow, the *regulatory craft approach*, which places problem solving at the centre of regulatory policymaking (Sparrow, 2003). Another approach to regulatory design is the *really responsive* account, according to which in designing regulatory systems attention has to be given to the behaviour, attitudes and cultures of the regulatory actors, the institutional settings of the different regulators, the different logics of regulatory tools and strategies, the regime's own performance over time and, finally, changes in each of these elements. Moreover, according to this approach, the regulatory challenges vary across the main tasks that regulators have to carry out, i.e. detecting undesirable or non-compliant behaviours, developing tools and strategies on the ground, assessing success of failure, and modifying tools accordingly (Baldwin *et al.*, 2012).

5. REGULATION AS POLICY INSTRUMENT: THE REGULATORY AGENCIES

When speaking of regulatory designs, the main institutional manifestation of the regulatory state is independent regulatory agencies (Gilardi, 2008). The rise of regulation as a policy instrument has been interpreted as a major shift in the way governments intervene in the economy, with implications for both policies and institutions. Specifically, the difference between the positive and

the regulatory state lies in the instruments used. While the action of the positive state depends on taxing and spending, that of the regulatory state lies on the production of rules, which is not subject to the same budget constraints (Gilardi, 2008: 19). The literature on the regulatory state has focused on Europe, but some scholars have emphasized the global nature of this trend (Levi-Faur, 2005; Jordana and Levi-Faur, 2004; Gilardi, 2008): the rise of regulation as a mode of governance characterizes countries in all regions of the globe. Some authors developed on this theory to claim that the regulatory state is part of a larger rise of *regulatory capitalism* (Levi-Faur, 2005; Braithwaite, 2008; Gilardi, 2008). This claim refers to how capitalism is shaped by regulatory regimes in which the regulatory state is one actor among others. Independent regulatory agencies can be defined as “*public organisations with regulatory powers that are neither elected by the people, nor directly managed by elected officials*” (Thatcher and Sweet, 2002: 2; Gilardi, 2008: 21-22). IRAs are part of the *agencification* trend that has characterised the OECD countries and they constitute a key regulatory tool in several sectors, from telecom to food safety, from environmental protection to energy.

A first generation of studies entailed a legalistic approach and strong emphasis on description rather than explanation (Cassese and Franchini, 1996; Merusi, 2000; Gentot, 1994; Custos, 2002; Decoopman, 2002), or provided general discussions (Morisi, 1997; Giraudi and Righettini, 2001). Much scholarly attention has focused on the origins of IRAs, by investigating the delegation of regulatory powers and posing questions about the problem of control: Gilardi argued that making regulators independent allows policy makers to increase the credibility of their commitments, while preventing future majorities to undo what the current government has decided (Gilardi, 2002; 2005; 2008: 22). Second, many scholars investigated the consequences of IRAs for policy making (Thatcher, 1994; 1998). Several studies have addressed the effects of independent regulators on the process of regulation itself, by identifying national patterns of interactions between regulators and politicians (Gehring, 2004; Wilks and Bartle, 2002; Thatcher, 2002, 2005). Third, literature has addressed the accountability and democratic legitimacy of independent regulators. This issue generated a broader debate on all kinds of institutions that do not conform to the representative model (i.e. IRAs, Central banks, the European Union), and the *democratic deficit* problem of the EU has been largely discussed: according to the critics, the European integration has increased executive power at the expense of national parliamentary control, the European Parliament is too weak, there are no real European elections, and the EU is too distant from its voters, whose

preferences remain far. According to the defenders, the EU is a regulatory state that produces efficient policies, and therefore technocracy is even better than majoritarian decision-making (Majone, 1994; 1999; 2001). As to the consequences for democratic legitimacy, Gilardi (2008) argues that independent regulators are concerned with technical issues, and therefore technocracy can be an appropriate solution, but also no decision is purely technical, and therefore it should not be insulated from political debate and democratic control (Gilardi, 2008: 25-26).

Recent efforts in the field of regulation and *agencification* have focused on assessing the establishment of regulatory agencies, their institutional designs, and their impact on democratic governance. In most cases, these studies have focused on OECD or EU countries and most empirical studies have mainly analysed single dimensions, with independence (Gilardi, 2002; 2005; 2008; Maggetti, 2010; Hanretty and Koop, 2012; Ennsner-Jedenastik, 2016; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007) and accountability (Biela and Papadopoulos, 2014; Koop, 2015; Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018) most commonly discussed. Indeed, several scholars investigated legitimacy and accountability of non-elected experts, together with the credibility of scientific expertise and the role of science within the policy process (Gilardi, 2008; 2005; 2002; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007). Moreover, several authors have stressed the need for regulators to be accountable as well as independent (Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018).

As to independence, it has been widely explored and discussed (Gilardi, 2008; 2005; 2002; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Edwards and Waverman, 2004; Elgie and McMenemy, 2005; Jordana *et al.*, 2009; Majone, 1994; Thatcher and Sweet, 2002; Christensen and Lægveid, 2007; Thatcher, 2002; 2004; Wonka and Rittberger, 2010), and many scholars distinguished between formal and de facto independence, accounting for implication of one dimension towards the other. Here, the focus is on formal independence, as *“the degree to which there are statutory provisions that decrease the possibility for politicians to influence agency decisions before they are made”* (Koop and Hanretty, 2018: 42). The rationale behind the delegation of regulatory tasks to autonomous agencies lies in the *“Two Logics of Delegation”*, formulated by Majone (1999), according to which when uncertainty about future events rises, so does the incentive to delegate. This is mainly due to the fact that the agent can react more flexibly and efficiently to changing the status quo. To this increase of delegation corresponds an intensification of the control mechanisms,

and thus the necessity of accountability. Koop and Hanretty improved our knowledge of independence (Koop and Hanretty, 2018; 2009; 2012; 2013), by looking at it as a matter of degree rather than as a quality that is present or absent, and taking explicitly into consideration accountability, as property that matters for performance (Koop and Hanretty, 2018: 40). Indeed, regulatory agencies may be tempted to misuse and abuse their public authority, if these activities are associated with worse performance, and if accountability mechanisms may provide incentives not to engage in these activities, we shall expect higher degrees of accountability to be associated with better performance (Koop and Hanretty, 2018: 46).

As to accountability, it has been widely investigated (Maggetti, 2010; Jordana *et al.*, 2015; Busuioc, 2009; 2012; Busuioc and Schillemans, 2014; Busuioc and Lodge, 2016; Bovens, 2005; 2007; 2010; Bovens *et al.*, 2014; Schillemans and Bovens, 2014) and the concept finds its origins in the delegation theory, according to which *“an agent is accountable to a principal if the principal can exercise control over the agent and delegation is not accountable if the principal is unable to exercise control”* (Lupia, 2003:35). As highlighted by Bovens (2010), much of the academic literature on accountability is rather disconnected, as many authors propose their own specific definition of the concept. According to Bovens (2010), it is possible to distinguish between the American discourse on one hand – mostly focused on normative issues (Considine, 2002; Klingner *et al.*, 2002; Koppell, 2005; O’Connell, 2005; Wang, 2002) – and the British, Australian, Canadian and continental European scholarly debates on the other hand – mostly focused on accountability as a mechanism (Scott, 2000; Bovens, 2007; Day and Klein, 1987; Goodin, 2003; Mulgan, 2003; Philip, 2009). As to the former, accountability is used as a normative concept, a set of standards for the behaviour of actors, a virtue – referring to substantive norms for the behaviours of actors. As to the latter, accountability is approached as a *“specific social relation or mechanism that involves an obligation to explain and justify conduct”* (Bovens, 2010: 951). Both the normative notion of accountability as a virtue and the notion of accountability as a mechanism are related to the legitimacy debate, and public accountability *“in the sense of transparent, responsive and responsible governance, is meant to assure public confidence in government and to bridge the gap between citizens and representatives and between the governed and government”* (Bovens, 2010: 954; Aucoin and Heintzman, 2000: 49-52). Moreover, accountability as a mechanism contributes to the legitimacy of public governance. This study deploys the definition of accountability as *“the ability to provide information on, and explanation of, one’s conduct”* (Koop and Hanretty, 2018: 44). Therefore, an agency is *“formally*

accountable to politicians to the extent that politicians can require the agency to provide information on, and explanation of, its conduct on the basis of statutory provisions” (Koop and Hanretty, 2018: 44).

6. REGULATORY EFFECTIVENESS AND REGULATORY FAILURE

Scholarly attention has been paid both to effectiveness of regulation and to its failure. Regulators fail when they do not produce (at reasonable costs) the outcomes that are stipulated in their mandates, or when they do not serve procedural or representative values properly (Baldwin *et al.*, 2012: 68). According to Baldwin and colleagues (2012), regulatory failure can be explained by different kinds of accounts. Public interests accounts draw upon the idea that regulators pursue some conception of the public interest and different interpretations of what the public interest might be and how is to be achieved are contested, leading to competing conceptions and, thus, to ineffective delivery of outcomes or confused procedures. A second account ascribes regulatory failure to *bounded rationality* (Simon, 1991) that affects individual and organizational decision-making, resulting in limited information, uncertainty, and ambiguity of knowledge. According to Simon’s account, rationality is limited when individuals make decisions: indeed, “*boundedly rational agents experience limits in formulating and solving complex problems and in processing information*” (1991: 129). Much of the existing literature focusing on regulatory failure has pointed to the self-interested behaviour of key actors engaged in the regulatory process, while ideas-based approaches have emphasized the role played by ideological conservatism in producing under-performance, either by failing to adapt ideas to new circumstances, or by rejecting information that challenges existing dominant understandings. A fourth account is provided by institutional theories, which suggest that institutional structures and arrangements, as well as social processes, significantly shape regulation. Failures, from such perspective, can be seen as the effects of inter and intra-institutional pressures, as well as the effects of the spread of regulation across layers of government and types of organization. Table 1.4 summarizes the different accounts for regulatory failure.

Table 1.4 - Regulatory failure

Broad approach	Theory	Failure-mechanism
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Interest-centred approaches	Public interest / interest group / economic theories	Collective action problems lead to regulation in favour of particular concentrated interests
Ideas-based approaches	Ideas and cultural theories	Inherent blackspots in any single approach has side-effects and will be exploited by opposition
Institutional approaches	Institutional design	Information asymmetries generate drift: coalitional drift (governments changing preferences over time), agency drift (agencies not following their statutory objectives), and industry drift (industry not following regulatory requirements).
	Layering	Side-effects of multiple regulatory regimes with different understandings and objectives operating side-by-side and overlapping
	Unintended consequences	Intended actions cannot foresee inherent unintended consequences – because of bounded rationality, side-effects, counter-learning, and changes in the wider environment
	Self-referential systems	Systems close themselves off from outside disturbance

Source: adapted from Baldwin et al. (2012: 77)

Literature on regulation and policy design has always been concerned with achieving effectiveness of regulatory instruments. Gilardi (2008) and Maggetti (2007) identified the quality of the regulatory design as the response to this effectiveness challenge (Levi-Faur, 2010). Recently, effectiveness has been defined as the creation of a frame for action that may shape a range of regulatory responses and it can be understood at three levels of analysis: the first is at the level of what includes an effective formulation environment that lead to effective design; the second concerns how effective instrument mixes can be effectively constructed to address complex policy objectives (i.e. at the process level); the third focuses on what constitutes the effectiveness of particular types of instruments (Peters *et al.*, 2018: 21). The governance turn encouraged much of the academic discussion about effectiveness in design at the level of instruments of the market and the state, as well as the dichotomous governance styles such as hierarchies and markets (Howlett, 2004; Koch, 2013; Peters *et al.*, 2018). This orientation entails the idea that the nature of the overall design space can have a significant bearing on how effectively intended design activities take place and, therefore, on the likely effectiveness of policy designs that emerge from them (Peters *et al.*, 2018: 22).

Determining what capacities are required in order to develop the design spaces needed to carry out complex design processes is a subject of interest in contemporary design studies (Considine, 2012; Peters *et al.*, 2018). Policy capacity has emerged as a major concern as governments are called to address increasingly complex problems and has attracted scholarly attention. Indeed, the increasing complexity of many contemporary policy issues together with rising expectations of the public present unprecedented challenges to the capacity of governments to make and implement effective policies (Wu, Ramesh and Howlett, 2015). Most scholars define policy capacity from the perspective of the government as *“affecting the ability governments to make intelligent choices”* (Painter and Pierre, 2005; Wu *et al.*, 2015: 2), to scan the environment and set strategic directions (Howlett and Lindquist, 2004), to weigh and assess the implications of policy alternatives (Bakvis, 2000), and to make appropriate use of knowledge in policy making (Parsons, 2004). Wu, Ramesh and Howlett define capacity as *“the set of skills and resources – or competences and capabilities – necessary to perform policy functions”* (2015: 2). Recent work on policy capacity has outlined the fundamental nature of the skills and resources that governments need to effectively formulate and implement policy (Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016): analytical, operational, and political. These exist at three levels: individual,

organizational, and systemic (Wu *et al.*, 2015). At the individual level, technical expertise, leadership and negotiation expertise, and political acumen are fundamental capacities for successful governance. At the organizational level, information mobilization capacities and administrative resources contribute toward overall policy capacity. At the system level, institutions and opportunities for knowledge creation and use need to exist alongside arrangements for accountability and securing political legitimacy.

Knill and Lenschow (2004) investigated the complex picture of coexisting and overlapping patterns of European regulation both within and across different policy sectors, developing a typology of different regulatory modes. In doing so, they focus on two dimensions of regulatory intervention: the level of obligation and the level of discretion. By combining obligation on one hand and discretion on the other, they identify four modes of intervention. (1) The substantive and procedural regulatory standards are the dominant form of intervention in the European single market and usually entail obligatory and detailed rules, being the most hierarchical mode of regulation. (2) The new instruments are mixes of regulatory tools, having a more indirect approach towards behaviour modification (European framework regulation on one hand, and economic and communicative instruments on the other). (3) The self-regulatory model is based on private actors setting rules and standards for the conduct of businesses, and on the shift of the level of control from the EU to the industry-level. (4) The Open Method of Coordination (OMC), instead, entails the independent formulation of national responses to policy benchmarks set for the EU. In their work, Knill and Lenschow (2004) attempted to assess whether a certain mode of regulation reflects good governance or not, and particular attention is paid to: (1) the extent to which the EU has the capacity of taking political decisions in a certain area, (2) the extent to which these decisions are actually implemented and complied with at the national level, and (3) the degree to which the policies in question achieve their intended objectives (problem-solving capacity) (Knill and Lenschow, 2004: 221). Accordingly, it is claimed that the capability of governments to take a regulatory decision is a necessary but not sufficient condition for effective regulation. This latter not only depends on legislative decisions, but also on the degree to which these decisions are actually implemented and complied with. It is generally argued that highly obligatory regulation has a higher potential for effective implementation, as the force of law can be used to impose the fixed standards or objectives (Baldwin and Cave, 1999: 35; Knill and Lenschow, 2004: 226). Indeed, the primary steering mechanism of regulatory standards is coercion, and behaviour modification is to be

achieved by hierarchical means of command and control. However, according to Knill and Lenschow (2004), effective decision-making and implementation are not sufficient to ensure effective problem-solving. With respect to the general aspects that affect the quality of regulatory design, they identify adjustment flexibility, danger of capture, context responsiveness, and predictability of outcomes.

Yet, high quality regulatory design cannot result in effectiveness unless regulatory implementation is effective, which involves both high-quality commands, and high-quality control. Indeed, the level of control *“is perhaps the most fundamental determinant of the effectiveness of regulation in meeting policy objectives”* (OECD, 2002: 74). Therefore, the control’s dimension is what is expected to play a difference-making role for effectiveness (and ineffectiveness) of the substantial dimension of regulation.

7. RISK REGULATION AND RISK GOVERNANCE: DEFINITIONS AND THEORETICAL APPROACHES

This dissertation examines the regulation of food safety, seeking to describe, compare, and explain differences in effectiveness of governance of regulation. To do so, it accounts for existing theories of food safety governance and of risk and its management.

Risk is understood in this thesis as *“an uncertain consequence of an event or an activity”* (Klinke and Renn, 2010: 9) and it always refers to a combination of the likelihood of potential consequences and the severity of consequences of human activities, natural events, or a combination of both. Such consequences can be positive or negative, depending on the values that people associate with them. Here, risk is distinguished from hazard. Hazard describes the potential for harm, which may never even materialise if, for instance, people are not exposed to the hazard. Hazard characterises the inherent property of the risk and related processes, whereas risk describes the potential effects that this hazard is likely to cause on specific targets.

The most complex questions arise when we look at how society and its various actors actually handle risks. Apart from the decision-making structure – the people and organisations that share responsibility for assessing and managing risk – the need for sufficient organisational capacity to create the necessary knowledge and implement the required actions, the political and cultural norms, rules and values within a particular societal context and the subjective perceptions of individuals and groups must also be considered.

The term *governance* has experienced great popularity in the literature on political science, comparative public policy, sociology, international relations, as well as risk research. Governance describes “*structures and processes for collective decision-making involving governmental and non-governmental actors*” (Nye and Donahue, 2000: 12). At the global level, “*governance embodies a horizontally organised structure of functional self-regulation encompassing state and non-state actors bringing about collectively binding decisions without superior authority*” (Wolf, 2002: 36). Risk governance translates the core principles of governance to the context of risk and risk-related decision-making. Risk governance has been defined as “*the complex process by which risks are identified, assessed, communicated, and managed*” (Renn and Walker, 2008: xxiii) but extends beyond the three conventionally recognised elements of risk analysis (risk assessment, risk management, and risk communication), including matters of institutional design and role, organizational capacity, stakeholder involvement, collaborative decision-making and political accountability. Indeed, risk governance not only includes a multifaceted, multi-actor risk process but also institutional arrangements (i.e. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors) and political culture, including different perceptions of risk. When analysing risk governance structures, it is necessary to select those factors and actors that, by theoretical reasoning and empirical analysis, are demonstrably of particular relevance with respect to the outcome of risk governance.

Klinke and Renn (2010) developed a general concept for integrative risk governance and referred to seriousness, complexity, scientific uncertainty and ambiguity as challenges posed to effective risk governance. Seriousness particularly refers to the “*inherent hazard potential of a risk agent to cause certainly and unambiguously significant harm to the environment or to human health*” (Klinke and Renn, 2010: 10). Complexity refers to “*the difficulty of identifying and quantifying causal links between a multitude of potential candidates and specific adverse effect*” (Klinke and Renn, 2010: 10; Renn and Walker, 2007; Renn, 2008). Examples of highly complex risk include sophisticated chemical facilities, synergistic effects of potentially toxic substances, failure risk of large interconnected infrastructures, and risks of critical loads to sensitive ecosystems.

In the risk governance process, one of the most controversial activities is delineating a judgment about the tolerability and the acceptability of a given risk (Klinke and Renn, 2010). The term *tolerable* refers to “*an activity that is seen as worth pursuing yet it requires additional efforts for risk reduction within reasonable limits*” (Kline and Renn, 2010: 17). The term *acceptable* refers to “*an*

activity where the remaining risks are so low that additional efforts for risk reduction are not seen as necessary” (Klinke and Renn, 2010: 17). The process of judging the tolerability and acceptability of a risk can be structured into two distinct components: risk characterisation and risk evaluation. The former determines the evidence-based component for making the necessary judgment on the tolerability and/or acceptability of a risk; while the latter determines the value-based component for making this judgment (Klinke and Renn, 2010). This separation of evidence and values is functional, and not necessarily organisational. However, the European regulatory system tends to favour an organisational separation, in the food area as well as in chemical regulation (Lofstedt and Vogel, 2001; Klinke and Renn, 2010). According to Black and Baldwin (2012), risks are conventionally categorized on the basis of two dimensions: probability and impact, being impact defined as “*an adverse event of different degrees of tolerability*” (Black and Baldwin, 2012: 4).

When considering risk handling in modern society, many influential factors come into play. One major aspect of risk governance concerns political culture, i.e. the so-called regulatory regimes or governmental styles. Each country and different risk domain within the same country may pursue different pathways for dealing with risk. Most scholars agree that many of the cognitive factors that govern risk perception are similar throughout the world (Rohrmann and Renn, 2009). Moreover, risk management styles are also becoming increasingly homogenous as the world becomes more globalised (Lofstedt and Vogel, 2001). In spite of distinct cultural differences among nations and the variations with respect to educational systems, research organisations, and structures of scientific institutions, assessment and management of risks have become universalities, in which the cultural background play a minor role only. This is particularly due to the role of science in proposing and justifying regulatory standards. Risk management rests on systematic knowledge on one hand, legally prescribed procedures and social values on the other. The prescriptions for managing risks may differ in many aspects – i.e. with regard to inclusion and selection rules, interpretative frames, action plans for dealing with evidence, etc. National culture, political traditions, and social norms influence the mechanisms and institutions for integrating knowledge and expertise in the policy arenas.

According to Klinke and Renn (2010), good governance rests on three components: knowledge, legally prescribed procedures, and social values. Criteria of good governance have been discussed extensively and in many different contexts (Knill and Renschow, 2003; Baldwin *et al.*, 2012; Jordana

and Levi-Faur, 2004). Central issues are sound scientific expertise, adequate inclusion of public concerns, consistency and coherence in making trade-offs between risks and benefits, non-discrimination and proportionality in designing risk management options and assurance of thorough monitoring and independent oversight during implementation. Moreover, governance structures should reflect criteria of transparency, effectiveness and efficiency, accountability, sustainability, equity and respect for the rule of law (Klinke and Renn, 2010). The White Paper on European Governance of the European Commission identifies as key elements of good governance are openness, participation, accountability, effectiveness, and coherence (EU 2001: 10).

Many approaches to risk have been developed over the past decades. As recalled by Hood, Rothstein and Baldwin (2001), the best known is the work of Beck (1992): according to Beck, we live in a risk society. As well as a risk society, we are also said to live in regulatory state (Majone, 1994). According to Hood and colleagues (Hood *et al.*, 2001), the two ideas of risk society and regulatory state could be linked in so far as risk and safety is often held to be one of the major drivers of contemporary regulatory growth, for example in the development of EU regulation (Scharpf, 1997; Beck, 1992).

According to Hood and colleagues (2001), substantial variation can be observed in the way regulation works and even neighbouring states may take very different approaches to regulating risks. Well-known examples include the conflict between the EU's precautionary approach to regulate food-related issues and the US' more resilient regulatory approach to such risks, and the ban on exports of UK beef by the EU during the BSE crisis while the product was permitted for sale within the UK. Some of the variations we can observe across risk regulation domains involve different approaches to standard setting. Some domains are dominated by a cost-benefit analysis culture, in which the costs of additional measures are weighted against benefits using explicit value-of-life calculations. Some others are dominated by various forms of quantified risk assessment culture, in which risks are expressed in elaborated numbers but the costs and benefits of regulation are not. By contrast, other risks are handled by a culture of inter-agency bargaining, or of wholly qualitative approaches.

The design of institutions and boundaries for risk regulation also vary considerably from one domain to another. Some risks and hazards are handled by state agencies staffed by specialists in risk management, with expert monitoring arrangements and dedicated specialist enforcers. Others are regulated by more generalist agencies, self-regulatory arrangements, or the law courts. In some

cases, one agency monopolizes the entire risk domain, while in others domain is divided up among a multiplicity of players for different stages or aspects of the regulatory task, amounting to a control system made up of multiple regimes.

Accordingly, Hood and colleagues (2001) developed the idea of risk regulation regimes, connoting the overall way risk is regulated in a particular policy domain. Their approach is institutional, focusing on the characterisation of institutions and formal rules, and beyond. In this sense, the term regime is used to denote the “*complex of institutional geography, rules, practice, and animating ideas that are associated with the regulation of a particular risk*” (Hood *et al.*, 2001: 9). Institutional geography can vary according to the territorial scale – from international to local jurisdiction, the level of integration – from a single agency handling all features of regulation to highly fragmented administration and complex overlapping systems, and the level of specialisation – from risk specific expertise to general purpose administration. Rules can vary in formality, from unwritten rules to statutory codes; targets, and sanctions (Hood, 1983; Baldwin, 1995; Black, 1997; Hood *et al.*, 2001). The notion of regime has been similarly developed in literature also to describe variety in systems of governance, in several fields (Hood *et al.*, 2001). Some institutional analyses that can be related to the notion of regimes include taxonomies of different types of policy instruments (Hood, 1983; Eliadis *et al.*, 2005; Howlett, 2000; Salamon, 2002; Hood and Margetts, 2007; McDonnell and Elmore, 1987; Schneider and Ingram, 1990; Bemelmans-Videc *et al.*, 1998), and institutional types and rule types, such as Elinor Ostrom’s work on the Institutional Analysis and Development framework (IAD: Ostrom, 1986; 2005; 2011). Hood, Rothstein and Baldwin (2001) linked theoretically risk regulation and institutional analysis, in the attempt of capturing the variety that is left out of other macroscopic approaches – i.e. *risk society* sociologist approach (Beck, 1992) – and to achieve a broader and more general perspective than of microscopic approaches – i.e. single feature analysis of the setting of safety standards alone, or the details of a particular hazard (Hood *et al.*, 2001).

Debates about institutional design bring together discussion of value, context, and instrumental alternatives and many different disciplines and analytic approaches can evidently contribute to such debates (Goodin, 1996; Hood *et al.*, 2001: 185). In their analysis of risk regulation regimes, Hood *et al.* (2001) distinguish among two main dimensions of regulation: the three elements of control on one hand – i.e. standard setting, information-gathering, and behaviour modification – and the instrumental and institutional elements on the other. As noted by Hood and colleagues (2001),

much debate on risk regulation tends to focus on standard setting, because it raises questions about the valuation of human life, or the way one risk is weighed against another. However, information-gathering and behaviour modification are the components by which risk regulation can best be assessed (Hood *et al.*, 2001: 21).

A control-theory perspective raises issues about the effectiveness of risk regulation, and how to change individual and organisational behaviour is another issue highly debated in the literature surrounding risk regulation. Indeed, behaviour modification can be a highly problematic component of risk regulation (Hood *et al.*, 2001). The preferences and incentive structures of bureaucrats can sometimes produce distortions (Dunleavy, 1991), and the attitudes and beliefs of those regulated can shape the outcome produced by implementation instruments in unexpected ways. Within a compliance culture, official bans or warnings about dangerous substances may discourage the consumption, while within an opportunistic culture, such policy instruments would work only if complemented by detection and application of sanctions.

Hood and colleagues (2001) stress that risk regulation varies markedly from one domain to another in structure, and it is possible to find multiple interlinked regulatory systems, as well as marked institutional diversity across control components, with different sets of organisations involved in standard setting, information gathering, and behaviour modification. In this latter, each control component may involve a different pattern of administrative geography, a separate pattern of regulatory capture, and different administrative or technical cultures.

8. GOVERNANCE OF FOOD SAFETY REGULATION

Food safety regulation is particularly relevant in Europe, due to the impact it exerts on public health and on the businesses of the agri-food sector. Its effects impinge on the Common Agricultural Policy (CAP) and the common European market on one hand, and on the protection of consumers and public health on the other. Within the last decades, the agri-food sector has been protagonist of deep changes, mainly due to the globalization of markets and the diffusion of new foodborne diseases. Globalization of the food sector has made possible the distribution of primary goods and processed food products all over the world, providing consumers with a great variety of choice and a strong economic convenience, but at the same time it shed the light over the great differences among different countries with respect to food safety regulations, and forced the EU institutions to

adopt restrictive rules to enable the traceability of foodstuffs and to guarantee consumer protection.

Food regulation evolved after the Second World War, when a growing need of fostering the legal environment emerged, to facilitate the circulation of foodstuffs at international level and to guarantee food security – intended as “*the physical, social and economic access of all people, at all times, to sufficient, safe and nutritious food*”². A first response developed in the 1960s, when the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) created the Codex Alimentarius Commission (CAC) in 1964³. This commission released the Codex Alimentarius – a set of standards and procedures aimed at ensuring safety, quality, and fairness of food production and international trade. Since its creation, the Commission meets every year to release updates of the procedures and standards, based on the most recent scientific knowledges. With the creation of the World Trade Organization (WTO) in 1994, the Codex acquired stronger legal relevance, as it has been recognized within the trade agreements between its members (i.e. the agreement on the application of Sanitary and Phytosanitary measures – the so-called SPS agreement). Today, the CAC counts 188 members, included the European Union⁴.

The same need of harmonization of regulations and free circulation of goods contributed to the birth of the European Economic Communities in 1957, bringing about the need for their Member States to harmonize food regulations at the supranational level, in order to encourage the circulation of foodstuffs within the European market. However, until the mid-1990s, European food regulation was centred on producer interests’ protection, mainly following international agreements aimed at facilitating international trade and the implementation of common standards, dealing with the regulatory limits imposed by geographical boundaries on one hand, and the increasing demand of supranational control of production processes and of quality of food products on the other.

² http://www.fao.org/fileadmin/templates/faotaly/documents/pdf/pdf_Food_Security_Cocept_Note.pdf

³ <http://www.fao.org/fao-who-codexalimentarius/en/>

⁴ <http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/>

Consumer protection and public health issues entered the European agenda in the 1970s, when the Consumer Protection Charter was released in 1973⁵. In 1992, the Treaty of Maastricht⁶ recognized the necessity of achieving a high level of consumer protection, in response to the increasing importance of the consumer as a legal subject, enjoying specific rights. Accordingly, in 1995 a Directorate General (DG) for Consumer Policy and Consumer Health Protection was established, which became the DG for Health and Consumer Protection (DG SANCO) in 1997, and the DG for Health and Food Safety – Public Health (DG SANTE) in 2014.

It has been only with the major several *food scares* and scandals occurred in the 1990s that the EU recognized the need for a deep reform of existing instruments and regulatory structures (Righettini, 2015). As noted in the introduction, the first major food crisis that demonstrated the limitation of EU food legislation occurred in 1995 in the UK. The Bovine Spongiform Encephalopathy (BSE) crisis had a direct impact on human health: from October 1996 to March 2001, 175 cases of the so-called *Variant Creutzfeldt-Jakob Disease* (vCJD) were reported in the UK, and 49 cases in other countries. Given the magnitude of the crisis, the overall European regulatory system was heavily criticized. The observers emphasized the poor internal management within the European Commission (EC), an unclear and unbalanced relationship between scientific opinions and political decisions, the unjustified weight of narrow national sectorial interests, and the poor implementation of the EU legal provisions on official controls.

A second food crisis occurred in 1999, when dioxin was introduced into the Belgian food chain, through contaminated fat used in animal feed and supplied to Belgian, French and Dutch farms. Meat products from poultry, pigs, cattle and eggs were contaminated, endangering human health. The dioxin food crisis confirmed the lack of an integrated approach to food safety along the entire food chain. There were no general traceability requirements covering the entire food chain, including feed; there were no established crisis management procedures to follow, and the then incomplete surveillance system failed to detect the BSE or the dioxin issues. Unsurprisingly, by 2002, consumers had no confidence in the EU governance of food safety⁷.

Therefore, EU regulators had to face the lack of credibility and the loss of consumers trust derived from the ineffectiveness of the governance design that was in place, and the demand for effective

⁵ <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=15956&lang=en>

⁶ Treaty on European Union, signed in Maastricht on 7 February 1992 https://europa.eu/european-union/sites/europaeu/files/docs/body/treaty_on_european_union_en.pdf

⁷ Source: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

consumer protection. As several authors stressed, higher effectiveness became the main motivation behind the reforms (Vos and Wendler, 2006; Vos, 2000; Chambers, 1999; Joerges and Neyer, 1997; Snyder, 1994; Westlake, 1997; Ansell and Vogel, 2006).

The principles that led to the establishment of the new European food safety regulation are laid down in the Green Paper on European Food Law, released by the European Commission in 1997⁸, followed by the White Paper on Food Safety released in 2000⁹.

The General Food Law (GFL) established through Regulation n. 178/2002 was adopted in 2002 and aims at ensuring a high level of protection of human life and consumers' interests in relation to food, while ensuring the effective functioning of the internal market. It sets out a comprehensive and harmonized legal framework, addressed to the EU institutions and Member States as well as to Food Business Operators (FBOs). The rationale is of an integrated regulatory approach, which includes not only sanitation standards, but also measures to protect the environment, the international trade, agriculture and soil consumption, worker safety, and sustainability. The field of regulatory intervention has progressively been extended to the whole food chain, from primary production to food processing, from transport to storage and retail sale, and on every other possible aspect, according to the so-called *from farm to fork* approach. One of the main elements introduced by the GFL is preventive control: the set of commands related to impositions, prohibitions, and sanctions is completed by a set of controls and procedures aimed at the prevention and supervision of the food chain. The rationale is the prevention of foodborne illnesses rather than the response to them, and the consequent containment of damages. The GFL also sets up an independent agency responsible for risk assessment and risk communication: the European Food Safety Authority (EFSA).

The general principles of food and feed law include the principle of risk analysis, of protection of consumers' interests, and of transparency, and are outlined in the Articles from 5 to 10:

- (1) ensuring a high level of protection of human life and health and the protection of consumers' interests, as well as fair practices in trade, considering animal health and welfare, plant health and environment protection;

⁸ http://europa.eu/rapid/press-release_IP-97-370_en.htm

⁹ https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-pub06_en.pdf

- (2) ensuring free movement of food and feed manufactured and marketed in the EU and facilitating global trade of safe food and feed, implementing international standards and agreements, *“except where this might undermine the high level of consumer protection pursued by the EU”*¹⁰.
- (3) The principle of risk analysis is established with respect to food and feed, and comprises three elements: risk assessment, risk management, and risk communication. Accordingly, risk assessment *“must be undertaken in an independent, objective, and transparent manner based on the best available science”*. Risk management is the process of *“weighing policy alternatives in the light of results of a risk assessment and selecting the appropriate actions necessary to prevent, reduce, or eliminate the risk. The decision makers need to consider a range of other information in addition to the scientific risk assessment”*, including socio-economic effects, feasibility of controlling and minimizing a risk, environmental impact. Risk communication is the interactive exchange of information throughout the overall risk analysis process, among scientists, decision makers, consumers, Food Business Operators, public authorities¹¹. At the EU level, risk assessment and risk communication are carried out by the European Food Safety Authority (EFSA), while risk management is carried out by the European Commission, in cooperation with the Member States.
- (4) The Article 7 of the GFL lays down the precautionary principle, which refers to specific situations where there is *“reasonable ground for concern that an unacceptable level of risk to health exists, or the available information and data are not sufficiently complete to enable a comprehensive risk assessment to be made”*¹². The principle provides that proportionate, non-discriminatory, transparent and coherent actions have to be taken. Moreover, measures taken should be provisional until when more comprehensive information concerning the risk can be assessed.
- (5) Finally, the transparency principle is established, in order to *“increase consumer confidence in food law”*. It includes public consultations with respect to new regulatory provisions related to food and feed, and obligation of information by the public authorities to the consumers with respect to possible food-related risks.

¹⁰ https://ec.europa.eu/food/safety/general_food_law/principles_en

¹¹ https://ec.europa.eu/food/safety/general_food_law/principles_en

¹² https://ec.europa.eu/food/safety/general_food_law/principles_en

The GFL establishes also an integrated system of monitoring and control. The Food Business Operators have primary legal responsibility for ensuring food safety (Article 19 of GFL), while Member States have the responsibility for enforcing food law, monitoring, and controlling that the requirements of food law are fulfilled. Moreover, Member States lay down the rules on measures and sanctions applicable to infringements of food and feed law. At the EU level, the Food and Veterinary Office (FVO) exercises control over the food safety systems across both the EU Member States and non-EU countries that export their products within the EU.

The GFL regulatory framework has been integrated with the adoption in 2004 of the so-called Hygiene Package, which provides harmonized hygiene requirements previously contained in a number of Directives. The rules provide that all Member States must adopt the same criteria for the establishment of the level of hygiene in food production and that hygiene and sanitary controls must be carried out according to the same standards across the all EU¹³.

Given the social and economic importance of the production and consumption of food to the EU, the two core objectives identified in the preamble of the General Food Law appear to be still relevant today, namely a high level of protection of health and consumers' interests on one hand, and the effective functioning of the internal market on the other.

Food safety regulation has become a multidisciplinary issue that is worthy of exploration, and in recent years many political scientists have undertaken empirical studies into differences across countries from the perspective of regulatory politics and public policy. Neo-institutionalism, rational choice theory, policy networks, and organizational culture theory are frequently used to study this issue.

Food safety policy is defined as *“the goals, rules, and structures that are designed to ensure food quality and address the risk of food contamination in order to promote and protect the health of humans, animals, and plants”* (Thomann, 2018: 5; Ansell and Vogel, 2006; Cafaggi, 2012; Redman, 2007; van der Heijden *et al.*, 1999). Food safety is widely recognized as crucial to effective health protection (Schmidt and Rodrick, 2003; Ugland and Veggeland, 2006; Thomann, 2018).

To tackle the policy problems related to the safety of the food products, food safety policies must govern the whole production and supply chain for food, including production, processing, storage, transportation, retail, and sale (Robson, 2013; Philipps and Wolfe, 2001; Thomann, 2018). These

¹³ Regulation n. 852/2004, 853/2004, and 854/2004 which became applicable on 1 January 2006.

governance structures comprise a set of normative objectives and standards (standard setting), processes for detecting deviations thereof (monitoring), and mechanisms for correcting non-compliant behaviour (enforcement). They involve public or private regulators who are responsible for these functions, and *regulatees* whose task is to adopt the rules and comply with them (Verbruggen, 2016; Thomann, 2018).

9. GOVERNANCE OF FOOD SAFETY: EMPIRICAL EXTENSIONS

The area of food governance has generated an extensive body of work, drawing the attention of several scholars, from a wide range of disciplines and perspectives. Over the years, political scientists and policy scholars have drawn their attention in studying food and agriculture policy-making as a “*generative empirical example in the theoretical development of policy studies*” (Daugbjerg and Feindt, 2017: 1566). These studies (Lowi, 1969; Olson, 1965; Sheingate, 2003; Browne, 1988; Jordan *et al.*, 1994; Marsh and Smith, 2000; Smith, 1993; Coleman *et al.*, 1996; Feindt, 2010; Skogstad, 1998; Coleman and Grant, 1998; Daugbjerg, 2003; Hooghe and Oser, 2016; Kay, 2003; Zhu and Lipsmeyer, 2015; Chou, 2012; Daugbjerg and Swinbank, 2016; Feindt and Flynn, 2009; Jackson and Deeg, 2012; Daugbjerg and Swinbank, 2009, 2015; Skogstad, 2008) have contributed to theoretical developments in public policy and political science within a number of research fields concerned with the explanation of policy outcomes, policy stability, and policy change (Daugbjerg and Feindt, 2017).

The regulation of food safety constitutes a particularly important dimension of public policy, and the issue relates to a set of contemporary questions (Ansell and Vogel, 2006: 5): multi-level governance of regulation, European integration and customization (Thomann, 2018), trade globalization, politicization of risk assessment and regulatory science, regulation of new technologies, hybrid forms of governance (and the shifting balance between public and private regulation), the agricultural protectionism phenomenon and the transatlantic divide.

Ansell and Vogel (2006) addressed these issues in their edited book “What’s the beef? The contested governance of European food safety” (2006) and proposed a model of *contested governance*, focusing their attention on causes, dynamics, and outcomes. Addressing the causes of contestation, they focus their theoretical and empirical attention on triggering events for policy change and institutional reforms, as well as on the specific questions of European integration and the contention surrounding the Common Agricultural Policy (CAP). The authors highlight trust and

legitimacy as dynamics of conflicts and institutional tensions, both generated by the shifting institutional design across levels of governance on one hand, and the internationalization of food markets on the other. As to the outcomes, the imperative of restoring trust and legitimacy interacts with the scope of producing wholesale institutional reforms (Ansell and Vogel 2006: 24).

Havinga, van Waarden, and Casey (2015) developed on this literature in their book “The changing landscape of food governance: public and private encounters”. They address the question of new, fragmented and complex regulatory patterns in the field of food regulation and the shift from public to private governance. In doing so, they grasp the opportunity to investigate a number of broader issues that have concerned regulatory governance scholars: the legitimacy, effectiveness, and consequences of public and private regulation, the interaction of regulatory networks, regulatory responses to crisis and contestation, and the distribution of power in regulatory arrangements (Havinga *et al.*, 2015: 3-4). Havinga (2015: 14) argues that new private and hybrid forms of food governance ask for a rethinking of the distinctions between the actors involved and the roles they play, and acknowledge interdependence, as well as conflicts of interests and power. Abels and Kobusch (2015: 14) contributed to the debate by analysing the national institutional arrangements concerning food safety agencies in 24 out of 27 EU Member States. The authors question whether the institutional choices can be explained by path dependency or rather as a phenomenon of Europeanization, and classify food risk governance regimes in three models: the bi-institutional model (risk assessment separated from risk management), the integrated model (risk assessment and risk management are carried out by the same institution), a fragmented model (during transition periods) (Havinga *et al.*, 2015: 14). New forms of private food governance are extensively investigated, and the authors point to the role of science in food governance, as well as to effectiveness as crucial criterion for the legitimacy of private forms of governance (Havinga *et al.*, 2015: 15). Several other authors analysed private forms of governance and food regulation (Cafaggi, 2012; Fuchs and Kalfagianni, 2010; Fulponi, 2006; Havinga, 2006; Henson and Humphrey, 2010; Lytton and McAllister, 2014; Marx, Maertens and Swinnen, 2012; Martinez *et al.*, 2007; Stanton, 2012; Verbruggen, 2013, 2016; Garcia Martinez *et al.*, 2013), and developed on this literature to discuss hybrid forms of food safety governance (Verbruggen and Havinga, 2017; Verbruggen, 2016; Thomann and Sager, 2017).

Recently, scholars have focused on how the resulting multiple and conflicting actor rationalities and the overlap of several regulatory roles affect the effectiveness and legitimacy of the decision-making and implementation of food safety policy (Thomann, 2018). By highlighting issues such as regulatory capture and deficient enforcement systems, Thomann (2018) suggests that food safety governance increasingly shares the characteristic of a wicked problem: indeed, hybridization of food safety governance implies that the multiple actors involved often diverge in how they define the problems and their strategic intentions. The globalization of both public and private food safety regulations has also led to new modes of accountability: from at the border public control to the direct responsibility of suppliers for safe food, enforced through inspections by retailers and third-party certifiers (Thomann, 2018: 4; Thomann and Sager, 2017). Thomann points to the capacity of food safety governance structures to deal with multiple frames, adjust actions to uncertain changes, and respond to changing agendas and expectations. According to the author, more research is needed to identify the conditions under which the regulatory structures ensure effective food safety (Thomann, 2018; Scharff *et al.*, 2009). Evidence suggests that the conditions required to effectively protect the public interest by self-regulation in the food industry include an overlap of norms, objectives, and interests of public and private regulation; effective monitoring and enforcing the compliance of businesses; the potential for self-evaluation; compliance with due process standards; and information management and data sharing (Havinga, 2006; Verbruggen, 2013; Thomann, 2018). Lytton and McAllister (2014) highlight the usefulness of the consumer vigilance and other mechanisms to ensure adequate accountability structures, including litigation, liability insurance, accreditation, media coverage, and network configurations. According to Thomann (2018), this is the way how both public and private actors can provide adequate solutions to the problem of food safety (Havinga *et al.*, 2015; Head and Alford, 2015).

Against this background, in sum, this research poses the question of effectiveness of governance of food safety regulation, and develops an explanatory model, improving on regulatory governance theories as well as on policy design and capacity theories.

This chapter presented an extensive literature review regarding the central concepts of regulation and its governance, policy designs and regulatory instruments, as well as regulatory designs. The review contains conceptual and theoretical insights about regulatory effectiveness, and how the debate has developed in the literature. It focuses on the institutional and organizational aspects of

regulatory policies, by summarizing current debates about quality of regulatory designs. The second part of the chapter extends the discussion to the field of risk regulation and risk governance, introducing the most acknowledged definitions and theoretical approaches. Finally, it focuses on governance of food safety regulation, by reviewing recent scholarly development in the field and identifying the issues worth of further exploration.

The next chapter will introduce the Institutional Analysis and Development (IAD) framework as the main theoretical foundation of this study and will identify the institutional elements that are particularly relevant to address the research question, by establishing a connection between the IAD and acknowledged regulation theories.

CHAPTER TWO

INSTITUTIONAL ANALYSIS OF REGULATORY DESIGNS

1. INTRODUCTION

Scholarly attention has been paid both to effectiveness of regulation and to its failures, and a number of approaches can be adopted in explaining how regulation either develops, succeeds, or fails (for an extensive review, see chapter 1). Some accounts emphasize external factors shaping regulation (such as the force of interest groups, dominant ideas, or the nature of economy), while others emphasize endogenous factors such as institutional cultures. Effectiveness of regulation has been explained by interest-based approaches, as well as by ideas-based and institutional approaches (Baldwin *et al.*, 2012). As to these latter, institutional approaches range from those that emphasize the importance of formal rules in shaping behaviours, to those stressing the importance of political rules of the games, to those that regard all human action as embedded in their social context (Baldwin *et al.*, 2012: 53).

This study investigates differences in effectiveness of food safety regulation across 15 EU countries and explains them by differences in domestic institutional designs. The focus is justified by a pragmatic consideration, inspired by the Institutional Analysis and Development framework (IAD: Ostrom, 2005; 2011): although regulatory effectiveness more directly depends on a wide array of non-institutional factors, the institutional dimension of governance is the one which shapes individual actors' strategies and behaviours (Ostrom, 2005; 2011) and achieves the desired outcome.

One of the main assumption of the IAD is that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20). A simplifying assumption that is frequently made in analytical theories is that individuals will take only those actions that are permitted or required. However, in settings where a high investment is not made in monitoring the actions of participants, considerable difference between predicted and actual behaviour can occur as a result of the lack of congruence between a model of legitimate behaviour and the illegal actions that individuals take (Ostrom, 2011: 22). This is particularly true in the policy area of food safety, where the spreading of new animal and human diseases (e.g. *Escherichia Coli* infections, Listeriosis, *Campylobacter*, *Salmonella*, and other

foodborne illnesses), the use and the contamination of some harmful products for the human and animal health as well as for the environment (e.g. the massive use of pesticides in agriculture) and the deliberate adulteration of food products (or substitution with lower value ingredients) shed light on the crucial role played by food safety regulation for the protection of public health. Within this policy area, monitoring and enforcement of regulation have a central stage, and the Institutional Analysis and Development constitutes the theoretical framework that makes the strongest claims with respect to the impact these activities exert over regulatory effectiveness, by identifying the coercive power of rules as the crucial element for the desired outcomes to occur.

Recently, much of the scholarly development of the IAD has offered a systematic approach to analyse policy designs, generating a considerable body of work (Carter *et al.*, 2015; Ostrom, 2005; Basurto *et al.*, 2010; Crawford and Ostrom, 1995; Crawford and Ostrom, 2005; Siddiki *et al.*, 2012; Siddiki *et al.*, 2011). However, not all elements in the framework are yet fully investigated and developed. So far, contributions focusing on the impact that monitoring and enforcement activities exert on operational outcomes are still missing. Hence, this study aims to contribute to the development of this literature, by establishing a connection between the IAD framework and acknowledged regulation theories.

This chapter undertakes theoretical work at three levels of analysis: first, it identifies the institutional elements and the general relationships among them through the IAD framework (section 2); then, it specifies which institutional elements are particularly relevant to address the research question in the light of existing theories (section 3), and finally, it constructs the explanatory model, involving precise assumptions about a limited set of conditions and deriving precise expectations about the results of combining these conditions (section 4). Specifically, section 2 reviews the theoretical framework and introduces the institutional elements that are relevant for this study. Section 3 applies the analytical scheme to the analysis of food safety regulatory designs. Section 4 discusses a mechanistic approach to institutional analysis and section 5 introduces the explanatory model, by defining the *explanandum* (section 6) and the *explanantes* (section 7).

2. THE INSTITUTIONAL ANALYSIS AND DEVELOPMENT FRAMEWORK: A REVIEW

Public policy research used to be undertaken mainly through the *stages heuristic* approach (Lasswell, 1956; Jones, 1970; Anderson, 1975; Brewer and deLeon, 1983), that divides the policy process into agenda setting, policy formulation and adoption, implementation, and evaluation. Over the past 30 years, this latter is being replaced by a number of new theoretical frameworks of the policy process, which have been either developed or modified, drawing upon *the shoulders of five giants*: the institutional rational choice family of frameworks, which focuses on how institutional rules alter the behaviour of rational individuals motivated by self-interest; the multiple-streams framework, developed by Kingdon (1984) drawing upon the garbage can model (Cohen, March and Olsen, 1972); the punctuated equilibrium framework, developed by Baumgartner and Jones (1993), arguing that policymaking is characterised by long periods of incremental change punctuated by short periods of major policy change; the advocacy coalition framework, developed by Sabatier and Jenkins-Smith (1988; 1993), which focuses on the interaction of advocacy coalitions within a policy subsystem; the policy diffusion framework, developed by Berry and Berry (1990; 1992) to explain variation in the adoption of specific policy innovations; the policy design theory, and the network approach.

Within the institutional rational choice family of framework, the one that makes the strongest claims to universality – extending its scope beyond Western settings – is the Institutional Analysis and Development (IAD) framework, developed by Elinor Ostrom (Ostrom, 1986; 2005; 2011), and improved over 40 years with her colleagues. The IAD has its roots in classic political economy (specifically the works of Hobbes, Montesquieu, Hume, Smith, Hamilton, Madison, and Toqueville); neoclassical microeconomic theory, institutional economics (the work of Commons and Coase); public choice theory (Buchanan and Tullock, Downs, Olson, Riker); transaction-cost economics (North, Williamson); and noncooperative game theory (Harsanyi and Selten, Luce and Raiffa, Shubik).

The IAD seeks to offer a common understanding of how actors' behaviour is structured, shaped, and constrained by institutions (Schlager and Cox, 2017). Institutions in this framework are rules – or governing arrangements – that shape the so-called *action-situations* (Kiser and Ostrom, 1982). According to Ostrom (1999), all policy situations are governed by institutional arrangements that are specific to demands of a particular time, place, and people. Institutions are important precisely

because they are intentional constructions that structure information and create incentives to act or not to act in a particular situation, thereby imposing constraints on the range of possible behaviours (Ostrom, 1999: 5).

Ostrom's framework draws upon three main assumptions. The first is that institutions are intentional constructions that structure information (Ostrom, 1999: 5). The second claims that institutions have a configurational nature: frequently, the impact on incentives and behaviours of one type of rule is not independent of the configuration of other rules (Ostrom, 2005; 2009; 2011). Finally, the third is that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20). The framework enables us to assess the most likely set of outcomes that can be achieved under alternative institutional arrangements, being motivated by a strong policy design imperative (Dunlop *et al.*, 2019).

The Institutional Analysis and Development constitutes a theoretical framework that is compatible with several institutional theories: depending upon the context of the decision, it is possible to use the framework as a foundation for investigating the explanatory power of complementary or competing theories and models (Ostrom, 2006: 26). To fully understand the *how* and *why* of institutional design, the IAD provides for the identification of the so-called *action-situation* and the *resulting patterns of interactions and outcomes*. Ostrom characterises the action-situation with seven clusters of variables: participants, positions, outcomes, action-outcome linkages, the control that participants exercise, information, and the costs and benefits assigned to outcomes. Similarly, an actor includes assumptions about four cluster of variables: the resources that the actor brings to a situation, the valuation an actor assigns to states of the world and to actions, the ways an actor acquires, processes, retains, and uses knowledge contingencies and information, and the processes an actor uses to select particular courses of action (Ostrom, 2009: 28). The action-situation is structured by three additional clusters of variables: the rules used by participants to order their relationships, the attributes of states of the world that are acted upon in these situations, and the structure of the general community within which any particular situation is placed (Kiser and Ostrom, 1982; Ostrom, 2009: 28). A common set of variables used to describe the structure of an action-situation includes: the set of participants, the specific positions to be filled by participants, the set of allowable actions and their linkage to outcomes, the potential outcomes that are linked to individual sequences of actions, the level of control each participant has over choice, the information available to participants about the structure of the action-situation, and the costs and

benefits – which serve as incentives and deterrents – assigned to actions and outcomes. Action-situations are the social spaces where individuals interact and actions take place, following institutional constraints that have prescriptive forces (Ostrom, 1986). The assumption entails individuals in a situation select actions from a set of *allowable actions* in the light of the full set of incentives arising from rules, and of the consequences associated to noncompliance (Ostrom, 1986; Harré, 1974). In the action-situation actors have roles and take decisions in the context of the information available to them.

The IAD framework focuses on the ways in which rules – in-form or in-use – shape the alignment of individual and collective interests. As to these latter, Ostrom argues that individuals do not always have access to the same information within an action-situation, and when joint outcomes depend on multiple actors contributing inputs that are costly and difficult to measure, incentives exist for individuals to behave opportunistically (Ostrom, 2009: 32; Williamson, 1975). Opportunism – defined by Ostrom as “*deceitful behaviour intended to improve one’s own welfare at the expense of others*” (2009: 32) – may take many forms, from inconsequential, maybe unconscious shirking, to a carefully calculated effort to defraud others. The opportunism of individuals worsens the problem of uncertainty in the action-situation, and the level of opportunistic behaviour is affected by the norms and institutions used to shape relationships within that action-situation, as well as by the attributes of the decisional context itself.

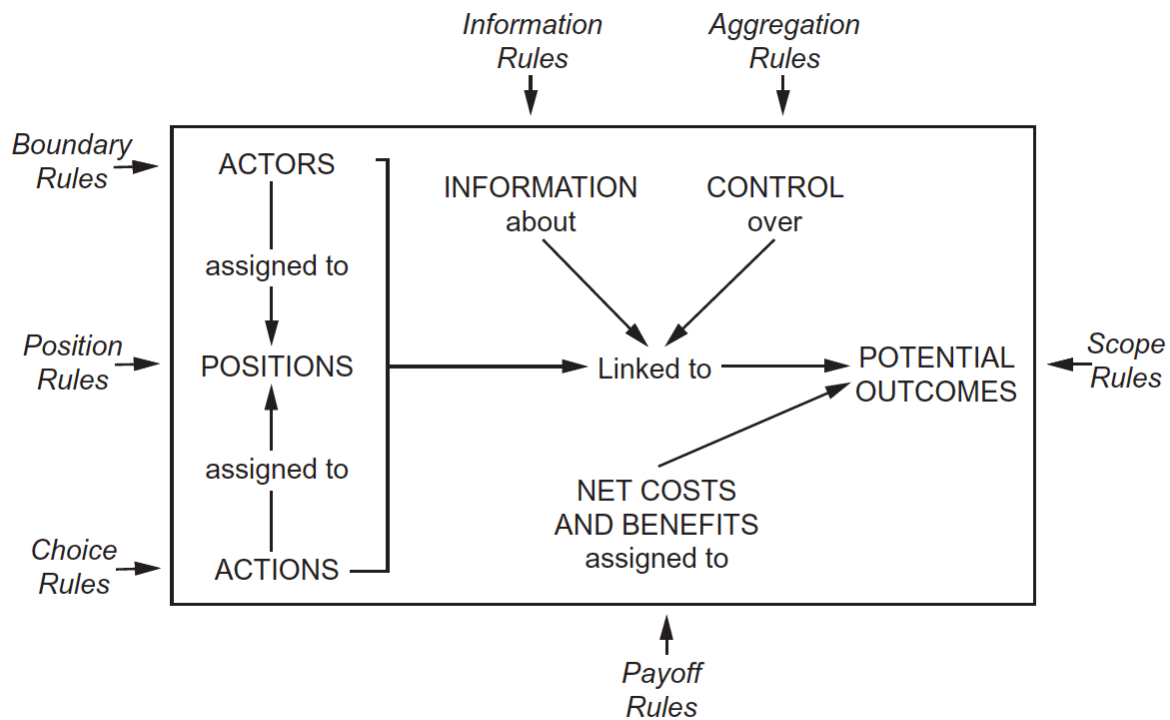
Ostrom’s framework explains the structure of an action-situation and its results with a set of *working rules*, defined as the set of rules to which participants would refer if asked to explain and justify their actions to the other participants (Ostrom, 2011: 18). With governance, it is to be asked where the rules that individuals use in action-situations originate. In addition to the legislation and regulations of the formal government, there are regional, local, and special governments’ laws. Within private firms and voluntary organisations, individuals are permitted to adopt many different rules about who is a member of firm or organisation, how benefits and costs are to be shared, and how decisions will be made. Most importantly, rules are not self-formulating, self-determining, nor self-enforcing, hence human agents must formulate them, apply them in particular situations, and attempt to enforce behaviour consistent with them (Ostrom, 2009: 37).

The literature identifies seven types of rules that define an action-situation: boundary rules, position rules, scope rules, choice rules, aggregation rules, information rules, and payoff rules (see Figure 2.1). Accordingly, outcomes of action-situations are the results of a sequence of actions expressed by these different types of rules, which reflect how the rules work together, not singly in isolation. These rules explain the action-situation because they mould the key factors of actual social spaces:

- boundary rules affect the number of participants, their attributes and resources, whether they can enter the situation freely, and the conditions they face for leaving;
- position rules establish positions in the situation.
- choice rules assign sets of actions that actors in positions at particular nodes may, must, or must not take.
- scope rules delimit the potential outcomes that can be affected and, working backward, the actions linked to specific outcomes.
- aggregation rules affect the level of control that a participant in a position exercises in the selection of an action at a node;
- information rules affect the knowledge-contingent information sets of participants;
- payoff rules affect the benefits and costs that will be assigned to particular combinations of actions and outcomes, and they establish the incentives and deterrents for action.

This way, it is possible to model the action-situation through the analysis of the constraints shaping its structure and results.

Figure 2.1 - Rules affecting the internal structure of action-situation



Source: Ostrom (2011: 33)

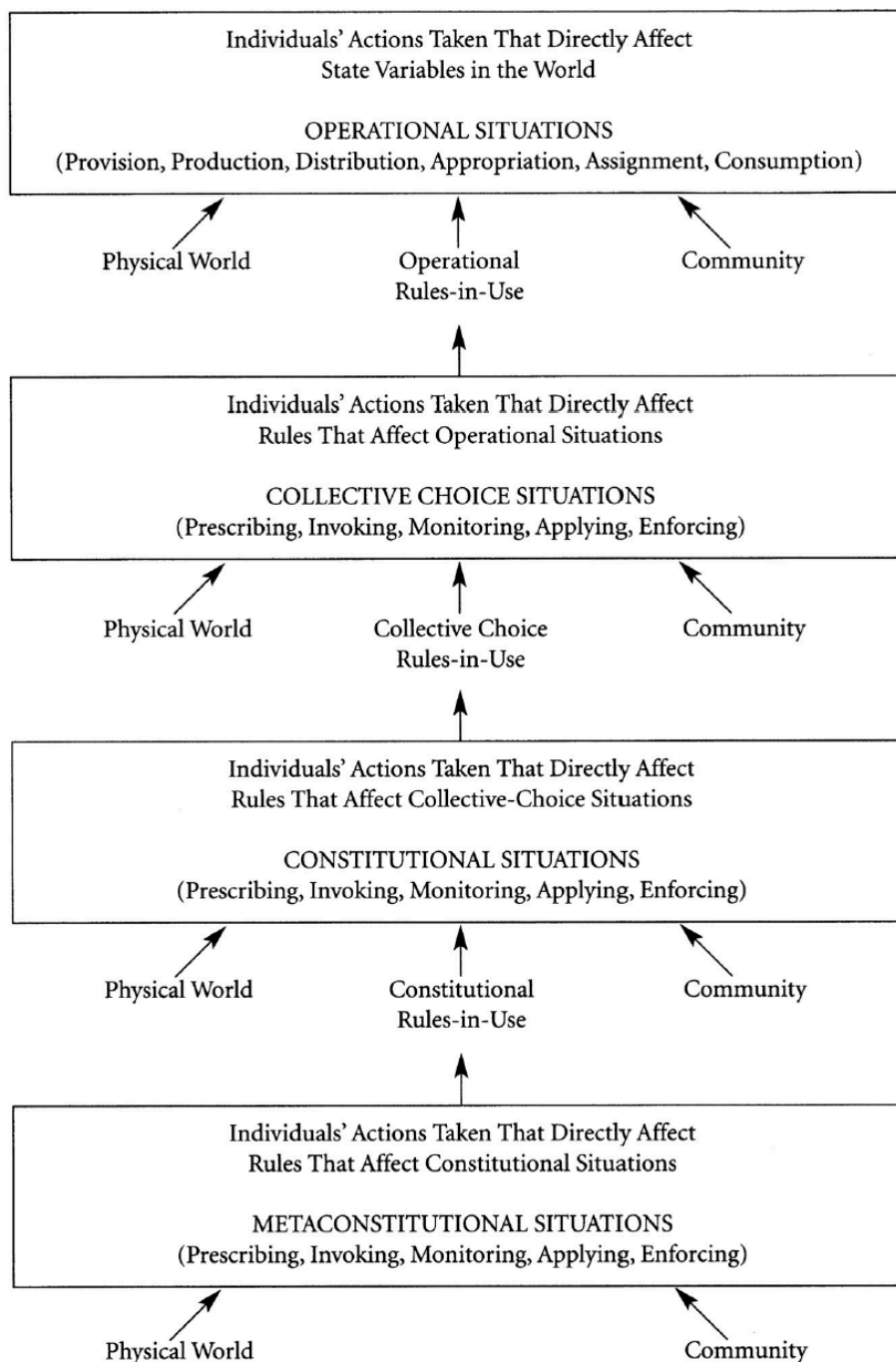
Ostrom conceptualizes rules as “shared understandings among those involved that refer to enforced prescriptions about what actions (or states of the world) are required, prohibited, or permitted” (Ostrom, 2009: 36). To understand the action-situation shaped by the rules, it is necessary to examine the actions and the outcomes that the rules permit, require, or prohibit, and the existing mechanisms to enforce them (Crawford and Ostrom, 1995: 583).

Although a rule configuration affects all of the elements of an action-situation, some of the variables of an action-situation are also affected by attributes of the physical and material world. What actions are physically possible, what outcomes can be produced, how actions are linked to outcomes, and what is contained in the actors’ information sets are affected by the world being acted upon a situation. The same set of rules may yield entirely different types of action-situations depending upon the types of events in the world being acted upon by participants.

An important development in institutional analysis is the investigation of linked action-situations. Indeed, most of the social reality is composed of multiple arenas linked sequentially or simultaneously. When actors wish to change the structure of incentives and deterrents faced by participants in socially constructed realities to control participants toward a different pattern of results, they do so by changing the rules participants use to order their interactions with particular

types of action-situations (Ostrom, 2009: 44). Besides multiple and nested action-situations at any one level of analysis, nesting of action-situations also occurs across several levels of analysis: all rules are nested in another set of rules that define how the first set of rules can be changed. Ostrom distinguishes three levels of rules that cumulatively affect the actions taken and outcomes obtained in any setting (Kiser and Ostrom, 1982): (1) operational rules that directly affect daily decisions made by participants in any setting, (2) collective-choice rules that affect operational activities and results through their effect in determining who is eligible and the specific rules to be used in changing operational rules, (3) constitutional-choice rules that affect operational activities and the rules to be used in crafting the set of collective-choice rules that, in turn, affect the set of operational rules.

Figure 2.2 - Levels of analysis and outcomes

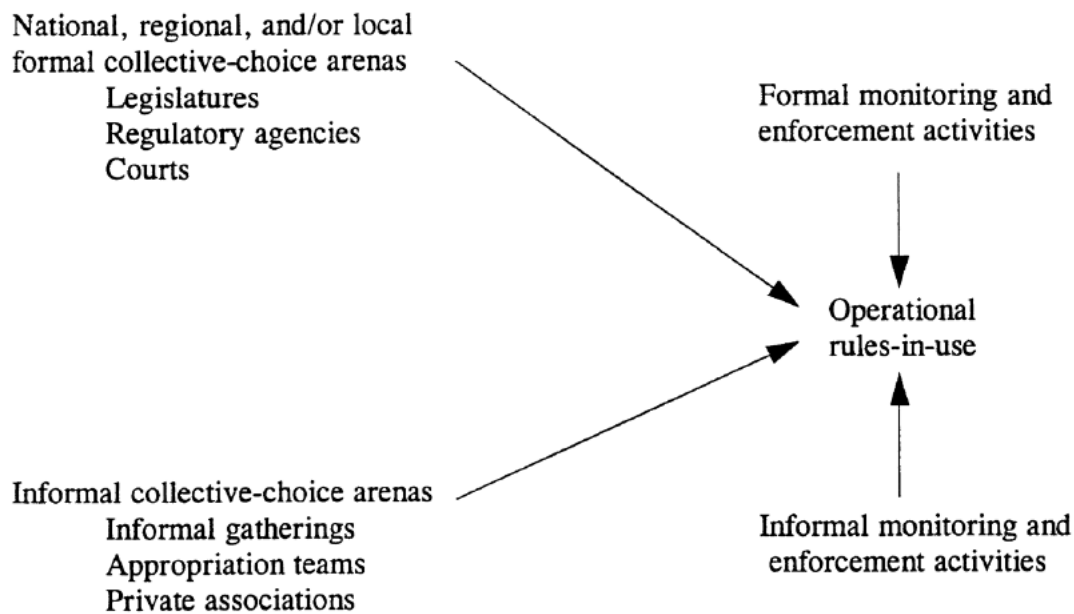


Source: Ostrom (2009: 45)

At each level of analysis there may be one or more action-situation(s) in which the decisions made at that level will occur, and in both collective-choice and constitutional situations activities involve prescribing, invoking, monitoring, applying, and enforcing rules (Lasswell and Kaplan, 1950; Ostrom, 2009: 46). The concept of action-situation does not imply a formal setting but can include it.

Governance regarding the rules that will be used to regulate the operational-choice level is usually carried out in one or more collective-choice situations (see Figure 2.3).

Figure 2.3 - Relationships of formal and informal collective-choice situations



Source: Ostrom (2009: 46)

What is distinctive about Ostrom’s notion of rules is that it entails monitoring and enforcement activities – which convey coercive power: indeed, rules are “*shared prescriptions (must, must not, or may) that are mutually understood and predictably enforced in particular situations by agents responsible for monitoring conduct and for imposing sanctions*” (Ostrom, 2009: 23). Accordingly, rules “*simply say what individuals must, must not, may, can, and cannot do upon monitoring and enforcement by an authoritative agency. Breaking rules is an option that is always available to participants in an action-situation but associated with breaking rules is a risk of being monitored and sanctioned. If the risk of sanctioning is high, participants can expect that others will make choice from within the set of permitted and required actions*” (Ostrom, 2011: 21).

As shown in Figure 2.3, governance regarding the rules that are used to regulate operational-level choices is usually carried out in the collective-choice action-situations. Thus, operational rules-in-use are affected by national, regional, and/or local formal collective-choice action-situations – in which legislatures, regulatory agencies, and courts do operate – and by formal monitoring and enforcement activities, to ensure predicted results in actions and, thus, behaviours. Ostrom

understands agencies as “*a set of institutional arrangements and participants who have a common set of goals and purposes, and who must interact across multiple action-situations at different levels of activity*” (Polski and Ostrom, 1999: 4). Moreover, the agencies operating within collective-choice action-situations exert control over information that is circulated in the operational action-situations. Being costly to monitor the actions of participants in the operational action-situation and/or to impose sanctions on them, “*those that are assigned these tasks may not be motivated to undertake them unless (1) the monitor or sanctioner face some probability of themselves being sanctioned for not monitoring and/or sanctioning, (2) social pressure to monitor or sanction is large and is salient to the monitor and sanctioner, (3) the monitor or sanctioner hold some strong moral commitment to their responsibilities, or (4) the payment schemes for the monitor or sanctioner create prudent rewards high enough to offset the costs*” (Ostrom, 2011: 153). Thus, not only the existence *per se* of monitoring and enforcement activities do exert an impact on operational outcomes, but also the institutional features of the agents carrying out those activities.

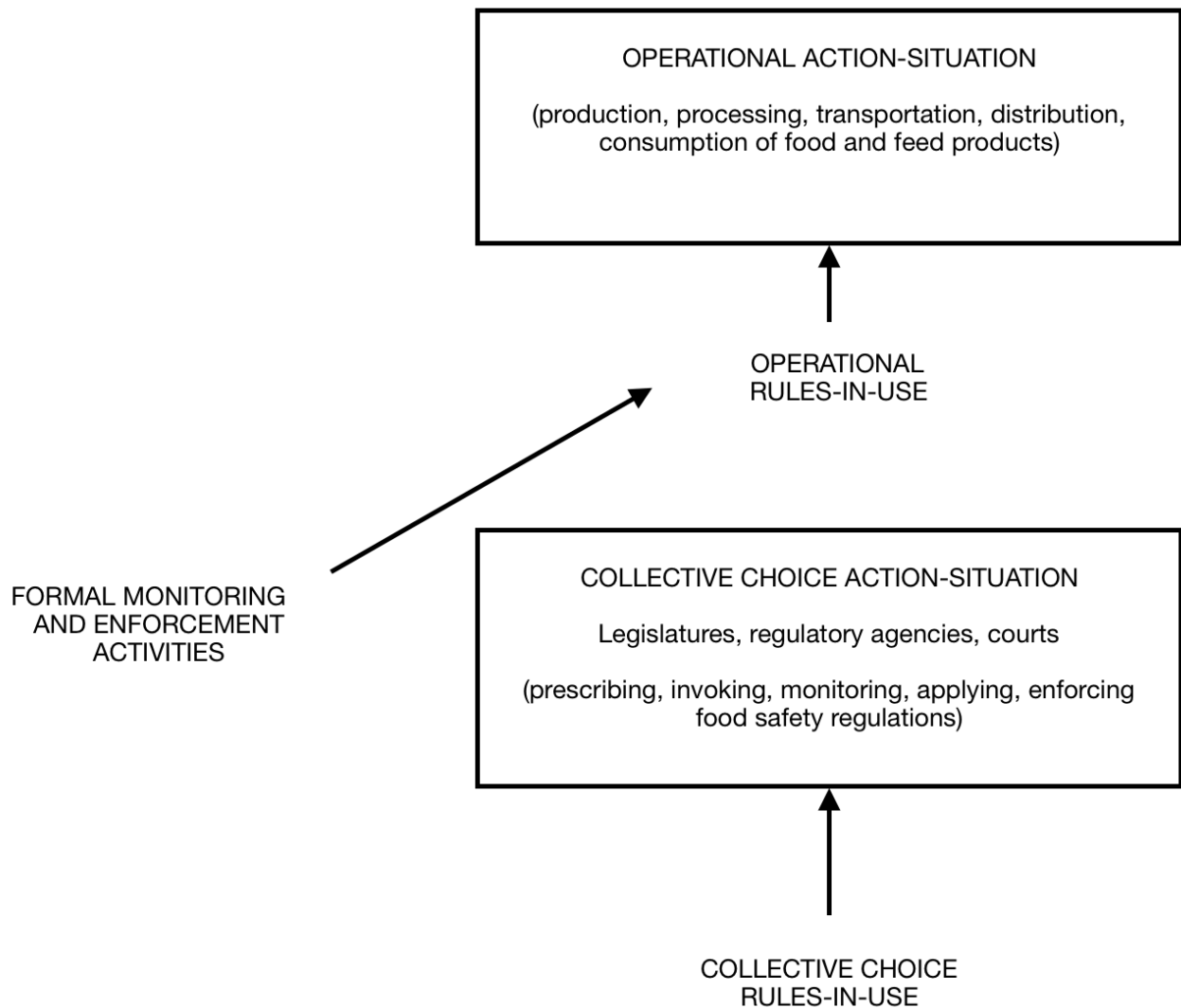
A first generation of studies made use of the IAD framework to conduct an extensive number of empirical studies: between the early 70s and the end of the 80s police service delivery in metropolitan areas has been investigated, shedding light on patterns of metropolitan organisation and local government more generally (Ostrom *et al.*, 1989; Parks and Oakerson, 1989; Oakerson and Parks, 1988; Stein, 1990; Parks *et al.*, 1982; Percy, 1984; Kiser, 1984; Whitaker, 1980). Later on, the IAD has been extensively used for the study of the common pool resources, generating a great body of work (Oakerson, 1992; Thomson *et al.*, 1992; Ostrom, 1992; Ostrom *et al.*, 1994; Ostrom *et al.*, 1992; Walker and Gardner, 1992; Hackett *et al.*, 1994; Weissing and Ostrom, 1991; 1993). In *Governing the Commons* (1990), Elinor Ostrom drew on the framework and on the analysis of several case studies to improve some aspects of a theory of common-pool resources. She examined the key design principles that characterised robust, self-organized institutions for achieving a sustainable resource use for very long periods of time as well as for developing a theory of institutional change. Finally, the IAD influenced a variety of other studies: Herzberg *et al.* developed models of social-choice situations and subjected them to empirical tests in experimental laboratories (Herzberg and Ostrom, 1986; Wilson and Herzberg, 1987; Herzberg and Wilson, 1988); the study of rural infrastructure in developing countries (Ostrom *et al.*, 1993), privatization processes (Walker, 1994), development processes (Ostrom *et al.*, 1993; Wunsch and Olowu, 1996; Shivakumar, 2005), constitutional dynamics in the American federal system (Jillson and Wilson,

1994; Ostrom 1991, 2006, 2007) and in the Canadian federal system (Sproule-Jones, 1993), the linking of local and global commons (Keohane and Ostrom, 1995), the study of social-ecological systems (Imperial, 1999; Anderies *et al.*, 2004), the use of agent-based models of behaviour within diverse institutional arrangements (Janssen and Ostrom, 2006), including behaviour within experimental laboratories (Jager and Janssen, 2002), the study of the success and failure of cooperatives (Jones, 2003), the study of fisheries policy (Imperial and Yandle, 2005), and many others.

3. THE INSTITUTIONAL ANALYSIS OF FOOD SAFETY REGULATORY DESIGNS

This study focuses on governance of food safety regulation, understood as a both procedural and substantial instrument, which entails a set of commands as well as controls (for an extensive review, see chapter 1). By making use of Ostrom's conceptualization of the action-situation and the modelling of nested action-situations, it is possible to understand the substantial dimension of regulation as the operational rules-in-use shaping operational action-situations, i.e. directly affecting day-to-day decisions made by participants in any setting. The procedural dimension of regulation can be understood as the collective-choice rules-in-use affecting the operational rules. In collective-choice action-situations, activities involve prescribing, invoking, monitoring, applying, and enforcing rules (Lasswell and Kaplan, 1950; Ostrom, 2007: 46), and governance regarding the rules is carried out at the collective-choice level of decision-making (see Figure 2.3). The operational rules-in-use are affected by national, regional, and/or local formal collective-choice action-situations – in which legislatures, regulatory agencies, and courts do operate – and by formal monitoring and enforcement activities, to ensure predicted results in actions and, thus, behaviours. Therefore, it is possible to model the governance of food safety as multiple and nested action-situations across different levels: the operational action-situation in which the activities of production, distribution, and consumption of food are carried out is affected by the formal collective-choice action-situation in which regulatory agencies exert control over the information circulated within operational action-situations and carry out formal monitoring and enforcement activities (see Figure 2.4).

Figure 2.4 - Levels of decision-making and outcomes of food safety action-situations



Source: own elaboration from Ostrom (2009)

By understanding the governance of food safety as a configuration of institutional elements that structure information and create incentives to act or not to act – thereby imposing constraints on the range of possible behaviours (Ostrom, 1999: 5) – it is possible to identify the features of the set of elements that are affecting effectiveness of governance in the light of institutional design and regulation theories.

First, the assumption that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20), enables me to select those institutional features of regulatory designs of monitoring and enforcement in order to investigate the impact they exert on the effectiveness of governance (i.e. the extent to which they ensure predicted results in actions and, thus, behaviours). Second, the assumption that institutions are intentional constructions that structure information (Ostrom, 1999:

5) enables me to identify the quality of regulatory designs as one of those institutional features, being the agencies operating in the collective-choice action-situation those who exert control over information which is circulated in the operational action-situation. Third, in light of the assumption of the configurational nature of institutions, it is possible to argue that the institutional arrangements of monitoring and enforcement activities and of control of information – jointly given – exert an impact on the effectiveness of operational outcomes.

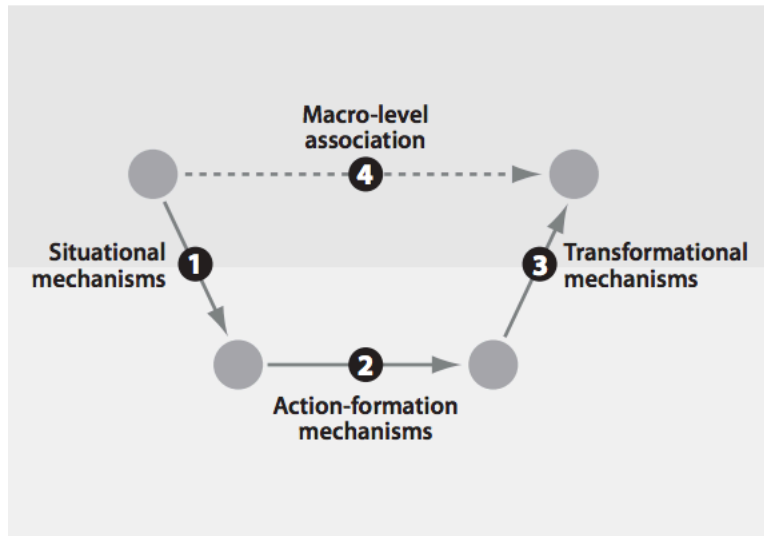
4. A MECHANISTIC APPROACH TO INSTITUTIONAL ANALYSIS

Making use of Ostrom's conceptualization of the action-situation and the modelling of participants' strategies and behaviours by the rules is compatible with a mechanistic approach (for an extensive review, see chapter 3). Recent literature on policy design (Capano and Howlett, 2019) shed light on the necessity of adopting a mechanistic perspective to focus on *"realistic causation* and to answer to *one of the most important questions for policy designs: how does a policy design encourage, constrain and otherwise structure policy targets' behaviour to achieve desired outcomes?"* (Capano and Howlett, 2019: 2).

Literature defines mechanisms in many ways, and this study draws upon the definition that generally describes a mechanism as a *"system with multiple components, which interact to produce some overall phenomenon"* (Fagan, 2012: 453). The distinction between components and the overall phenomenon reveals the hierarchical structure of mechanisms, and any mechanistic explanation consists of *"an explanandum that is explained and explanans that does the explaining, and a relation connecting the two"* (Fagan, 2012: 453). Specifically, this work adopts the notion of mechanism developed by Hedström (2005): *"different types of structural configurations of actors can be said to constitute different social mechanisms"*, and the mechanisms can be described in terms of their entities (and their properties) and the way in which the entities are linked to one another. This understanding conceives the core entities of the mechanism as the *beliefs, desires, and opportunities of the actors*. In other words, the explanation of individual action refers to the mechanism – that is, *"the constellation of beliefs, desires, and opportunities by which such individual actions are regularly brought about"* (Hedström, 2005: 26-27). The theoretical perspective behind mechanism-based explanations is centrally concerned with the reciprocal relation of actions on one hand and beliefs, desires, and opportunities of individuals on the other (Hedström, 2005; Barzelay,

2007). Thus, the basic entities for explanation are human agents and their relations, as illustrated by the so-called Coleman's boat (see Figure 2.5).

Figure 2.5 – A typology of social mechanism: the Coleman's boat



Source: Hedström and Ylikoski (2010: 59).

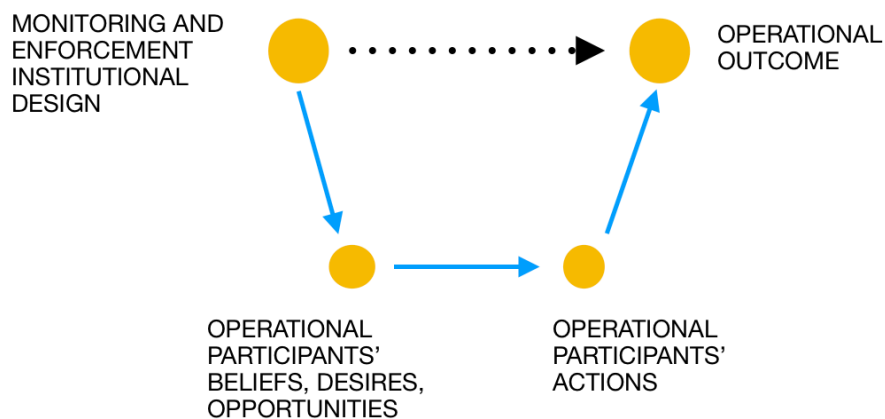
A basic point of the mechanistic approach is that explanations that simply relate macro properties to each other are unsatisfactory, because they do not specify the causal mechanisms by which macro properties are related. Deeper explanatory understandings require opening up the black box of the causal mechanisms that have generated the macro-level observation. According to Hedström, “a mechanism-based explanation describes the causal process selectively” by determining how much the entities (and their properties) make a *relevant difference to the outcome* (Hedström and Ylikoski, 2010). Thus, one should identify the situational mechanism by which social structures constrain individuals’ action and shape their desires and beliefs (arrow 1), describe the action-formation mechanism linking individuals’ desires, beliefs and opportunities to their actions (arrow 2), and specify the transformational mechanisms by which individuals, through their actions and interactions, generate the intended outcome (arrow 3) (Hedström and Ylikoski, 2010). Yet, by adopting a *diversity-oriented* strategy (Ragin, 1987; 2008; Schneider and Wagemann, 2012; Mahoney and Goertz, 2006) - instead of unfolding the generative process - it is possible to focus on the configuration that can account for its occurrence, as an unobserved chemical reaction¹⁴.

¹⁴ Chapter 3 tackles both ontological and methodological questions related to the research design, by addressing in detail current thinking on causal mechanisms and mechanistic explanations. This study combines systematic cross-case comparison – by identifying regularities – with within-case analysis – by focusing on the underlying mechanisms and the configurations that unfold their effects.

Hedström's notion of mechanism entails the notion of *structural configurations* (Hedström, 2005) and allows me to consider how the institutional features of monitoring and enforcement modify beliefs, desires, and opportunities of individual actors, thus resulting in behaviour modification (Hedström, 2005; Howlett, 2002; Howlett and Ramesh, 2002; Ostrom, 2005). This understanding is compatible with Ostrom's notion of institutions (Ostrom, 2005; 2011) and the drawing assumptions of her IAD. First, the assumption that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20), enables me to select those institutional features of regulatory designs of monitoring and enforcement as *properties of the entities* (i.e. agents) that make *a relevant difference to the outcome* (Hedström and Ylikoski, 2010). Second, in light of the assumption of the configurational nature of institutions, it is possible to argue that the institutional arrangements of monitoring and enforcement and of control of information – jointly given – modify beliefs, desires, and opportunities of individual actors (Hedström, 2005; Howlett, 2002; Howlett and Ramesh, 2002; Ostrom, 2005). Indeed, rules' configurations are the constraints that shape action-situations structure and results – and therefore, participants' behaviours. Institutional theories emphasize the importance of formal rules in shaping behaviour, and the notion that the institutional structure and its arrangements significantly shape regulation and its results. Specifically, the IAD identifies the coercive power of rules as the crucial element for the desired outcomes to occur. Drawing upon this tenet enables me to conceive the mechanism of individual actions as shaped by the rules and their monitoring and enforcement, and to claim that by changing the institutional configurations – i.e. the institutional arrangements of monitoring and enforcement activities and of control of information – the mechanism changes accordingly (i.e. the beliefs, desires, opportunities of the individual actors in the operational situation) and the desired change of behaviour is obtained. Indeed, when agencies wish to change the structure of incentives and deterrents faced by participants in operational action-situations to control participants toward a different pattern of results, they do so by monitoring and enforcing the rules participants use to order their interactions with particular types of action-situations (Ostrom, 2007: 44).

Therefore, it is possible to model the institutional configurations that unfolds the effects of the underlying mechanism by constraining individuals' action and shaping their desires and beliefs through monitoring and enforcement (see Figure 2.6).

Figure 2.6: A mechanistic explanation of operational outcomes



Source: own elaboration.

Against this background, this study undertakes theoretical work by drawing upon the Institutional Analysis and Development framework and yields an explanatory model for effectiveness of governance, by focusing on the institutional configurations that unfold the effects of the underlying mechanism.

5. THE EXPLANATORY MODEL: DEFINING THE EXPLANANDUM AND THE EXPLANANTES

Regulatory governance and design theories have always been concerned with achieving effectiveness in regulatory instruments (for an extensive discussion, see chapter 1), and institutional theories suggest that institutional structures and arrangements significantly shape regulation and its effectiveness. Specifically, the institutional design theory identifies in information asymmetries the main regulatory failure-mechanism: agency drift on one hand and industry drift on the other are particularly contributing to the failure of regulation, and several scholars identify in the quality of regulatory design the response to this effectiveness challenge (Gilardi, 2008; Maggetti, 2007; Levi-Faur, 2010). Debates about quality of regulatory designs bring together discussion of independence and accountability (Gilardi, 2002; 2005; 2008; Maggetti, 2008; Hanretty and Koop, 2012; Enns-Jedenastik, 2015; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Biela and Papadopoulos, 2014; Koop, 2015; Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018), and recent design literature extensively discussed policy (and regulatory) capacity, highlighting their fundamental nature to produce effective outcomes (Peters *et al.*, 2018; Considine, 2012; Ramesh and Howlett, 2015; Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016).

Accordingly, to address the research question of effectiveness of governance of food safety regulation across EU-15, institutional design and regulation theories are particularly useful. Drawing upon the IAD as general framework of institutional analysis, I aim to test the explanatory power of complementary or competing theories and models (Ostrom, 2006: 26). This way, this research aims contributes substantially to enriching the debate about quality of regulatory designs on one hand, and of policy capacity on the other. Ultimately, the study argues in favour of their fundamental nature to jointly produce effective outcomes.

6. THE EXPLANANDUM

Public policy literature commonly defines policy outcomes as the behavioural changes needed to address a policy problem, and there is a great debate and a long tradition of defining and measuring effectiveness in public policy research. Recently, Peters and colleagues (2018) tried to disentangle questions concerning design, effectiveness, and public policy. In doing so, they argue that considerations on effectiveness can nourish a more policy-oriented debate by providing insights on the meaning of effectiveness that might be of interest to policymakers. Commonly, effective refers to *“successfully producing a desired or intended result* and effectiveness is about *success (outcome) and the ability to be successful (means)”* (Peters *et al.*, 2018: 41). Peters and colleagues (2018) discuss a definition of effectiveness that is *“less about success and intended results than about the actual effects”*. Drawing upon this notion, effective means operative, existing in fact, or producing an effect, and effectiveness is about the acknowledgement of the production of an effect (Peters *et al.*, 2018: 41-42). According to Peters and colleagues (2018), *“it is particularly important to adopt an effectiveness questioning which encompasses both meanings: effectiveness as success in producing intended results and effectiveness as production of effects that are to be characterised”* (2018: 42).

Here, effectiveness is understood as both production of effects and as goal achievement (Skærseth and Wettestad, 2008; Levi-Faur, 2011; Thomann, 2018), being interested in whether domestic food safety regulatory designs succeed in resolving the food safety problems they are designed to address.

7. THE EXPLANANTES

7.1 Independence and accountability of risk assessment

There is a consolidated strand of literature that accounted for *agencification*, legitimacy and accountability of non-elected experts, together with credibility of scientific expertise and the role of science within the policy process (Gilardi, 2008; 2005; 2002; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007). This section addresses these issues, underlying the relevance of independence and accountability as important elements of a sound institutional design, and exploring modes of governance among domestic institutions. Agencies have been defined as a non-departmental public organization primarily involved in the decision-making process, which may also be responsible for fact-finding, monitoring, adjudication, and enforcement (Vos and Wendler, 2006). The shift of the regulatory arena towards autonomous agencies finds its origin in the act of delegation, defined as “*an act where one person or group – called a principal – relies on another person or group – called an agent – to act on the principal’s behalf*” (Lupia, 2003: 33). Within the EU food safety action-situation, the European Commission (principal) delegated to the European Food Safety Authority (agent) risk assessment’s tasks. The autonomy of the agency is constituted by the act of its establishment as a separate organization and the institutionalization of a policy space in which the agency’s role becomes *taken for granted*. Rule-making, fact-finding, monitoring, adjudication, and enforcement capacities are defining characteristics of regulatory agencies, but also other organizations, both within and outside the state, can successfully acquire and implement these features (Abels and Kobusch, 2015). According to Abels and Kobusch (2015: 6), this definition allows the different agencies to be characterized according to their scope or functions and their role within the regulatory process.

As discussed in chapter 1, this study draws upon Levi Faur’s definition of regulation as “*the promulgation of prescriptive rules as well as the monitoring and enforcement of these rules by social, business, and political actors on other social, business, and political actors*” (Levi-Faur, 2010: 9).

Drawing upon Abels and Kobusch theoretical argument, the food safety regulatory process can be deconstructed in (1) fact-finding, (2) rule-making, (3) monitoring, (4) enforcement, and (5) adjudication. At the EU level, the EFSA is responsible for fact finding, while the Council, the European Commission (EC), and the European Parliament are responsible for rule-making, monitoring, and enforcement; finally, adjudication is under the responsibility of the European Court of Justice (ECJ). At the domestic level, every Member State implemented different institutional designs.

Independence and accountability are the two most discussed features of regulators, and several authors have stressed the need for regulators to be accountable as well as independent (Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018). As to independence, it has been widely explored and discussed in relation to the so-called Independent Regulatory Agencies (IRAs) (Gilardi, 2008; 2005; 2002; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Edwards and Waverman, 2004; Elgie and McMenamin, 2005; Jordana *et al.*, 2009; Majone, 1994; Thatcher and Sweet, 2002; Christensen and Lægveid, 2007; Thatcher, 2002; 2004; Wonka and Rittberger, 2010), and many scholars distinguished between formal and de facto independence, accounting for implication of one dimension towards the other. Here, the focus is on formal independence, as *“the degree to which there are statutory provisions that decrease the possibility for politicians to influence agency decisions before they are made”* (Koop and Hanretty, 2018: 42). The rationale behind the delegation of (here, risk assessment) tasks from the principal to the agent lies in the *“Two Logics of delegation”*, formulated by Majone (1999), according to which when uncertainty about future events rises, so does the incentive to delegate. This is mainly due to the fact that the agent can react more flexibly and efficiently to changing the status quo. To this increase of delegation corresponds an intensification of the control mechanisms, and thus the necessity of accountability. Koop and Hanretty improved our knowledge of independence (Koop and Hanretty, 2018; 2009; 2012; 2013), by looking at it as a matter of degree rather than as a quality that is present or absent, and taking explicitly into consideration accountability, as property that matters for performance (Koop and Hanretty, 2018:40). Indeed, regulatory agencies may be tempted to misuse and abuse their public authority, if these activities are associated with worse performance. If accountability mechanisms may provide incentives not to engage in these activities, we shall expect higher degrees of accountability to be associated with better performance (Koop and Hanretty, 2018:46).

Accountability has been widely investigated (Maggetti, 2010; Jordana *et al.*, 2015; Busuioc, 2009; 2012; Busuioc and Schillemans, 2014; Busuioc and Lodge, 2016; Bovens, 2005; 2007; 2010; Bovens *et al.*, 2014; Schillemans and Bovens, 2014) and the concept finds its origins in the delegation theory, according to which *“an agent is accountable to a principal if the principal can exercise control over the agent and delegation is not accountable if the principal is unable to exercise control”* (Lupia, 2003: 35). This study deploys the definition of accountability as *“the ability to provide information on, and explanation of, one’s conduct”* (Koop and Hanretty, 2018: 44). Therefore, an agency is

“formally accountable to politicians to the extent that politicians can require the agency to provide information on, and explanation of, its conduct on the basis of statutory provisions” (Koop and Hanretty, 2018: 44). Drawing upon the same theoretical argument behind the conceptualization of formal independence, accountability is here conceptualized and operationalized as formal accountability, being to some extent compatible with independence. This is supported by recent literature (Maggetti *et al.*, 2013; Koop and Hanretty, 2018; Busuioc, 2009; Quintyn and Taylor, 2007; Majone, 2001), claiming that agencies can be both independent and accountable.

My claim is that independence and accountability of domestic institutions carrying out risk assessment tasks are two institutional properties contributing to effectiveness of food safety governance.

*H1: ACC * IND → EFF*

H1 formulates a directional expectation¹⁵ towards combination(s) of conditions affecting effectiveness and implies that independence and accountability are conditions unfolding their effect only in combination, assuming conjunctural causation (Schneider and Wagemann, 2012).

This claim is supported theoretically by the literature, which claims we expect higher degrees of accountability to be associated with higher quality of regulatory decision-making, while independence improves levels of expertise and long-term and opportunities for misuse and abuse of power are being curbed. Hence, the two concepts are mutually supporting (Majone, 2001). Busuioc (2009) contributed to the contemporary debate about the accountability of European agencies, claiming a distinction between the notion of accountability and that of control. In doing so, she claims that accountability and independence are not contradictory. Accountability is understood as *“a relationship between an actor and a forum, in which the actor has the obligation to explain and justify his or her conduct, the forum can pose questions and pass judgment, and the actor might face consequences”* (Bovens, 2007: 111-112). On the other hand, control includes both ex ante and ex post mechanisms of directing behaviour (Scott, 2001: 39), as well as *ongoing control*, understood as *“an informal type of direct control exercised by a principal vis-à-vis an agent in which the agent’s actions are steered and / or determined by the principal”* (Busuioc, 2009: 14). In her

¹⁵ QCA makes use of directional expectations as so-called simplifying assumptions, in order to theorize about whether a given configuration of conditions not present in the dataset would display the outcome or not. A substantive theoretical and / or empirical knowledge gives a clear notion of how a condition contributes to an outcome (when present or absent) and helps in formulating a directional expectation of how the condition could be related to the outcome. For an in-depth description, see the method’s section of chapter 3.

conceptualization, Busuioc (2009) understands *ex ante* control as the basic mandate comprising the powers and tasks of the agent (i.e. statutory provisions or founding legislation of the agency) and the *ex post* control as accountability, in the conception presented by Bovens (2007). In this scenario, accountability mechanisms are *indispensable*, and independence and accountability can co-exist (Busuioc, 2009: 17).

7.2 Institutional separation of regulatory functions

Since the BSE crisis, food safety regulation has undergone great changes both in the EU and within the Member States, attracting interest of several scholars in the last two decades (Vos and Wendler, 2006; Abels and Kobusch, 2015; Dreyer and Renn, 2009; Ansell and Vogel, 2006)¹⁶. Insights have been drawn from the established strand of literature related to agencies and regulatory governance. This section addresses the question on the institutional separation of risk assessment from risk management, as prescribed in the General Food Law (Regulation n. 178/2002). The functional separation of the two aims of the food safety regulatory process finds its origins in the rationale behind *agencification* and the so-called “Two logics of delegation” (Majone, 2001) that underlie the delegation of power to the European Commission (the logic of efficiency and the logic of credibility) – and it draws upon the debate towards “*scientification of politics*” and “*politicization of science*” (Weingart, 1999). According to some scholars, the first appears to be fundamental for the legitimacy and accountability of non-elected experts, while the second undermines the credibility of scientific expertise. However, in the view of many scholars, the question of how to organize the relationship between scientific expertise and political decision-making in the governance of food risks is still not sufficiently solved. It is precisely through the full institutional separation of risk assessment from risk management that it has increasingly become clear that scientific activities cannot be carried out in complete isolation and in a political vacuum (Ansell and Vogel, 2006). The National Research Council’s Red Book has already pointed out a central criticism of full organizational separation stating that “*simply separating risk assessment from the regulatory agencies would not separate science from policy*” (NRC 1983:139). The question is: how then to account for the inherent interlinkage between the scientific and the political aspects of food safety governance without compromising the generally agreed functional differentiation between actions aimed at assessing risks and actions aimed at managing risks? (Ansell and Vogel, 2006). According to Abels and Kobusch (2015), the separation of risk assessment (conducted by independent experts) from risk

¹⁶ For an extensive review, see chapter 1.

management (conducted by elected and accountable officials – who have to take expertise into account but are not bound to the scientific opinions) might solve the intrinsic problems of *scientification* and *politicization*, and thus, of legitimacy and accountability, as well as of credibility. One of the most important lessons learnt from the BSE crisis was that mixing scientific and regulatory responsibilities might risk the independence and trustworthiness of the underlying expertise. Several scholars (Borrás *et al.*, 2007; Hellebø, 2004; Abels and Kobusch, 2015) think of European food safety regulation as reinforcing credible commitment and consumer trust. Within the regulatory process, science holds a privileged position, and the several crises of food safety have also been crises of expertise. Weingart (1999) argues that the *scientification* of politics would *necessarily* lead to the politicization of science, as any measure backed by science could only be opposed by stronger counter-arguments. Thus, scientific divergence would be stressed to legitimize opposing political measures. This is where the separation of risk assessment from risk management is believed to ease science from political pressure. Moreover, the balanced distribution of competences within the EU did not lead to the institutionalization of a superior European scientific institution. Hence, Member States preserved an opportunity for the inclusion of national perspectives on risk assessment. As a result, EFSA is neither featured with regulatory powers nor its opinions are legally binding for the Commission. The opinions issued by EFSA rank equal with national opinions. From a normative perspective, this is the consequent institutional separation of risk assessment from risk management (Abels and Kobusch, 2015). Empirically, we can identify two different models: a separate model in which responsibilities are separated between institutions, and a structurally more integrated model: out of 28 Member States, 9 opted for a separated system. This study asks whether differences in the system (separation vs. integration) contribute to explain differences in the effectiveness. Busuioc (2009) revisited the academic debate on accountability of European agencies. In her work, she claims a distinction between the notion of independence of agencies and that of formal institutional separation, claiming that independence and formal institutional separation deserve a separate investigation. Accordingly, this work formulates expectations on how the single conditions could be related to the outcome and on their conjunctural explanatory power. Here, the expectation is that the institutional separation of the regulatory functions – as prescribed in the risk analysis instrument at the EU level – does contribute to effectiveness of governance.

H2: SEP → EFF

7.3 Policy capacity

Several scholars have assessed success and failures of governance, claiming that capacity is a factor affecting effectiveness and efficiency of any single governance mode (Howlett, 2009; Howlett and Ramesh, 2016). Among others, Howlett and Ramesh claim that “*governance is intimately linked to policy success and, therefore, to policy capacity*” (2016: 302). Policy capacity is mainly understood by the literature as a function of three competences which affect the ability of governments, that are analytical competences, managerial competences, and political competences. These skills rely on the availability of adequate resources that exist at individual, organizational, and system level. Howlett and Ramesh (2016) operationalized policy capacity as follows (see Table 2.1).

Table 2.1 - Dimensions and levels of policy capacity

Resource level	Individual Capabilities	Organizational Capabilities	System Capabilities
Skill dimension			
Analytical competences	Policy analytical capacity	Organizational information capacities	Knowledge system capacity
Managerial competences	Managerial expertise capacity	Administrative resource capacity	Accountability and responsibility system capacity
Political competences	Political acumen capacity	Organizational political capacity	Political-economic system capacity

Source: Howlett and Ramesh (2016: 302)

Capacity has been broadly defined as “*the ability to perform functions, solve problems, set and achieve objectives*” (Milio, 2007), or “*the ability to accomplish intended actions*” (Huber & McCarty, 2004: 481). Also, determining what capacities are required in order to develop the design spaces needed to carry out complex design processes is a subject of interest in contemporary design studies (Considine, 2012; Peters *et al.*, 2018). Recent work on policy capacity has outlined the fundamental nature of the skills and resources governments need to effectively formulate and implement policy (Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016). These exist at three levels: individual, organizational, and systemic (Wu *et al.*, 2015). At the individual level, technical expertise, leadership and negotiation expertise and political

acumen are fundamental capacities for successful governance. At the organizational level, information mobilization capacities and administrative resources contribute toward overall policy capacity. At the system level, institutions and opportunities for knowledge creation and use need to exist alongside arrangements for accountability and securing political legitimacy.

There is a consolidated literature claiming that policy capacity can contribute to improved policy outcome (Howlett and Ramesh, 2016; Koop and Hanretty, 2018; Huber and McCarty, 2004). Accordingly, my claim is that, with particular respect to risk management functions (i.e. monitoring and enforcement), capacity does play a prominent role for effective governance.

H3: CAP → EFF

Moreover, focusing on capacity allows to investigate the possible implication of the risk of capture. In the debate about why regulatory agencies fail monitoring, control, and enforcement, capture is an influential concept. According to a narrow conceptualisation, regulatory capture is the process through which *regulatees* end up manipulating the agencies that are supposed to control them (Dal Bò, 2006). One way to understand this phenomenon is to think of a three-tier hierarchy comprising a political principal, a regulator, and the target. This understanding enables to consider also how the political principal might want to respond to the risk that the regulator may be captured by the target. As highlighted by Huber and McCarty (2004), the incentives of civil servants to comply with legislation are diminished by reduction in capacity. This means that capacity is a feature of the system as a whole, but it is affecting all parts of the bureaucracy, including food safety regulation, and it enhances incentives of civil servants to comply with legislation, reducing the risk of capture and contributing to effectiveness of governance.

7.4 Summing up

The conceptualization of the explanatory conditions for effectiveness is summarized in the table below (Table 2.2).

Table 2.2 – Explanatory conditions

CONDITION	THEORY	LITERATURE
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Independent Risk Assessment (INDRA)	Independent Regulatory Agencies IRAs, Regulatory State, <i>agencification</i>	Gilardi (2002, 2005), Koop and Hanretty (2018), Maggetti (2007, 2013), Gilardi and Maggetti (2011), Majone (1994, 2001)
Accountable Risk Assessment (ACCRA)	IRAs, accountability, Regulatory State, <i>agencification</i>	Gilardi (2002, 2005), Koop and Hanretty (2018), Maggetti (2007, 2013), Gilardi and Maggetti (2011), Majone (1994, 2001, Busuioc (2009), Maggetti et al. (2013)
Institutional separation of RA from RM (SEP)	<i>scientification</i> of politics and politicisation of science, separation vs. integration, Two logics of delegation	Majone (2001), Weingart (1999), Abels and Kobusch (2015), Levi-Faur (2011), Ansell and Vogel (2006), Borrás <i>et al.</i> (2007)
Capacity of Risk Management (CAPRM)	Policy capacity	Howlett and Ramesh (2016), Howlett (2009), Huber and McCarty (2004), Koop and Hanretty (2018)

This chapter made use of Ostrom’s conceptualization of the action-situation to model the governance of food safety as a configuration of institutional elements that structure information and create incentives to act or not to act - thereby imposing constraints on the range of possible behaviours (Ostrom, 1999: 5). It identified the agencies that carry out monitoring and enforcement activities and exert control over the information which is circulated in the operational action-situation as unit of analysis of this research. In doing so, it specified the institutional elements relevant to address the research question (i.e. which institutional features do affect effectiveness of governance of food safety regulation?) in light of regulatory governance and design theories: independence, accountability, and policy (and regulatory) capacity. Finally, it yielded a model explaining differences in governance effectiveness by involving precise assumptions about a limited set of explanatory conditions and by deriving precise expectations about the result of combining these conditions.

The assumption about the configurational nature of institutions determines the need to undertake empirical work by employing Qualitative Comparative Analysis (QCA) – which provides a range of

institutional configurations of causal conditions and explores the links of the institutional configurations to the outcome (i.e. effective governance of food safety regulation) through (combinations of) necessary and sufficient conditions. The next chapter addresses in detail the research design of this study, by tackling both methodological and ontological questions.

CHAPTER THREE

THE RESEARCH DESIGN: ONTOLOGICAL AND METHODOLOGICAL QUESTIONS

1. INTRODUCTION

This chapter introduces the research design of this study, by tackling both ontological and methodological questions. Social science research is usually built upon the ontological question – which is about what we study and is related to the existence of a real and objective world – and the methodological question – which refers to the techniques that are used to acquire the knowledge about the object of our research (Corbetta, 2003: 12-13; Della Porta and Keating, 2008: 21).

Recent literature on policy design (Capano and Howlett, 2019) shed the light on the necessity of adopting a mechanistic perspective to focus on *“realistic causation and to answer to one of the most important questions for policy designs: how does a policy design encourage, constrain and otherwise structure policy targets’ behaviour to achieve desired outcomes?”* (Capano and Howlett, 2019: 2). Drawing upon this tenet, this study aims to combine systematic cross-case comparison – by identifying regularities – with within-case analysis – by focusing on the underlying mechanisms and the configurations that unfold their effects.

The method’s choice should be *“guided by the goal of achieving a good fit between theories and research aims on the one hand, and the method-specific assumptions on the other”* (Schneider and Wagemann, 2012: 12). Drawing upon the IAD assumption about the configurational nature of institutions, in this study I undertake empirical work by employing Qualitative Comparative Analysis (QCA) – which provides a range of institutional configurations of causal conditions and explores the links of the institutional configurations to the outcome (i.e. effective governance of food safety regulation) through (combinations of) necessary and sufficient conditions. Good case-based research is built on extensive contextualization and deep understanding of the cases at hand (Rihoux and Ragin, 2009). Here, I argue that the sector of food safety regulation is an illustrative and likely case for assessing the impact the institutional features of monitoring and enforcement exert over operational outcomes and, thus, effectiveness of governance.

The chapter is structured as it follows. Section 2 reviews current thinking on the concept of causal mechanism and on mechanistic explanations. Section 3 elaborates on the methods and introduces the set-theoretic approach that guides the explanatory analysis in chapters 4, 5 and 6. Section 4 describes Qualitative Comparative Analysis as technique. Section 5 discusses case selection and, finally, section 6 provides an overview of the regulatory designs of the 15 EU countries under scrutiny.

2. CAUSAL MECHANISMS: DEFINITIONS AND THEORETICAL APPROACHES

During the last decades, mechanistic explanations have received considerable attention in the social sciences as well as in the philosophy of science (Hedström and Ylikoski, 2010). Causal analysis establishes a causal effect on the cross-case level and involves a complementary causal explanation through the analysis of causal mechanisms (Cartwright, 2004; Gerring, 2005; Rohlfing and Schneider, 2018). In principle, causal inference is feasible with a valid identification strategy and does not need to shed light on the underlying mechanisms (Gerring, 2010; Rohlfing and Schneider, 2018). However, causal explanations that focus on the link between a cause and an effect yield theoretical and policy-related added value and should be an integral component of causal analysis (Rohlfing and Schneider, 2018). The importance of opening the black box between cause and effect has long been acknowledged in the qualitative literature (Bennett and Elman, 2006). The literature on mechanisms has grown rapidly, and mechanistic explanations have been mainly discussed in the context of biological sciences (Bechtel and Richardson, 1993; Bechtel, 2006; 2008; Craver, 2007; Darden, 2006; Glennan, 2002; Thagard, 1999; Wimsatt, 2007), whereas in the social sciences have been mainly discussed by Abbott (2007), Beach (2016), Beach and Pedersen (2013), Coleman (1990), Elster (1989, 2007), Falletti and Lynch (2008, 2009), Gerring (2005, 2010), Gross (2009), Hedström (2005), Hedström and Swedberg (1998), Mahoney (2001), Mayntz (2004), Morgan and Winship (2007), Schmidt (2006), Tilly (2001), Wikström (2006), Ylikoski (2010), Hedtsröm and Ylikoski (2010: 2). Accordingly, this section summarizes current thinking on the concept of causal mechanism and existing theoretical approaches.

Political scientists largely agree that causal mechanisms are crucial to understanding causation, and recently an interest in mechanistic explanation has raised, as well as the level of sophistication of qualitative positivist methodologies (Brady and Collier, 2010). However, the question of what is

meant by causal mechanism is largely contested. Here, I summarize the most acknowledged definitions.

- (1) The simplest definition of a causal mechanism treats it as synonymous with independent variable or causal factor that help explain outcomes¹⁷. Accordingly, Boudon (1998: 172) defines a mechanism as *“the well-articulated set of causes responsible for a given social phenomenon”*. Other definitions see mechanisms as intervening variables, events, or processes that explain how one variable influence another.
- (2) Other scholars view causal mechanisms as underspecified causal propositions that can be applied to a wide range of cases. Accordingly, Elster (1998: 45) defines mechanisms as *“frequently occurring and easily recognizable causal patterns that are triggered under generally unknown conditions or with indeterminate consequences”*. This definition assumes that a mechanism identifies a cause-effect relationship that is applicable to analytical constructs that are not observed.
- (3) Realist scholarship understands a causal mechanism as *“an unobserved entity, process, or structure that acts as an ultimate cause in generating outcomes”* (Mahoney, 2001: 4)¹⁸. According to Mahoney, explanation by causal mechanisms requires some entity, process, or structure that is treated “as if” exists (being hypothetical) and can serve as an ultimate cause. Generating outcomes means that causal mechanisms can explain both specific events and the existence of associations between variables and is the final cause of the things that take place in the world (Mahoney 2001: 5). Against this background, Mahoney (2001) points to mechanisms as ultimate causes that come before both independent and dependent variables, and that produce the relationship that exists between these variables.

¹⁷ Several authors raised critiques over these definitions. Here, I summarize the most acknowledged. According to Mahoney (2001), this definition explains a correlation by appealing to another correlation, which will need an additional mechanism that will require explanation. Therefore, the distinction between an independent variable and a mechanism becomes arbitrary. According to Hedström and Ylikoski (2010) the notion of mechanism as intervening variable misses the structure of the mechanism: *when a mechanistic explanation opens the black box it discloses this structure*, turning the black box into a transparent box and making visible how the participating entities and their properties, activities, and relations produce the effect of interest (Hedström and Ylikoski, 2010: 4).

¹⁸ This notion has been criticized by Mayntz (2004), who claims that most of the mechanisms constituting an automobile’s engine – for example – are quite visible when one opens up the hood. Also Hedström and Ylikoski (2010) argue that *there is nothing in the notion of a mechanism that would imply that it is by definition unobservable, [...] and similarly, to require that the mechanism is sufficient for the effect is an all too strong requirement: a mechanism can involve irreducibly stochastic elements and thus affect only the probability of a given effect* (Hedström and Ylikoski, 2010: 3).

(4) Beach (2016) treats mechanisms as *“theoretical systems linking causes and outcomes, defining a mechanism as a theory of a system of interlocking parts that transmits causal forces between a cause (or a set of causes) and an outcome”* (Rohlfing, 2012; Beach and Pedersen, 2016; Beach, 2016: 465). Beach defines the parts of causal mechanisms in terms of *“entities that engage in activities that transmit causal forces from cause to outcome, understanding entities as the factors engaging in activities, where the activities are what transmits causal forces through a mechanism”* (Beach, 2016: 465). Therefore, each part of a mechanism is necessary to give rise to the subsequent part, and the parts will exhibit *productive continuity*, meaning that each of the parts logically leads to the next part, and there not large logical holes in the causal story linking X and Y (Beach, 2016: 465; Machamer *et al.*, 2000). A mechanism can be schematically represented as: $X \rightarrow [A \rightarrow B \rightarrow C] \rightarrow Y$ and productive continuity lies in the arrows and their transferal of causal forces from one part of the mechanism to the next. A missing arrow leaves an explanatory gap in the productive continuity of the mechanism – i.e. an inability to specify an activity connecting A and B (Machamer *et al.*, 2000; Beach, 2016).

There is strong consensus in philosophy of science that a mechanism is *“a complex causal system with multiple components, which interact to produce some overall phenomenon”* (Fagan, 2012: 450)¹⁹. The distinction between components and the overall phenomenon reveals the hierarchical structure of mechanisms, and any mechanistic explanation consists of *an explanandum that is explained and explanans that does the explaining, and a relation connecting the two* (Fagan, 2012: 453). This study draws upon this definition of causal mechanism, which is compatible with a necessity/sufficiency notion of causation, as well as with Hedström’s notion of mechanism (for an extensive discussion, see chapter 2).

¹⁹ Goertz (2017) summarized a number of definitions of mechanism, developed in philosophy: *“Mechanisms are entities and activities organized such that they are productive of regular changes from start or set-up to finish or termination conditions”* (Machamer *et al.*, 2000: 3). *“Mechanisms are generally understood as consisting of interacting components that generate a causal regularity between some specified beginning and end points”* (Steel, 2008: 40). *“A mechanism underlying a behaviour is a complex system which produces that behaviour by the interaction of a number of parts according to direct causal laws”* (Glennan, 1996: 52). *“A mechanism is a structure performing a function in virtue of its component parts, components operations, and their organization. The orchestrated functioning of the mechanism is responsible for one or more phenomena”* (Bechtel and Abrahamsen, 2005: 423). *“A mechanism is the pathway or process by which an effect is produced, or a purpose is accomplished”* (Gerring, 2008: 178).

For an extensive discussion, see Goertz (2017).

According to Capano and Howlett (2019), the mechanistic account is a *“promising basis for strengthening both the explanatory and prescriptive commitment of policy design studies”* (2019: 4). Literature agrees that mechanisms are *“theoretical propositions about causal tendencies”* (Hedström, 2005: 108) and thus middle range theories (Mayntz, 2004; Pawson, 2000), *“are sets of entities and activities organised to produce a regular series of changes from a beginning state to an end one”* (Capano and Howlett, 2019: 5; Darden, 2006; Machamer *et al.*, 2000). Capano and Howlett (2019) draws upon the notion of mechanism as *“a causal structure that explains the empirical outcome”* (Baygstad *et al.*, 2016: 83; Capano and Howlett, 2019: 5) and they argue that the adoption of a mechanistic approach means theorising about *“the system that produces outcome through the interactions of a series of parts that transmit causal forces from X to Y”* (Beach and Pedersen, 2016: 176). As highlighted by Capano and Howlett, in the sequence $X \rightarrow Y$ the mechanism is something that X triggers which leads to Y occurring, that generates the observed relationship between X and Y (2019: 17). From a policy design perspective this relationship is of great interest, as it implies that the development of policy tools X triggers a mechanism M which can alter a response in policy targets T altering their behaviour in the direction of Y.

Here, systematic cross-case comparison – by identifying regularities – is combined with within-case analysis – by focusing on the underlying mechanism and the configurations that unfold its effect.

3. THE METHODOLOGICAL QUESTION

This research poses the question of effectiveness of governance of food safety regulation and revealing the conditions under which some institutional factors make regulation effective requires a comparison of systematically varying institutional settings, countries, and instances of successful or failed regulatory outcomes. In this study, I adopt a set-theoretic methodological approach that explicitly accounts for such contextual contingencies (Mahoney and Vanderpoel, 2015; Schneider and Wagemann, 2012; Thomann, 2018).

Three characteristics make set-theoretic methodology especially suitable to address the research question of this work. First, set-theoretic methods conceive of social phenomena as sets rather than variables. An empirical case is either a member of a given set or not, and the membership of a case to a set can also vary in degree. Defining sets entails reflection about the properties that make cases comparable in light of a given research question (Sartori, 1991). This approach takes *“into account the fact that most social science concepts establish qualitative differences between cases in*

principle, but that cases manifest adherence to these criteria in various degrees” (Schneider and Wagemann 2012, p. 16). Second, this focus on set membership identifies in patterns of necessity and of sufficiency the basis on which the relationship between sets is assessed. Necessary conditions are “*central prerequisites for enabling an outcome: their absence is a barrier for the same outcome*” (Thomann, 2018: 53). Furthermore, if the presence of a conditions also implies the occurrence of the outcome, then the condition is sufficient. Third, set-theoretic methods specifically model three aspects of causal complexity: conjunctural causation, asymmetrical causation, and equifinality (Rihoux and Ragin, 2009; Schneider and Wagemann, 2012).

Qualitative comparative analysis (QCA) is a diversity-oriented strategy which is employed for causal analysis and the results reveal patterns of necessity and / or sufficiency across set of cases or observations. It combines within-case analysis and formalized cross-case comparison and is suitable for analysing intermediate-N of cases through analysis of similarities and differences in a search for necessary and sufficient conditions. A term is sufficient if its presence is associated with the presence of the outcome, and the term is necessary if the outcome is present only if the term is present. It compares configurations of causes – that is, the effects of the contemporaneous presence/absence of a combination of factors, not of the presence or absence of each of them. Although still following a deterministic logic, it allows for multiple causation through the analysis of several different combinations of causes.

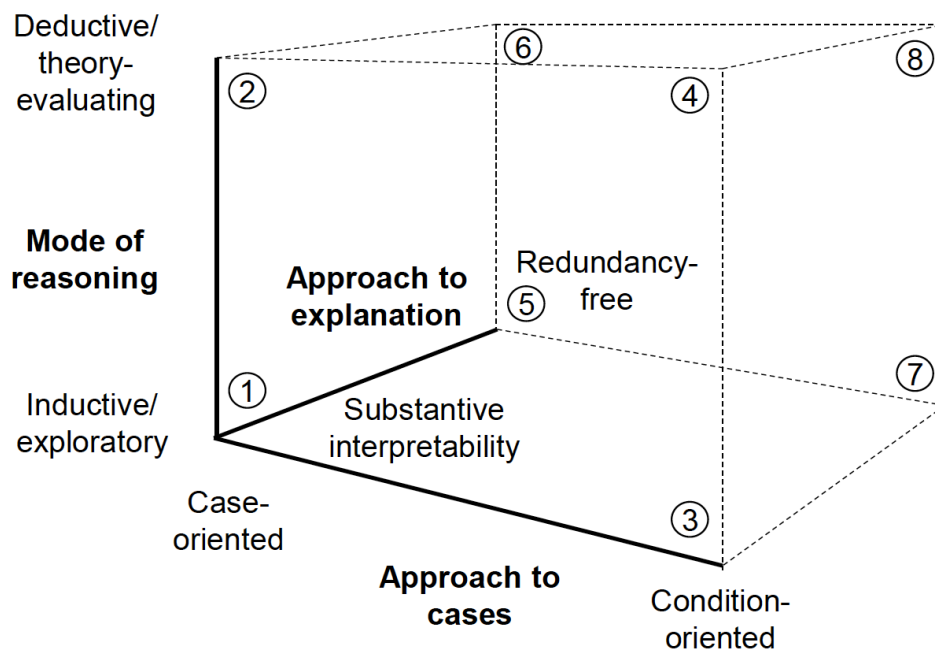
QCA is a methodology based on set-theory and operates through the Boolean logic. The main aim of QCA is an exhaustive explanation of how a certain outcome is produced, asking about necessary and sufficient conditions. QCA models causal complexity, which includes three features: (1) conjunctural causation, (2) asymmetrical causation, and (3) equifinality (Rihoux and Ragin, 2009; Schneider and Wagemann, 2012). Instead of assuming isolated effects of single variables, the assumption of conjunctural causation “foresees the effect of a single condition unfolding only in combination with other conditions” (Schneider and Wagemann, 2012: 78). The method implies the assumption that appropriate performance (effectiveness) can have a different explanation than deficient performance (causal asymmetry). Finally, the assumption of equifinality allows for different, mutually nonexclusive explanations of the same phenomenon.

According to the literature, establishing inference entails addressing three main issues coherently (Thomann and Maggetti, 2017): first, clarifying the question of external validity; second, establishing

measurement and internal validity; third, adopting a mode of reasoning (Adock and Collier, 2001; Blatter and Blume, 2008; Brady and Collier, 2010; King, Keohane and Verba, 1994; Mahoney and Goertz, 2006). The QCA approach has a strong case orientation (Rihoux, 2013) and entails the analysis of small or intermediate set of selected cases that allow for generalization limited to the cases studied (external validity); an in-depth attention to each case as an interpretable whole to ensure internal validity; and an inductive and iterative mode of reasoning (Ragin, 1987, 2000; Rihoux and Ragin, 2009; Schneider and Wagemann, 2012).

According to Thomann and Maggetti (2017), current approaches to QCA differ on three main axes: the approach to cases, the approach to explanation, and the mode of reasoning (see Figure 3.1).

Figure 3.1: Approaches to QCA



Source: Thomann and Maggetti (2017: 7).

As to the approach to cases, QCA is configuration oriented, since it conceives cases as a configuration of attributes (Rihoux, 2013: 238; Thomann and Maggetti, 2017: 7). The traditional approach is case-oriented, which analyses particular cases using deep contextual knowledge: in addition to cross-case inference, in-depth case knowledge plays a pivotal role in establishing measurement and internal validity (Thomann and Maggetti, 2017: 7-8). A second approach is condition-oriented, which understands cases primarily in terms of set of conditions.

As to the approach to explanation, one approach emphasizes the substantive interpretability of QCA results in the light of *“substantive and theoretical knowledge, not just methodological technique”* (Ragin, 2008: 173). This approach implies that when analysing sufficient conditions, the parsimonious solution assumes all logical remainders that help eliminate redundancies to be sufficient for the outcome (Thomann and Maggetti, 2017: 8). Additionally, this approach interprets selected necessary conditions as crucial explanatory factors, without which a given event could not have occurred (Goertz, 2006; Schneider and Wagemann, 2012; Thomann and Maggetti, 2017). Another approach emphasizes redundancy-free models, deriving causality from conditions that are both minimally sufficient and contained in a minimally necessary condition for an outcome. That is, only a parsimonious solution that effectively eliminates all causally irrelevant (redundant) factors and has very high coverage, is causally interpretable (Baumgartner, 2015; Baumgartner and Thiem, 2017; Thiem and Baumgartner, 2016; Thomann and Maggetti, 2017). Both approaches refer to the INUS theory of causation and agree that *“a set relation alone is not enough to postulate a cause”* (Schneider, 2016: 2; Thiem, Baumgartner *et al.*, 2016).

As to the mode of reasoning, QCA can be used inductively or deductively. However, it should be noted that QCA has an inherent iterative element that involves conceptual and theoretical considerations, as well as a back-and-forth between prior knowledge and cases.

The method's choice should be *“guided by the goal of achieving a good fit between theories and research aims on the one hand, and the method-specific assumptions on the other”* (Schneider and Wagemann, 2012: 12). This research aims to investigate differences in effectiveness of food safety regulation across 15 EU countries and to explain them by differences in domestic governance designs. This study is a diversity-oriented comparative research that aims to answer to a *causes of effects* empirical research question, starting with *effectiveness of food safety regulation* and asking for its reasons. Here, an event counts as a cause when its presence or absence makes a difference to the presence or absence of the effect (i.e. difference making approach to causal claims). In doing so, this research is configured as positive empirical research, strongly informed by theory and logic, with an explanatory aim, and identifies Qualitative Comparative Analysis as the suitable technique to find out the necessary and sufficient (combinations of) design conditions associated with high / low effectiveness of food safety regulation across the EU-15.

4. QUALITATIVE COMPARATIVE ANALYSIS: THE TECHNIQUE

Qualitative comparative analysis (QCA) is a diversity-oriented strategy which is employed for causal analysis and the results reveal patterns of necessity and / or sufficiency across set of cases or observations. QCA is a methodology based on set-theory and operates through the Boolean logic. Sets can be understood as formalized representations of concepts and, formally, there are two main types of sets: crisp and fuzzy. The first implies that an element is either inside the set or outside, while the latter can have an infinitely large number of possible values, and elements are not just in or out but more or less included in a given set, starting from the value 0 (completely out) to the value 1 (completely inside). Three anchor points define a set: full membership (membership score equal to 1), full non-membership (membership score equal to 0), and crossover point (membership score of 0.5). Between the extremes of full membership and full non-membership, a set can have more or less fine-grained membership scores, from four-point sets (0, 0.33, 0.67, 1) to continuous sets. Cases on different sides of the crossover point are different in kind, while cases with different memberships on the same side of the crossover point are different in degree (Ragin, 2014:72).

This method operates through the Boolean logic, and the three operations that can be applied for both crisp and fuzzy sets are: (1) set negation (i.e. finding the complement of set A from the universe U, which is another set written as $\sim A$, formed by all other elements from the universe U that are not in A); (2) logical AND (i.e. a conjunction, which takes a true value only when all its elements are true, and that can be interpreted as an intersection); (3) logical OR (i.e. a disjunction). Set negation is used to include the absence of a condition or an outcome in the analysis, while set intersection assesses a case's membership score in a combination of conditions, and set union assesses the membership score in alternative conditions for a given outcome.

The main aim of QCA is an exhaustive explanation of how a certain outcome is produced, asking about necessary and sufficient conditions. QCA models causal complexity, which includes three features: (1) conjunctural causation, (2) asymmetrical causation, and (3) equifinality (Rihoux and Ragin, 2009; Schneider and Wagemann, 2012). Instead of assuming isolated effects of single variables, the assumption of conjunctural causation "foresees the effect of a single condition unfolding only in combination with other conditions" (Schneider and Wagemann, 2012:78). The method implies the assumption that appropriate performance (effectiveness) can have a different explanation than deficient performance (causal asymmetry). Finally, the assumption of equifinality allows for different, mutually nonexclusive explanations of the same phenomenon.

Fuzzy set QCA uses set theory and Boolean algebra to formally analyse to what extent certain conditions or combinations of conditions are present or absent when a phenomenon of interest (i.e. the outcome) occurs or fails to occur. Therefore, the method identifies complex combinations of conditions that are necessary and / or sufficient for a certain outcome. An explanation X is necessary for effectiveness (Y) if Y cannot occur without X. X is sufficient for effectiveness if X always leads to effectiveness. QCA helps identifying different empirical patterns that can be interpreted in terms of necessity and sufficiency, and these patterns can include one or several conditions, but also combinations of two or more. Usually, in empirical reality we find combinations of conditions being sufficient for an outcome rather than single ones (Goertz and Levy, 2007: 26). The single conditions that are part of the combination are called INUS conditions: they are neither necessary nor sufficient by themselves, but part of (at least one) combination of conditions that are sufficient for the outcome.

Based on a dialogue with the cases and theory, the membership of each case is first determined in each set (a process called *calibration*), and then in each logically possible configuration. Calibration is a fundamental operation in Qualitative Comparative Analysis: it is a transformational process from the raw numerical data to set membership scores, based on a certain number of qualitative anchors or thresholds. The entirety of logically possible configurations is represented in the rows of a *truth table*. A truth table has 2^k rows, with k being the number of causal conditions included in the explanatory model. By looking at whether the cases assigned to a truth table row agree in displaying the outcome, it is possible to assess whether a given configuration of conditions can be regarded as sufficient for the outcome. In QCA *limited diversity* appears when some truth table rows remain empty, namely there are no empirical cases in the data set that belong to those rows, and they are called *logical remainders*.

During the following *logical minimization* process, configurations to the same outcome are compared pairwise and, when found identical but for a single varying condition, the condition is dropped as irrelevant. Minimization proceeds until so-called “prime implicants” are found, that contain no irrelevant conditions. Each prime implicant is a term of the QCA solution and it identifies the conditions responsible for their outcome. In Standard Analysis (Ragin and Sonnett, 2005), minimization also makes use of unobserved types as so-called “counterfactuals”, for establishing irrelevance of a condition, following the argument that the outcome would still have occurred if the condition had been different. In the minimization process the use of simplifying assumptions is based on counterfactuals, to theorize about whether a given configuration of conditions not present

in the dataset would display the outcome or not. Ragin and Sonnett (2005) introduced the notion of “easy counterfactuals” as those cases in which substantive knowledge gives a clear notion of how a condition contributes to an outcome (when present or absent). Therefore, it would be possible to formulate a directional expectation of how the condition could be related to the outcome, which serves as simplifying assumption.

The truth table analysis yields three different solution terms: complex, parsimonious, and intermediate (Ragin, 2014). The complex solution does not include any simplifying assumption in the analysis, while the parsimonious solution identifies the minimal possible causal expression for the configurations leading to the outcome (prime implicants). Finally, the intermediate solution includes the selected simplifying assumptions.

QCA provides for parameters of fit to assess how well the cases in a data set fit a relation of necessity or sufficiency: consistency and coverage (Ragin, 2014: 44). Consistency is a measure of the degree to which a relation of necessity or sufficiency between a (combination of) causal condition(s) and an outcome is met in a given data set (Ragin, 2014) and it ranges from 0 to 1, with 0 indicating no consistency and 1 indicating perfect consistency. Coverage provides a measure of empirical relevance of the pattern of explanation, by gauging “*the size of the overlap of two sets relative to the size of the larger set*” (Ragin, 2014: 57) ranging from 0 to 1.

5. CASE SELECTION

It is widely established in the QCA community that this methodological approach has a strong case orientation (Rihoux, 2013) and entails the analysis of small or intermediate set of selected cases that allow for generalization limited to the cases studied (external validity); moreover, an in-depth attention to each case as an interpretable whole to ensure internal validity (Ragin, 1987, 2000; Rihoux and Ragin, 2009; Schneider and Wagemann, 2012). QCA is also configuration oriented, since it conceives cases as a configuration of attributes (Rihoux, 2013: 238; Thomann and Maggetti, 2017: 7). The traditional case-oriented approach analyses particular cases using deep contextual knowledge: in addition to cross-case inference, in-depth case knowledge plays a pivotal role in establishing measurement and internal validity (Thomann and Maggetti, 2017: 7-8).

Given that causal inference in QCA is not based on inferential statistics, results hold for the cases that have actually been examined. Therefore, it is possible to generalize to other cases on the basis of clearly specified *scope conditions* (Walker and Cohen 1985; Schneider and Wagemann, 2007), which “*delimit the universe of cases for which the causal relation examined is claimed to hold*”

(Schneider and Wagemann, 2007: 21). Specifying the scope of the results is helpful in addressing external validity and under case-oriented approaches – as QCA – cases are selected for which obtaining in-depth knowledge is crucial, relevant, and feasible for answering the research question (Mahoney and Goertz, 2006; Thomann and Maggetti, 2017). Therefore, QCA should generally define scope conditions that provide evidence about the relevant factors to explain positive and negative findings as well as delimit the context in which inferences apply (Schneider and Rohlfing, 2016; Thomann and Maggetti, 2017). Even though QCA solutions do not apply beyond the scope condition, they allow for lesson learning, *as they ascribe generative power to particular complexes of necessary and sufficient conditions proven to explain cases without contradiction* (Damonte and Capano, 2015: 9).

In comparative research the cases must share enough background characteristics and the primary consideration in delimiting cases for small-N and intermediate-N comparative studies is the outcome. A second consideration concerns the extent of diversity within the selected universe. In this regard, a maximum of heterogeneity over a minimum number of cases should be achieved (Berg-Schlosser and De Meur, 2009). Hence, both cases with a “positive” and cases with a “negative” outcome should be included.

This analysis narrows to the European Union, as this allows for variation in the outcome and the explanatory conditions yet maintaining some background conditions constant. Indeed, cases are nested in contexts, defined as *“the relevant aspects of a setting (analytical, temporal, spatial, or institutional) in which a set of initial conditions leads to an outcome of a defined scope and meaning via a specified causal mechanism, that is, those aspects that allow the mechanism to produce the outcome”* (Falleti and Lynch, 2009: 1152). As highlighted by Blatter and Haverland (2012: 98), by applying a configurational thinking we differentiate between contextual factors and necessary conditions within causal configurations that (perhaps, in combination with other conditions) have been shown to be sufficient for the outcome.

To emphasize the effects of governance designs, this study narrows on those EU Member States in which the implementation of the European reform has consolidated (with the Regulation 178/2002). As all the Member States accessing the EU in 2004 and 2007 – the central and eastern European countries, but also Malta and Cyprus – have this regulatory system still in the making, this

study identifies its scope condition in the EU 15. Of these, Luxembourg was removed because of its dimensional and economic uniqueness.

6. FOOD SAFETY REGULATORY DESIGNS OF THE EU 15

The actual governance of food safety performs two key functions: risk assessment, and risk management. Together with risk communication – which can be considered as a complementary function – they structure the food safety action-situation, as components of the so-called risk analysis tool.

At the EU level, the general principles of food and feed law are outlined in the General Food Law Regulation (Regulation 178/2002), which covers all stages of the production, processing and distribution of food, as well as feed. The General Food Law (GFL) establishes the principle of risk analysis, drawing food and feed regulations upon its three inter-related components: risk assessment, risk management, and risk communication. Regulation 178/2002 assigns to the European Food Safety Authority (EFSA) risk assessment and risk communication tasks, while all decisions related to risk management are reserved for the European Commission in cooperation with the Member States.

At the domestic level, national regulations shape the food safety action-situations, and differences across Member States can be disclosed. Indeed, EU Member States have implemented different designs and several classifications of national food safety regimes have been discussed in the literature (Vos and Wendler, 2006; Abels and Kobusch, 2015; Dreyer and Renn, 2009). For the purpose of this analysis, food safety governance is understood to include the three elements of risk analysis and, thus, matters of institutional design (Dreyer and Renn, 2009). Risk analysis is intended as the regulatory instrument which shapes and structures the food safety (operational) action-situation and includes monitoring and enforcement activities. Risk assessment and risk management (together with risk communication) are carried out by a set of actors, according to some cogency and conditionality of the prescriptions, and in the light of the consequences for noncompliance. Table 3.1 describes food safety governance designs in the 15 EU Member States under institutional analysis²⁰.

Table 3.1 – Food safety governance designs across 15 EU Member States

²⁰ As outlined in section 5, this study narrows on those Member States in which the implementation of the European reform has consolidated (with the Regulation 178/2002). As all the Member States accessing the EU in 2004 and 2007 have this regulatory system still in the making – the Central and Eastern European Countries, but also Malta and Cyprus – I identify my scope condition in the EU 15, i.e. the countries that joined the European Union before 2004. Of these, Luxembourg was removed because of its dimensional and economic uniqueness.

	RISK ASSESSMENT	RISK MANAGEMENT	RISK COMMUNICATION
AUSTRIA	AGES Austrian Agency for Health and Food Safety	BMG Ministry of Health BMLFUW Federal Ministry of Agriculture, Forestry, Environment and Water Management BAES Federal Office for Food Safety	AGES Austrian Agency for Health and Food Safety
BELGIUM	FASFC Federal Agency for the Safety of the Food Chain FAMHP Federal Agency for Medicines and Health Products FPS Federal Public Service for Health, Food Chain Safety and Environment CODA-CERVA Veterinary and Agrochemical Research Centre WIV-ISP Scientific Institute of Public Health BSHC Belgian Superior Health Council	FASFC Federal Agency for the Safety of the Food Chain FPS Federal Public Service for Health, Food Chain Safety and Environment	FASFC Federal Agency for the Safety of the Food Chain FPS Federal Public Service for Health, Food Chain Safety and Environment
DENMARK	DTU National Food Institute, Technical University of Denmark DCA Danish Centre for Food and Agriculture DCE Danish Centre for Environment and Energy	DVFA Danish Veterinary and Food Administration DAA DFA	

FINLAND	<p>EVIRA Finnish Food Safety Authority Finnish Zoonosis Centre (of EVIRA and THL) THL National Institute for Health and Welfare FIMEA Finnish Medicines Agency TUKES Finnish Safety and Chemicals Agency VALVIRA National Supervisory Authority for Welfare and Health</p>	<p>MMM Ministry of Agriculture and Forestry STM Ministry of Social Affairs and Health EVIRA Finnish Food Safety Authority TUKES Finnish Safety and Chemicals Agency VALVIRA National Supervisory Authority for Welfare and Health Finnish Customs</p>	<p>STM EVIRA Finnish Food Safety Authority</p>
FRANCE	<p>ANSES French Agency for Food, Environmental and Occupational Health and Safety</p>	<p>MAAPRAT Ministry of Agriculture, Food, Fisheries, Rural Affairs and Land Use Planning MEFI Ministry of Economy, Finance and Industry MASS Ministry of Health and Social Affairs</p>	<p>MAAPRAT Ministry of Agriculture, Food, Fisheries, Rural Affairs and Land Use Planning MEFI Ministry of Economy, Finance and Industry MASS Ministry of Health and Social Affairs ANSES French Agency for Food, Environmental and Occupational Health and Safety</p>

GERMANY	<p>BfR Federal Institute for Risk Assessment</p> <p>RKI Robert Koch Institute</p> <p>UBA Federal Environmental Agency</p> <p>FLI Friedrich Loeffler Institute</p> <p>JKI Julius Kohn Institute</p> <p>MRI Max Rubner Institute</p>	<p>BVL Federal Office of Consumer Protection and Food Safety</p>	<p>BfR Federal Institute for Risk Assessment</p>
GREECE	<p>YAAT Ministry of Rural Development and Food</p> <p>YYKA Ministry of Health and Social Welfare</p> <p>EFET Hellenic Food Authority</p> <p>EOF The National Organization for Medicines</p>	<p>YAAT Ministry of Rural Development and Food</p> <p>YYKA Ministry of Health and Social Welfare</p> <p>EFET Hellenic Food Authority</p> <p>EOF The National Organization for Medicines</p>	<p>YAAT Ministry of Rural Development and Food</p> <p>YYKA Ministry of Health and Social Welfare</p> <p>EFET Hellenic Food Authority</p> <p>EOF The National Organization for Medicines</p>
IRELAND	<p>FSAI Food Safety Authority of Ireland</p> <p>DAFM Department of Agriculture, Food and the Marine</p> <p>Health Service Executive HSE</p>	<p>FSAI Food Safety Authority of Ireland</p> <p>DAFM Department of Agriculture, Food and the Marine</p>	<p>FSAI Food Safety Authority of Ireland</p>
ITALY	<p>Ministry of Health</p> <p>National Committee for Food Safety</p> <p>National Health Institute (ISS)</p> <p>Experimental Institutes of Zooprohylaxis</p>	<p>Ministry of Health</p> <p>MPAAF Ministry of Agriculture, Food and Forestry Policies</p>	<p>Ministry of Health</p> <p>MPAAF Ministry of Agriculture, Food and Forestry Policies</p>

LUXEMBOURG	OSQCA Organisation for the Safety and Quality of the Food Chain ASTA Agricultural Technical Services Administration ASV Veterinary Service Administration Ministry of Health SECUALIM	MAVDR Ministry of Agriculture, Viticulture and Rural Development Ministry of Health SECUALIM OSQCA Organisation for the Safety and Quality of the Food Chain ASTA Agricultural Technical Services Administration ASV Veterinary Service Administration	MAVDR Ministry of Agriculture, Viticulture and Rural Development Ministry of Health SECUALIM OSQCA Organisation for the Safety and Quality of the Food Chain
NETHERLANDS	NVWA Netherlands Food and Consumer Product Safety Authority - Office for Risk Assessment and Research (BuRO) CVI Central Veterinary Institute RIKILT Wageningen Bio-veterinary Research Institute of Food Safety RIVM National Institute of Public Health and the Environment	VWS Ministry of Health, Welfare and Sport EZ Ministry of Economic Affairs NVWA Netherlands Food and Consumer Product Safety Authority	NVWA Netherlands Food and Consumer Product Safety Authority
PORTUGAL	ASAE Economy and Food Safety Standards Authority	MAMAOT Ministry of Agriculture, Sea, Environment and Spatial Planning DGAV Food and Veterinary Directorate MEE Ministry of Economy and Employment	ASAE Economy and Food Safety Standards Authority

		ASAE Economy and Food Safety Standards Authority DGADR Directorate-General for Agriculture and Rural Development	
SPAIN	MAGRAMA Ministry of Agriculture, Food and Environment AECOSAN Spanish Food Safety and Nutrition Agency	MAGRAMA Ministry of Agriculture, Food and Environment MSSSI Ministry of Health, Social Services and Equality AECOSAN Spanish Food Safety and Nutrition Agency	AECOSAN Spanish Food Safety and Nutrition Agency
SWEDEN	LV National Food Agency SVA Swedish National Veterinary Institute	RK Ministry of Rural Affairs LV National Food Agency JV Swedish Board of Agriculture	LV National Food Agency JV Swedish Board of Agriculture SVA Swedish National Veterinary Institute
UK	FSA Food Standard Agency DEFRA Department for Environment, Food and Rural Affairs VMD Veterinary Medicines Directorate CRD Chemicals Regulation Directorate of HSE	FSA Food Standard Agency DEFRA Department for Environment, Food and Rural Affairs	FSA Food Standard Agency DEFRA Department for Environment, Food and Rural Affairs

Looking at different actors involved in the food safety regulatory process and tasks assigned to them, it is possible to detect some clusters of countries with similar institutional arrangements. On the one hand Austria, France, Germany have food safety agencies which carry out risk assessment and risk communication, as EFSA does at the EU level. On the other, in Belgium, Denmark, Finland, Greece, Ireland, the Netherlands, Portugal, Spain, Sweden and UK food safety agencies carry out both risk assessment and communication and risk management tasks. Looking at the assignment of tasks to different types of institutions, it is possible to highlight that in some countries risk assessment is carried out not only by the national food safety competent agency, but together with other institutions (both independent experts and political officials). For instance, Austria and France assigned risk assessment tasks only to the national competent food safety agency, while in Belgium risk assessment is carried out by the national food safety agency (AFSCA), together with other experts (CODA-CERVA, WIV-ISP), the Federal Agency for Medicines and Health Products (FAMHP), and the Federal Public Service for Health, Food Chain Safety and Environment (FPS) (see Table 3.2).

Table 3.2 – Risk assessment function: distribution of regulatory tasks

Country	Agency	Other expert	Ministry	Other political executive
Austria	AGES Austrian Agency for Health and Food Safety			
Belgium	FASFC Federal Agency for the Safety of the Food Chain FAMHP Federal Agency for Medicines and Health Products	CODA-CERVA Veterinary and Agrochemical Research Centre WIV-ISP Scientific Institute of Public Health		FPS Federal Public Service for Health, Food Chain Safety and Environment BSHC Belgian Superior Health Council
Denmark		DTU National Food Institute, Technical		

		University of Denmark DCA Danish Centre for Food and Agriculture DCE Danish Centre for Environment and Energy		
Finland	EVIRA Finnish Food Safety Authority FIMEA Finnish Medicines Agency TUKES Finnish Safety and Chemicals Agency VALVIRA National Supervisory Authority for Welfare and Health	Finnish Zoonosis Centre THL National Institute for Health and Welfare		
France	ANSES French Agency for Food, Environmental and Occupational Health and Safety			
Germany	BfR Federal Institute for Risk Assessment UBA Federal Environmental Agency	RKI Robert Koch Institute FLI Friedrich Loeffler Institute JKI Julius Kohn Institute MRI Max Rubner Institute		

Greece	EFET Hellenic Food Authority EOF The National Organisation for Medicines		YAAT Ministry of Rural Development and Food YYKA Ministry of Health and Social Welfare	
Ireland	FSAI Food Safety Authority of Ireland			DAFM Department of Agriculture, Food and the Marine
Italy		ISS National Health Institute Experimental Institutes of Zooprophyllaxis	Ministry of Health	National Committee for Food Safety
Netherlands	NVWA Netherlands Food and Consumer Product Safety Authority - Office for Risk Assessment and Research (BuRO)	CVI Central Veterinary Institute RIKILT Institute of Food Safety RIVM National Institute of Public Health and the Environment		
Portugal	ASAE Economy and Food Safety Standards Authority			DGAV Food and Veterinary Directorate DGADR Directorate-General for Agriculture and

				Rural Development
Spain	AESAN Spanish Food Safety and Nutrition Agency		MAGRAMA Ministry of Agriculture, Food and Environment	
Sweden	LV National Food Agency	JV Swedish Board of Agriculture SVA Swedish National Veterinary Institute		
UK	FSA Food Standard Agency		DEFRA Department for Environment, Food and Rural Affairs	VMD Veterinary Medicines Directorate CRD Chemicals Regulation Directorate

The same highlights can be made looking at the assignment of risk management tasks. In countries where risk assessment and risk management are assigned to different institutions, risk management is usually carried out by competent ministries. In those Member States where risk assessment is not strictly separated from risk management, the latter is carried out together by agencies and ministries. Some countries assigned risk management tasks to deferral offices – Austria, Belgium, and Germany – while in Portugal the Food and Veterinary Directorate (DGAV) and the Directorate General for Agriculture and Rural Development (DGADR) carry out risk management tasks together with the Ministry of Agriculture, Sea, Environment and Spatial Planning (MAMAOT), and the Economy and Food Safety Standard Authority (ASAE) (see Table 3.3).

Table 3.3 – Risk management function: distribution of regulatory tasks

Country	Agency	Ministry	Other political executive
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Austria		BMG Ministry of Health BMLFUW Federal Ministry of Agriculture, Forestry, Environment and Water Management	BAES Federal Office for Food Safety
Belgium	FASFC Federal Agency for the Safety of the Food Chain		FPS Federal Public Service for Health, Food Chain Safety and Environment
Denmark	Danish Veterinary and Food Administration DVFA Danish Agriculture Agency DAA Danish Fisheries Agency DFA		
Finland	Finnish Food Safety Authority EVIRA Finnish Safety and Chemicals Agency TUKES National Supervisory Authority for Welfare and Health VALVIRA	Ministry of Agriculture and Forestry MMM Ministry of Social Affairs and Health STM	
France		Ministry of Agriculture, Food, Fisheries, Rural Affairs and Land Use Planning MAAPRAT Ministry of Economy, Finance and Industry MEFI Ministry of Health and Social Affairs MASS	

Germany			BVL Federal Office of Consumer Protection and Food Safety
Greece	EFET Hellenic Food Authority EOF The National Organisation for Medicines	YAAT Ministry of Rural Development and Food YYKA Ministry of Health and Social Welfare	
Ireland	FSAI Food Safety Authority of Ireland		DAFM Department of Agriculture, Food and the Marine
Italy		Ministry of Health Ministry of Agriculture, Food and Forestry Policies MIPAAF	
Netherlands	Netherlands Food and Consumer Product Safety Authority NVWA	VWS Ministry of Health, Welfare and Sport EZ Ministry of Economic Affairs	
Portugal	ASAE Economy and Food Safety Standards Authority	MAMAOT Ministry of Agriculture, Sea, Environment and Spatial Planning MEE Ministry of Economy and Employment	Food and Veterinary Directorate DGAV Directorate-General for Agriculture and Rural Development DGADR
Spain	Spanish Food Safety and Nutrition Agency AECOSAN	MAGRAMA Ministry of Agriculture, Food and Environment MSSSI Ministry of Health, Social Services and Equality	
Sweden	LV National Food Agency		JV Swedish Board of Agriculture

UK	FSA Food Standard Agency	DEFRA Department for Environment, Food and Rural Affairs	
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In sum, the sector of food safety regulation is an illustrative and likely case for assessing the impact the domestic institutional features of monitoring and enforcement exert over operational outcomes and, thus, effectiveness of governance. The governance of food safety regulation is gaining regulatory importance since scandals related to foodborne diseases have raised public awareness of the importance of food safety and have triggered a regulatory response in the EU. As outlined earlier, the domestic agencies carrying out monitoring and enforcement activities on one hand and controlling information that is circulated in operational action-situations on the other serve as the units of analysis for researching explanatory factors for effectiveness.

The next chapters will present and discuss the operationalization of the outcome (chapter 4) and of the explanatory conditions (chapter 5).

CHAPTER FOUR

GAUGING THE EFFECTIVENESS OF FOOD SAFETY REGULATION

1. INTRODUCTION

In both developed and developing countries, food safety has become of major concern in the political agenda of the governments. In response to *food scares*, which occurred in the last decades, many countries have engaged into a deep regulatory reform all over the world, and particularly within the European Union. The spreading of new animal and human diseases (e.g. Escherichia Coli infections, Listeriosis, Campylobacter, Salmonella, and other foodborne illnesses), the use and the contamination of some harmful products for the human and animal health as well as for the environment (e.g. the massive use of pesticides in agriculture), shed light on the crucial role played by food safety regulation for the protection of public health. The governance of food safety regulation is a complex multi-level system of interactions between institutions (both public and private, local and global) and individuals (citizens and consumers).

Within this complex scenario, the effectiveness of food safety regulation takes centre stage, and its measures become crucial to establish what makes regulation effective and, on the other side, what hinders it.

This chapter tackles the question of how we can think of and measure effectiveness of food safety regulation. Although effectiveness is itself a highly contentious issue, it can be understood as goal achievement (Skjærseth and Wettstad, 2008; Levi-Faur, 2011; Thomann, 2018). Accordingly, the question of effectiveness entails gauges to establish whether food safety regulation realizes its objectives.

Dealing with the concept of food safety, the literature discriminates between “delivered safety” and “perceived safety”, and suggests that the effectiveness of its regulation can be measured on both dimensions (Righettini, 2015). This chapter contributes to the existing empirical literature with a new measure of delivered food safety.

The chapter is structured as follows. Section 2 introduces the concept of effective regulation; section 3 systematically evaluates existing measures; section 4 proposes a new measure of delivered food safety.

2. WHAT IS EFFECTIVE REGULATION?

Public policy literature commonly defines policy outcomes as the behavioural change needed to address a policy problem, and there is a great debate and a long tradition of defining and measuring effectiveness in public policy research. Recently, Peters and colleagues (2018) tried to disentangle questions concerning design, effectiveness, and public policy. In doing so, they argue that considerations on effectiveness can nourish a more policy-oriented debate by providing insights on the meaning of effectiveness that might be of interest to policymakers. Commonly, effective refers to *“successfully producing a desired or intended result”* and effectiveness is about *“success (outcome) and the ability to be successful (means)”* (Peters et al., 2018: 41). Peters and colleagues (2018) discuss a definition of effectiveness that is *“less about success and intended results than about the actual effects”*. Drawing upon this notion, effective means operative, existing in fact, or producing an effect, and effectiveness is about the acknowledgement of the production of an effect (Peters et al., 2018: 41-42). According to Peters and colleagues, *“it is particularly important to adopt an effectiveness questioning which encompasses both meanings: effectiveness as success in producing intended results and effectiveness as production of effects that are to be characterised”* (2018: 42).

Here, effectiveness is understood not only as production of effects but also as goal achievement (Skærseth and Wettestad, 2008; Levi-Faur, 2011; Thomann, 2018), being interested in whether domestic food safety regulatory designs succeed in resolving the food safety problems they are designed to address.

Food regulation can be defined as the set of instructions aimed at exerting an impact on food consumers and the quantity and quality of food products, as well as on food producers, processors and distributors, with regards of consequences for human health and for the environment. This definition entails the notion of food security – intended as *“the access of all people at all times to sufficient, safe, and nutritious food²¹”*, the relationship between nutrition and health, the notion of food safety – intended as *“the assurance that food will not cause harm to the consumer²²”*, and the impact of food production on the environment.

²¹ http://www.fao.org/fileadmin/templates/faoitaly/documents/pdf/pdf_Food_Security_Concept_Note.pdf

²² <http://www.fao.org/food-safety/en/>

Food safety regulation is aimed at the minimization of food-related risks, deriving from the contamination of food, feed, and water (i.e. presence of bacteria, toxic substances, etc.). The problem of food safety derives from food frauds on one hand, and from the presence of harmful substances within the products that are used during the production process on the other.

3. THE EFFECTIVENESS OF FOOD SAFETY REGULATION: EXISTING DIMENSIONS AND MEASURES

The literature dealing with the concept of food safety discriminates between “delivered safety” and “perceived safety” and suggests that the effectiveness of food safety regulation can be measured on both dimensions (Righettini, 2015). The concept refers to a set of conventionally recognized elements – a high level of protection of public health and consumers, minimization of food-related risks, prevention of food borne illnesses. The distance between delivered and perceived safety is mainly due to risk communication strategies that are implemented: it is proved that being constantly exposed to news related to food frauds, sophistication of food products, and food borne outbreaks decreases the level of perceived safety, and thus, of confidence of consumers in the capacity of governance to be effective (Righettini, 2015; Caduff and Bernauer, 2006; Ansell and Vogel, 2006). Moreover, *good news is no news* and consumers are not exposed to news on how much their food is *safe* as much as they are to news on how much their food is *unsafe*²³.

This section reviews the existing empirical literature in order to assess how effectiveness of food safety regulation has been measured.

Perceived food safety can be understood as the perception of protection of human health and consumers interests, as well as of the functioning of the internal market – being the two core objectives of the General Food Law (EU Regulation 178/2002) and, more broadly, established and recognized objectives of any food safety regulation²⁴.

Most of the existing studies focus on the willingness to pay (WTP), together with consumer preferences and behavioural insights, such as how newspaper coverage of food safety-related issues affects consumer confidence, how consumer confidence affects the willingness to pay for organic

²³ <https://www.efsa.europa.eu/en/news>

²⁴ The Codex Alimentarius identifies consumers’ health protection as its main objective, as well as ensuring fair practices in the food trade; the Food and Drugs Administration (USA) lists in its strategic plan for the period 2017-2020 the prevention of foodborne illness and the protection of public health as main goal.

products, or how the perceived safety of product groups influences general consumer confidence in the safety of food²⁵. However, existing studies are partial, often referring to few EU Member States or comparing only extra-EU countries or regions, and this makes the existing measures not suitable to respond to the research question of this study. Referring to consumers' trust towards food safety regulation in Europe, the 2010 wave of Eurobarometer survey offers some insights: EU citizens worry the most about chemical residues in foods, pollutants and animal cloning, and levels of concerns about food-related risks are generally higher than in 2005 (when the previous Eurobarometer survey was conducted); public confidence in sources of information on food safety is highest in health professionals (84%) and personal contacts (82%), followed by scientists (73%) and national and European food safety agencies (64%) and lowest in national governments (47%), food manufacturers (35%) and retailers (36%)²⁶. However, perceptions have been measured at the national level only with regard to the sources of information, while with respect to the role of public authorities in ensuring the safety of food products, perceptions have been measured only at the EU level, disregarding the perceived reliability of the national implementation process, nor citizens' confidence in their national governments and national agencies. The same considerations can be made regarding some Eurobarometer surveys on the consumers' perception of their protection within the EU market: those surveys investigated perceptions and experiences of consumers in a range of areas, including domestic and cross-border commerce, consumer confidence in online shopping, perceptions of the product safety environment and of consumer protection (particularly with respect to their rights as consumers)²⁷. However, perceptions have been measured with regard to public authorities and consumers' organizations in general (without referring to any particular public authority, neither at the EU level, nor at the domestic level), and food products were not considered.

Delivered food safety can be understood as the "objective" level of protection of human health and consumers' interests ensured by a governance system.

²⁵ See: R.M. Yeung et al., *Food safety risk: consumer perception and purchase behaviour*, 103 *British Food Journal* 170 (2001); K.G. Grunert, *Food quality and safety: consumer perception and demand*, 32(3) *European review of agricultural economics* 369 (2005); S. Naspetti, R. Zanolini, *Organic food quality and safety perception throughout Europe*, 15(3) *Journal of Food Products Marketing* 249 (2009); G.C. Harper, A. Makatouni, *Consumer perception of organic food production and farm animal welfare*, 104 *British Food Journal* 287 (2002)

²⁶ Source: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_354_en.pdf

²⁷ In particular, see Flash Eurobarometer 397 (2014) Consumer attitudes towards cross-border trade and consumer protection

<http://ec.europa.eu/COMMFronOffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/FLASH/surveyKy/2031>

Empirical literature on food safety widely refers to food safety and food safety performance (Le Vallée and Charlebois, 2015; Tuominen *et al.*, 2003; Garcia Martinez *et al.*, 2006), Food Safety Management Systems (FSMS) and their performance and effectiveness (Kirezieva *et al.*, 2013; Jacxsens *et al.*, 2011; 2010; Luning *et al.*, 2015; Osés *et al.*, 2012, Kafetzopoulos *et al.*, 2013; Vladimirov, 2011; Tomašević *et al.*, 2013; Escanciano and Santos-Vijande, 2014), compliance to regulation (Fairman and Yapp, 2004; 2005; Zorn *et al.*, 2013; Romano *et al.*, 2004; Herzfeld and Jongeneel, 2012; Henson and Heasman, 1998), transparency (Deimel *et al.*, 2008; Beulens *et al.*, 2005), food quality and Quality Assurance Systems (QAS, FSQMS) (Carcea *et al.*, 2009; Trienekens and Zuurbier, 2008; Rozan *et al.*, 2004; Manning and Baines, 2004), food authenticity (Carcea *et al.*, 2009) (see Table 4.1).

Table 4.1 – Proxies of effectiveness and their operationalizations²⁸

Proxy of effectiveness	Operationalization
Food safety	Expiry date, presence of GMOs, absence of pesticides, origin of products
Food safety performance	Number of recorded international food safety violations of traded raw and minimally processed foods. Indicators of food safety chemical risks, microbial risks, food consumption, inspections and audits

²⁸ The systematic review included several studies, among which: J.C. Le Vallée, S. Charlebois *Benchmarking Global Food Safety Performances: The Era of Risk Intelligence*, 78(10) *Journal of Food Protection* 1896 (2015); M.G. Garcia Martinez *et al.*, *Food safety performance in European Union accession countries: benchmarking the fresh produce import sector in Hungary*, 22(1) *Agribusiness* 69 (2006); K. Kirezieva *et al.*, *Assessment of food safety management systems in the global fresh produce chain*, 52(1) *Food research international* 230 (2013); P.A. Luning *et al.*, *Performance assessment of food safety management systems in animal-based food companies in view of their context characteristics: a European study*, 49 *Food Control* 11 (2015); D.P. Kafetzopoulos *et al.*, *Measuring the effectiveness of the HACCP food safety management system*, 33(2) *Food Control* 505 (2013); Z. Vladimirov, *Implementation of food safety management system in Bulgaria*, 113 *British Food Journal* 50 (2011); R. Fariman, C. Yapp, *Compliance with food safety legislation in small and micro-businesses: enforcement as an external motivator*, 3(2) *Journal of Environmental Health Research* 44 (2004); T. Herzfeld, R. Jongeneel, *Why do farmers behave as they do? Understanding compliance with rural, agricultural, and food attribute standards*, 29 *Land Use Policy* 250 (2012); S. Henson, M. Heasman, *Food safety regulation and the firm: understanding the compliance process*, 23 *Food Policy* 9 (1998); M. Deimel *et al.*, *Transparency in food supply chains: empirical results from German pig and dairy production*, *Journal on Chain and Network Science* 21 (2008); A.J. Beulens *et al.*, *Food safety and transparency in food chains and networks: relationships and challenges*, 16(6) *Food Control* 481 (2005).

Proxy of effectiveness	Operationalization
Food safety Management System (FSMS) output and Food Safety and Quality Management System (FSQMS) output	FSMS output = function of (Broad context; FSMS context; FSMS activities) operationalized through indicators of context, incentives, costs, benefits and difficulties of implementation
Compliance	Costs, barriers, drivers, benefits of compliance
Transparency	<p>Structural determinants of transparency: supply chain, product and transaction characteristics</p> <p>Behavioural determinants of transparency: cultural aspects and social embeddedness, transactors' behaviour and the quality of business relationships between suppliers and customers</p> <p>Observable effects of transparency: indicators of chain performance, perceived transparency</p>
Food quality	Price, guarantees, manufacturer's or distributor's trademark, alliances between brands, umbrella brand, origin or appellation of origin, adverts, packaging
Food authenticity	Economic adulteration of high value foods; mis description of the geographical, botanical or species origin; non-compliance with the established legislative standards and implementation of non-acceptable process practices; mis description of name of food and noncompliance with requirements of legal name; adulteration of foods or substitution with lower value ingredients; the mis description of geographical species, variety and production origin; the non-declaring of certain processes in

Proxy of effectiveness	Operationalization
	the ingredients or preparation of food; and incorrect quantitative ingredient declarations.

As summarized in Table 4.1, this strand of empirical literature has mainly relied on partial indicators of effectiveness and on single-item proxies. Most of the existing studies include surveys and / or interviews to the Food and Business Operators (FBOs), who are the target of the regulation, disregarding the positions of the regulators and of the monitoring, control and enforcement bodies, as well as of the beneficiaries of regulation, i.e. of citizens and consumers.

Specifically, food safety and food safety performance have been measured in the literature through a series of indicators, such as the expiry date, the indication of presence/absence of Genetically Modified Organisms (GMOs), the absence of pesticides and the indication of origin of the product as proxies of food safety. Accordingly, several dimensions of food safety and food safety performance have been identified and operationalized (see Table 4.2): food safety chemical risks, microbial risks, food consumption indicator, inspections and audits, food safety risk management, compliance, and food safety management systems (FSMS).

Table 4.2 – Food safety related variables

VARIABLES / DIMENSIONS	OPERATIONALIZATION
FOOD SAFETY CHEMICAL RISKS	amount of pesticides used in each of the 17 OECD countries, expressed through kilograms of active ingredients per hectare, TDS
FOOD SAFETY MICROBIAL RISKS	performance scores across each of five foodborne illnesses
FOOD CONSUMPTION INDICATOR	reporting and frequency of national food or nutrition intake surveys

INSPECTIONS AND AUDITS			rates of inspections and audits, measured by whether a country had strict risk-based inspection policies and carried out frequent inspections
FOOD SAFETY RISK MANAGEMENT			national food safety response capacity, food recalls, food traceability, and radionuclides standards
CONTEXT IN FSMS			FSMS context, activities, output: stereotypical description, performance indicators and broad context (agro-climatic, market and public policy environment, and food safety governance), product, production, organization and chain characteristics
PERFORMANCE OF FSMS			preventive measures, intervention processes, monitoring systems, control strategies, core assurance activities, setting system requirements, validation, verification, documentation and record keeping context factors, core safety control activities, core assurance activities
INCENTIVES TO IMPLEMENTATION		FSMS	increase product safety, comply with regulatory requirement, increase product quality, marketing, comply with customer requirement, access to new market (export), reduce production costs
COSTS TO IMPLEMENTATION		FSMS	Investment in new equipment, Civil works in the plant, External consultants, Product investigation/analysis, Staff training, Staff time in documenting system, System documentation, Structural changes to plant
BENEFITS TO IMPLEMENTATION		FSMS	Increased safety and quality of the products, Increased working discipline of staff, Increased customer confidence, Legal instrument against complains, Increased product shelf-life, Increased ability to access new overseas markets, Increased product sales and prices, Reduced production costs

DIFFICULTIES TO FSMS IMPLEMENTATION	Recouping costs of implementing HACCP, Need to retrain supervisory/managerial staff and production staff, Reduced staff time available for other tasks, Attitude/motivation of supervisory/managerial staff and of production staff, Reduced staff time to introduce new products, Lack of support of inspection service/governmental institutions, Lack of pre-requisite programs/good hygienic or manufacturing practice
COSTS OF COMPLIANCE	local control units (control costs, personnel costs, total food control related income), food control costs per control object (control visits, samples, notifications, administrative burden)
BARRIERS TO COMPLIANCE	money, time, experience, information, support, interest, knowledge, trust, awareness, motivation, formal management systems
DRIVERS OF COMPLIANCE	legislative requirement, industrial standard compliance, environmental protection, insurance requirements, customer pressure, improving business efficiency, employee and investors pressure

Management studies widely explored food safety management systems (FSMS) and some related variables have been considered: context factors, performance and effectiveness, as well as incentives, costs, benefits and difficulties of implementation. Those studies are conducted among FBOs, usually through surveys and/or interviews.

Among the plethora of key variables presented in the literature as a proxy of effective food safety regulation there is compliance. Literature widely discusses compliance with food safety regulation and several dimensions are generally assessed, including costs, barriers and drivers. However, none of the empirical contributions included in the review actually explained the operationalization process of the variable, and literature just identifies the major dimensions of the concept (see Table 4.2). Usually, data are collected through surveys and/or interviews to those subjects who have to comply with regulation: the FBOs. Some qualitative studies (Fairman and Yapp 2004; 2005) include interviews with experts, enforcement bodies and trade associations, in order to better understand

compliance dimensions, while Zorn and colleagues (2013) used data from a control body to make quantitative analysis.

This review reveals that existing measures aim to respond to different research questions, mainly focused on the organizational level (making use of management and performance indicators) and on the role of FBOs. This makes the existing empirical measures of delivered safety not suitable for my research question, which is aimed at investigating effectiveness of food safety regulation at the national level, and at investigating differences in the national governance designs, with respect to public authorities – regulators, monitoring and enforcement bodies, as well as national governments and agencies. To do so, comparable data on regulatory designs from EU member states are needed.

4. TOWARDS A DIFFERENT OPERATIONALIZATION OF EFFECTIVENESS

This study contributes to the existing empirical literature developing a new measure of delivered food safety. The gauge is based on the Rapid Alert System for Food and Feed (RASFF) data. As a tool that ensures *“the flow of information to enabling swift reaction when risks to public health are detected in the food chain”*²⁹, the RASFF provides notifications about food safety related risks occurring across its members (EU-28 national food safety authorities, European Commission EC, European Food Safety Authority EFSA, European Free Trade Association EFTA authority, Norway, Liechtenstein, Iceland, and Switzerland), recording original notifications together with follow-up notifications.

Regulation n. 178/2002 establishes the functioning of the RASFF (Article 35), as well as its scope and procedures (Articles 50, 51, and 52). Regulation 16/2011 lays down the implementing measures for the System, laying down the duties of the RASFF network members and defining the different types of notifications that can be transmitted and updated. The Rapid Alert System for Food and Feed plays a crucial role *“not only as a tool for information exchange, but for contributing to the safety of food and feed in the EU”*³⁰. Indeed, food safety is the result of a complex process of risk assessment, management, and communication (i.e. risk analysis) and RASFF effectiveness reflects the level of

²⁹ https://ec.europa.eu/food/safety/rasff/how_does_rasff_work/legal_basis_en

³⁰ Source: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

delivered food safety within its members (Liuzzo *et al.*, 2013; Righettini, 2015; Righettini and Bazzan, 2017).

Drawing upon this tenet enables me to develop a new measure of effectiveness, that allows for comparability across countries (i.e. all members of RASFF) and years (the RASFF portal provides information about notifications exchanged since its establishment in 1979), for which data are available and constantly updated³¹.

As outlined by the European Commission itself, the effectiveness of RASFF can be assessed in terms of achievement of its main objectives – namely, information exchange between members of the network on (a) direct or indirect risks in relation to food or feed, (b) the follow-up to notified direct or indirect risks, (c) measures to contain risk.

The new metrics understands delivered food safety as the quality of the response of the domestic system to food-related risks about which they get information through the RASFF network – exchanged information, quality of notifications transmitted, and reaction to the risk (see Table 4.3). According to the European Commission³², the number of notifications transmitted through the network provides an overview of the quantity of information exchanged by member of the RASFF, while the number of follow-up notifications is an indicator of the reactivity of the members to the risk identified. Along with Member States and the European Food Safety Authority (EFSA), the European Commission is involved in the RASFF, and is responsible for managing the network³³. This implies that the Commission must verify notifications in light of their completeness, legibility and correctness prior to transmitting them to all members of the network. Moreover, the EC must transmit alert notifications and their follow-ups to all members of the network within 24 hours after reception, upon verification³⁴. Therefore, the number of rejected notifications can be considered an indicator of quality of the notifications transmitted. As to the timing, being the EC responsible for ensuring an efficient exchange of information among the members of the network, it is not possible to assess the quality of the notifications in terms of efficiency of the members which originally transmitted them.

³¹ <https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1>

³² Source: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

³³ Art. 50 Reg. 178/2002 par. 1: [...] *The Commission shall be responsible for managing the network.* Source: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&from=en>

³⁴ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:006:0007:0010:EN:PDF>

Among the indicators described by the European Commission as indicators for the effectiveness of RASFF, the indicator of reactivity of the members to the risk identified has been selected, as recognized indicator of the contribution of the member to the safety of food and feed in the EU³⁵.

Table 4.3 – RASFF effectiveness

RASFF effectiveness	Information exchange	Follow up to notified direct or indirect risks	Measures to contain risk	Quality of notifications transmitted	Reactivity of the members to the risk identified
Indicators	Number of notifications transmitted	Number of follow up notifications	Number of follow up notifications	Number of rejected notifications	Number of follow up notifications

Source: Own elaboration from

https://ec.europa.eu/food/sites/food/files/gfl_fitc_external_study_rasf_manage_crisis.pdf

In order to control for country size, the number of notifications and follow-ups is divided for the population size (per 100000 inhabitants)³⁶. Table 4.4 shows the new gauges of effectiveness, calculated as the annual average for the period 2014-2016.

Table 4.4 – Delivered food safety across 15 EU Member States (2014-2016)

Indicators	Number of notifications transmitted (2014-2016) per 100000 inhabitants	Number of follow up notifications (2014-2016) per 100000 inhabitants	Number of rejected notifications (2014-2016) per 100000 inhabitants
Austria	0,57	2,309	0,011

³⁵ To the extent that a follow up notification signifies a reaction from another member of the network in addressing the risk identified, it can serve as an indicator for the effectiveness of the RASFF not only as a tool for information exchange, but for contributing to the safety of food and feed in the EU (Source: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en)

³⁶ Source: <https://ec.europa.eu/eurostat/web/population-demography-migration-projections/population-data>

Belgium	1,49	2,498	0,062
Denmark	1,59	2,992	0,158
Finland	1,28	1,772	0,018
France	0,35	0,668	0,012
Germany	0,40	0,698	0,032
Greece	0,56	0,764	0,046
Ireland	0,92	2,882	0,148
Italy	0,78	1,076	0,064
Luxembourg*	2,20	6,886	0,174
Netherlands	1,56	2,901	0,029
Portugal	0,33	0,853	0,077
Spain	0,37	1,325	0,075
Sweden	0,80	2,069	0,071
UK	0,49	0,554	0,026

Source: RASFF portal³⁷

Looking at the countries' performances, the best performing countries in terms of notifications transmitted are Luxembourg, Denmark, the Netherlands, Belgium and Finland, while the worse performing are Portugal, France, Spain and Germany. In terms of follow-up notifications transmitted, the best performing countries are Luxembourg, Denmark, the Netherlands and Ireland, while the worse performing are UK, France, Germany and Greece. Finally, in terms of quality of the notifications transmitted, the worse performance is the one of Luxembourg, followed by Denmark and Ireland.

³⁷ <https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1>

As to Luxembourg, data are presented, even though it is dropped from the analysis because of its dimensional and economic uniqueness. For an extensive discussion of case selection, see chapter 3.

Effectiveness plays a crucial role within the complexity of food safety governance and understanding how to measure it becomes crucial when assessing which institutional conditions affect (or hinder) effective regulation (i.e. the outcome this study wants to explain). In the attempt of giving a perspective on effectiveness of food safety regulation, my contribution to the literature is both conceptual and substantive. First, underlying the necessity of clarification in the conceptualization of effectiveness, and assessing existing measures, this study shed the light on weaknesses and strengths, drawing from definitions to measurements. Second, it proposes a new empirical measurement of effectiveness, drawing upon existing and comparable data.

The gauge is based on the Rapid Alert System for Food and Feed (RASFF) data. As a tool that ensures *“the flow of information to enabling swift reaction when risks to public health are detected in the food chain”*, the RASFF provides notifications about food safety related risks occurring across its members, recording original notifications together with follow-up notifications. The new metrics understands delivered food safety as the quality of the response of the domestic system to food-related risks about which they get information through the RASFF network – exchanged information, quality of notifications transmitted, and reaction to the risk.

Future analysis may explore further implications of the functioning of the European food alert system for effectiveness of food safety governance, expanding the analysis to the EU 28 and the other members of the RASFF network.

CHAPTER FIVE

CONDITIONS FOR EFFECTIVE GOVERNANCE OF FOOD SAFETY REGULATION: GAUGING DIFFERENCES IN NATIONAL INSTITUTIONAL DESIGNS

1. INTRODUCTION

Drawing upon the Institutional Analysis and Development framework (IAD) developed by Elinor Ostrom, chapter 2 modelled the governance of food safety as multiple and nested action-situations and identified the agencies carrying out monitoring and enforcement and exerting control over information as unit of analysis of this research. In doing so, it specified the institutional elements relevant to address the research question (i.e. which institutional features do affect effectiveness of governance of food safety regulation?) in the light of regulatory governance and design theories: independence, accountability, and policy capacity (for an extensive review, see chapter 1). Finally, it constructed the explanatory model, involving precise assumptions about a limited set of conditions and deriving precise expectations about the results of combining these conditions:

- (1) Independence of actors carrying out risk assessment
- (2) Accountability of actors carrying out risk assessment
- (3) Institutional separation of risk assessment from risk management
- (4) Capacity of actors carrying out monitoring, control, and enforcement (as part of risk management).

This chapter addresses the operationalization of the explanatory conditions, discussing the sources of data collection and the coding operations. The chapter is structured as follows. Section 2 presents and discusses operationalization of independence and accountability; section 3 discusses the institutional separation of risk assessment from risk management; section 4 presents and discusses operationalization of policy capacity. Finally, section 5 summarizes the explanatory conditions and their gauges.

2. INDEPENDENCE AND ACCOUNTABILITY

National legal frameworks and domestic regulations in the EU 15 serve as the units of analysis and my gauges of formal independence and accountability draw upon the statutory provisions governing national agencies involved in risk assessment, as function of food safety governance.

There are several approaches to quantify empirically the independence of bureaucratic organisations or agencies (Gilardi, 2008; 2005; 2002; Verhoest *et al.*, 2004; Wonka and Rittberger, 2010). Differing results are usually linked to different concepts and operationalizations of agency autonomy or independence (Wonka and Rittberger, 2010:2). Most attempts to build an index of agency independence draw upon the same elements of institutional design.

It appears plausible to take *de facto* independence as central indicator for agency effectiveness in its regulatory tasks. However, as highlighted by Abels and Kobusch (2015), some major arguments point rather to using a formal index, especially in the case of risk assessment tasks: first, risk assessment is conducted prior to any regulatory decisions, thus it is probably not subject to such exterior pressure as discretionary decision-making; second, as risk assessment is usually not occupied with single decisions, both political and industrial pressure is limited. Moreover, to rely on formal independence also seem appropriate regarding the items of the index: the executive director and the management board dispose both of a certain amount of discretion to act and hold office for an extended period of time in order to implement a long-term strategy, and the agency conserves a certain amount of discretion and control both over the use of resources and in its field of competency, being entitled to decide without checking back with government (or, in the case of EFSA, with the European Commission). This is coherent with the focus of this study on governance design, rather than on non-institutional factors, and the tenet that the institutional dimension of governance is the one on which intervention is relatively easier.

One of the most consolidated gauges of formal independence is the index developed by Gilardi (2008; 2005; 2002), who measured independence scores of 33 regulators. Several scholarly works followed (Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Koop and Hanretty, 2018; 2009; 2012; 2013), and formal independence of regulatory agencies have been investigated across countries and sectors. However, only 7 food safety national agencies are ranked, and data is no longer up to date (Gilardi, 2002). This study aims to contribute to the existing empirical literature providing formal independence and accountability measures on food safety agencies across 15 EU Member States.

The formal independence of an agency derives from its founding statute, which lays down its institutional design and determines its features (Abels and Kobusch, 2015). Hence, the founding

regulations and the statutory provisions of the national food safety agencies have served as data, which have been coded according to the items developed by Gilardi (2002). His formal independence index is composed of five dimensions: status of the agency head, status of the members of the management board, relationship with government and parliament, financial and organizational autonomy, and the extent of delegated regulatory competencies (Gilardi, 2002: 146). The indicators associated to these dimensions are described in Table 5.1. Each indicator is numerically coded on a scale from 0 to 1. Drawing upon this consolidated index ensures comparability with existing empirical measures and is in line with empirical literature which employed Qualitative Comparative Analysis (QCA) (Maggetti, 2009; 2007).

Table 5.1 – Formal independence of agencies

Dimensions and indicators	Response	Coding
Relationship with government and parliament		
Is the independence of the agency formally stated?	Yes	1
	No	0
Financial and organizational autonomy		
What is the source of the agency's budget?	fees levied on the <i>regulatees</i>	1
	both government and fees levied on <i>regulatees</i>	0,5
	government	0
How is the budget controlled?	by the agency	1
	by the accounting office or court	0,67
	by both the agency and the government	0,33
	by the government only	0
Which body decides on the agency's internal organisation?	the agency	1
	both the agency and the government	0,5
	the government	0

Which body is in charge of the agency's personnel policy (hiring and firing staff, deciding on its allocation and composition)?	the agency both the agency and the government the government	1 0,5 0
Regulatory competencies		
	the agency only the agency and another independent authority the agency and the parliament the agency and the government the agency has only consultative competencies	1 0,67 0,5 0,33 0
Status of the agency head		
Term of office	over 8 years 6 to 8 years 5 years 4 years fixed term under 4 years or under discretion of the appointer no fixed term	1 0,8 0,6 0,4 0,2 0
Who appoints the agency head?	members of management board a complex mix of the parliament and government parliament government collectively one or two ministries	1 0,67 0,5 0,33 0
Dismissal	dismissal is impossible possible, but only for reasons not related to policy	1 0,67 0,33 0

	no specific provisions for dismissal possible at the appointer's discretion	
May the agency head hold other offices in government?	No only with permission of the government Yes	1 0,5 0
Is the appointment renewable?	No Yes once Yes, more than once	1 0,5 0
Is independence a formal requirement for the appointment?	Yes No	1 0
Status of the members of the management board		
Term of office	over 8 years 6 to 8 years 5 years 4 years fixed term under 4 years or under discretion of the appointer no fixed term	1 0,8 0,6 0,4 0,2 0
Who appoints the agency head?	members of management board a complex mix of the parliament and government parliament government collectively one or two ministries	1 0,67 0,5 0,33 0
Dismissal	dismissal is impossible possible, but only for reasons not related to policy	1 0,67 0,33

	no specific provisions for dismissal possible at the appointer's discretion	0
May the agency head hold other offices in government?	No only with permission of the government Yes	1 0,5 0
Is the appointment renewable?	No Yes once Yes, more than once	1 0,5 0
Is independence a formal requirement for the appointment?	Yes No	1 0

Source: Gilardi (2002: 881-883)

Gilardi aggregate the indicators first at the dimension level, and then into a single independence index, which is the mean of the five-dimensions' indexes. This aggregation attributes the same weight to all indicators, and thus, the same relevance to all the five dimensions. This aspect can be problematic, and the question of how to weight the single dimensions will be discussed in detail in the next chapter (chapter 6), when the calibration process is addressed.

Koop and Hanretty (2018; 2009) improved on Gilardi's index, adding the literature with a separate measure of formal accountability. Gilardi's index include the dimension related to the relationship with government and parliament, asking: which are the formal obligations of the agency vis-à-vis the government and vis-à-vis the parliament? (none, presentation of an annual report for information only, presentation of an annual report that must be approved, the agency is fully accountable). Koop and Hanretty (2018) claim these dimensions as conceptually linked to accountability, and separated them from the independence index. The result is a formal accountability index, which is described in Table 5.2.

Table 5.2 – Formal accountability of agencies

Items	Response	Coding
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Is the agency required to send information upon request to government?	Yes No	1 0
Is the agency required to send information upon request to parliament?	Yes No	1 0
Is the agency required to submit an annual plan to government?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1
Is the agency required to submit an annual or multiannual plan to parliament?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1
Is the agency required to submit an annual itemized budget to government?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1
Is the agency required to submit an annual itemized budget to parliament?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1
Is the agency required to submit an annual activity report to government?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1
Is the agency required to submit an annual activity report to parliament?	No formal obligations Yes, for information Yes, for approval Fully accountable	0 0,33 0,67 1

Is the agency required to submit an annual financial report to government?	No formal obligations	0
	Yes, for information	0,33
	Yes, for approval	0,67
	Fully accountable	1
Is the agency required to submit an annual financial report to parliament?	No formal obligations	0
	Yes, for information	0,33
	Yes, for approval	0,67
	Fully accountable	1

Source: adapted from Koop and Hanretty (2018)

This study adds the empirical literature on food safety regulatory governance by recording the institutional features of independence and accountability of 15 domestic agencies and exploring their institutional diversity. Table 5.3 details the coding of one domestic food safety agency with respect to independence, and Table 5.4 with respect to accountability. Coding of the founding regulations and statutory provisions of all the national agencies under scrutiny is detailed in the Appendixes A5.1 and A5.2.

Table 5.3 – Coding of independence of the Austrian agency for food safety (AGES)

		AUS - AGES	
		TEXT	CODE
Relationship with government and parliament			0
Is the independence of the agency formally stated?	1 = Yes 0 = No	The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.	0

Financial and organizational autonomy			0,125
What is the source of the agency's budget?	fees levied on the regulatees = 1 both government and fees levied on regulatees = 0.5 government = 0	<p>(5) ... The registered capital of the Agency amounts to € 1 000 000 and must be paid in full by the Federal Minister of Health and Women as well as by the Federal Minister of Agriculture, Forestry, Environment and Water Management.</p> <p>Federal funds</p> <p>§ 12. (1) The Confederation [...] to provide a base grant of EUR 55.2313 million for 2006 and a base grant of EUR 54.5046 million per year from 2007 onwards</p> <p>[...] (3) Half of the amounts referred to in paragraphs 1, 2 and 8 shall be borne by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and by the Federal Ministry of Health and Women by the end of December 31, 2006. As of 1 January 2007, 40% of these amounts are to be borne by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and 60% by the Federal Ministry of Health and Women.</p> <p>[...]</p> <p>[...] (8) The tariff rates are hedged on the basis of the consumer price index (CPI 2010) published by the Federal Statistical Office or the index replacing it and are annual, for the first time from 1 January 2016, with effect from 1 January to adapt to each calendar year. [...]</p>	0,5

<p>How is the budget controlled?</p>	<p>by the agency = 1 by the accounting office or court = 0.67 by both the agency and the government = 0.33 by the government only = 0</p>	<p>The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year [...]</p>	<p>0</p>
<p>Which body decides on the agency's internal organisation?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.</p>	<p>0</p>

<p>Which body is in charge of the agency's personnel policy (hiring and firing staff, deciding on its allocation and composition)?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.</p>	<p>0</p>
<p>Regulatory competencies</p>	<p>the agency only = 1 the agency and another independent authority = 0.67 the agency and the parliament = 0.5 the agency and the government = 0.33 the agency has only consultative</p>	<p>Tasks of the agency § 8. (1) The Agency shall carry out the research required to fulfill its tasks and provide relevant scientific knowledge. (2) In order to achieve the objective stated in § 1 and § 1 and to protect the health of humans and livestock, the Agency shall in particular fulfill the following tasks [...] (2a) In order to achieve the objectives set out in the International Treaty on Plant Genetic Resources for Food and Agriculture, Federal Law Gazette III No. 98/2006, the Agency must fulfill the following tasks, other than subordinate departments of the Federal Ministry of Agriculture, Forestry, Environment and Forestry Water management are responsible for [...]</p>	<p>0,33</p>

	competencies = 0		
Status of the agency head			0,4883
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0	The term of office is five years.	0,6

<p>Who appoints the agency head?</p>	<p>members of management board = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0</p>	<p>The management of the agency consists of up to three members who are to be appointed in accordance with the provisions of the Staffing Act, Federal Law Gazette I No. 26/1998</p>	<p>0</p>
<p>Dismissal</p>	<p>dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the</p>	<p>No specific provisions for dismissal</p>	<p>0,33</p>

	<p>appointer's discretion = 0</p>		
<p>May the agency head hold other offices in government?</p>	<p>no = 1 only with permission of the government = 0.5 yes = 0</p>	<p>If a federal official enters into an employment relationship with the agency as managing director, then this federal official is granted leave of absence for the duration of this employment relationship.</p>	<p>1</p>
<p>Is the appointment renewable?</p>	<p>no = 1 yes once = 0.5 yes more than once = 0</p>	<p>The term of office is five years.</p>	<p>1</p>

Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0
Status of the members of the management board			0,4883
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0	The term of office is five years.	0,6
Who appoints the members of the management board?	agency's head = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively =	The management of the agency consists of up to three members who are to be appointed in accordance with the provisions of the Staffing Act, Federal Law Gazette I No. 26/1998	0

	0.33 one or two ministries = 0		
Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0	No specific provisions for dismissal	0,33

May the members of the management board hold other offices in government?	no = 1 only with permission of the government = 0.5 yes = 0	If a federal official enters into an employment relationship with the agency as managing director, then this federal official is granted leave of absence for the duration of this employment relationship.	1
Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0	The term of office is five years.	1
Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0

Table 5.4 – Coding of accountability of the Austrian agency for food safety (AGES)

		AUS - AGES	
		TEXT	CODE

<p>Is the agency required to send information upon request to government?</p>	<p>1 = Yes, 0 = No</p>	<p>(6) Within the scope of the tasks entrusted to it, the Agency shall, at the request of the Federal Minister for Health and Women or the Federal Minister for Agriculture, Forestry, Environment and Water Management, carry out the following activities: [...]</p> <p>The members of the Supervisory Board are obliged to provide comprehensive information to the respective appointing Federal Minister.</p>	<p>1</p>
<p>Is the agency required to send information upon request to parliament?</p>	<p>1 = Yes, 0 = No</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual plan to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>§ 8a. (1) The Agency shall submit an annual work program to the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management. The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year as proposed by the Agency and submitted to the management for budget preparation. The content of the work program, including any key topics in the work program, must be agreed in good time with the owners' ministries. Work program and budgeting must cover the strategic orientation of the Agency.</p>	<p>0,67</p>

<p>Is the agency required to submit an annual plan to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual itemized budget to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>§ 8a. (1) The Agency shall submit an annual work program to the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management. The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year as proposed by the Agency and submitted to the management for budget preparation. The content of the work program, including any key topics in the work program, must be agreed in good time with the owners' ministries. Work program and budgeting must cover the strategic orientation of the Agency.</p>	<p>0,67</p>

<p>Is the agency required to submit an annual itemized budget to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual activity report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual activity report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual financial report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>

Is the agency required to submit an annual financial report to parliament?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0
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Table 5.5 shows the gauges of independence and accountability of the national food safety agencies of the member states under analysis, as result of the coding of the statutory provisions.

Table 5.5 – Independence and accountability indexes of EU-15

CASE	INDEPENDENCE	ACCOUNTABILITY
AUS - AGES	0,286	0,234
BEL - FASFC	0,419	0,132
DEN - DVFA	0,399	0,198
FIN - EVIRA	0,416	0,268
FRA - ANSES	0,682	0,334
GER - BFR	0,861	0,234
GRE - EFET	0,613	0,066
IRE - FSAI	0,401	0,233
ITA - ISS	0,256	0,201
NET - NVWA	0,655	0,166
POR - ASAE	0,475	0,8
SPA - AECOSAN	0,757	0,201
SWE - LV	0,917	0,199
UK - FSA	0,406	0,399

3. INSTITUTIONAL SEPARATION OF RISK ASSESSMENT FROM RISK MANAGEMENT

The institutional separation of risk assessment from risk management is a condition which is either present or absent, hence it is coded 1 when present and 0 when absent (see Table 5.6). The coding is based on the data provided in the EU Food Safety Almanac published in 2017 by the Bundesinstitut

für Risikobewertung (BfR), the German Federal Institute for risk assessment³⁸. This document gives an overview of the competent public institutions and the structures of food safety regulatory regimes within the EU and was prepared in collaboration with EFSA. Data have been cross-checked with data found through a web-based research on the official websites of the national institutions responsible for food safety across the 15 EU countries under analysis, as well as national legal frameworks and domestic regulations concerning food safety and the distribution of regulatory competencies.

Table 5.6 – Institutional separation of risk assessment from risk management in the EU-15

COUNTRY	INSTITUTIONAL SEPARATION
AUSTRIA	1
BELGIUM	0
DENMARK	1
FINLAND	0
FRANCE	1
GERMANY	1
GREECE	0
IRELAND	0
ITALY	0
NETHERLANDS	1
PORTUGAL	0
SPAIN	0
SWEDEN	0
UK	0

4. POLICY CAPACITY

The scholarly literature offers a number of different definitions of policy capacity that highlight different dimensions. At the core of most conceptualisations is the capacity to allocate resources, knowledge and experience of staff resources, coordination and networking among individuals and organisations, monitoring and audit activities, access to and use of information and evidence. This

³⁸ Source: https://www.bfr.bund.de/en/publication/eu_almanac-192693.html

understanding is coherent with the items assessed by the Food and Veterinary Office (FVO) through its audits (conducted within the EU Member States) and with the food safety policy sector specificity: staff resources, training, coordination and networking, audits, monitoring, risk-based control systems, verification of effectiveness of controls.

My gauge of capacity is based on the evaluation reports released by the FVO on the monitoring-control-enforcement systems of each member state. Evaluations draw upon the audits conducted by the FVO on a 5-year period, and they report the progresses made by the member states implementing recommendations made by the FVO. Data have been cross checked with the legal provisions regarding food safety and statutory provisions of the domestic institutions carrying our monitoring, control, and enforcement activities.

In order to operationalize the explanatory condition, an index of responsiveness to recommendations is constructed - as a proxy of capacity - calculating the ratio between the number of actions taken by the member states in response to the recommendations made by the FVO, over the number of total recommendations received. Then, the number of actions taken over the total recommendations is cross checked with the number of actions in progress, in order to control for the number of actions still required and those labelled in the reports as *closed for other reasons* (see Table 5.7).

Table 5.7 – Capacity of monitoring-control-enforcement of risk assessment

	Action taken / Total	In progress / Total	Closed for another reasons / Total closed	Still required / Total
AUSTRIA	0,78	0,13	0,09	0,01
BELGIUM	0,94	0,05	0,00	0,01
DENMARK	0,86	0,08	0,05	0,01
FINLAND	0,83	0,10	0,08	0,00
FRANCE	0,81	0,08	0,12	0,00
GERMANY	0,78	0,04	0,19	0,00
GREECE	0,57	0,07	0,38	0,01
IRELAND	0,87	0,01	0,10	0,02
ITALY	0,70	0,05	0,26	0,01
NETHERLANDS	0,80	0,09	0,11	0,01
PORTUGAL	0,64	0,08	0,30	0,02

SPAIN	0,74	0,06	0,21	0,00
SWEDEN	0,91	0,08	0,00	0,01
UK	0,70	0,06	0,23	0,04

Food and Veterinary Office's reports address in detail the progresses made by member states on the implementation of FVO recommendations, distinguishing between horizontal and sector specific issues, including organization and implementation of official controls, monitoring, and enforcement. Therefore, the responsiveness to horizontal recommendations (considered by FVO itself as more urgent) are considered separately to sectoral ones (animal health, food of animal origin, imports of animals and food of animal origin, feeding stuffs and animal nutrition, TSE and Animal By-Products ABP, veterinary medicinal products VMP and residues, foodstuffs and food hygiene, imports of food of plant origin, plant protection products PPP and residues, animal welfare, plant health, quality labelling) (see Table 5.8). This allowed me to grasp capacity at a deeper level of analysis, and to formulate stronger theoretical arguments for the calibration process, which will be addressed in the following chapter (see chapter 6).

Table 5.8 – Horizontal and sectoral responsiveness

	Horizontal action taken / Horizontal recommendations	Sectoral action taken / Sectoral recommendations
AUSTRIA	1	0,76
BELGIUM	1	0,94
DENMARK	1	0,86
FINLAND	0,63	0,84
FRANCE	1	0,81
GERMANY	1	0,78
GREECE	1	0,57
IRELAND	1	0,87
ITALY	1	0,7
NETHERLANDS	1	0,8
PORTUGAL	1	0,64
SPAIN	0,67	0,74
SWEDEN	1	0,91

UK	0	0,7
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5. SUMMING-UP

This chapter focused on the identification of the explanatory conditions for effectiveness of food safety governance, discussing their conceptualization and operationalization (see Table 5.9).

Table 5.9 – Conceptualization and operationalization of the explanatory conditions

CONDITION	THEORY	LITERATURE	OPERATIONALIZATION
Independent Risk Assessment (INDRA)	IRAs, accountability, Regulatory State, <i>agencification</i>	Gilardi (2002, 2005), Koop and Hanretty (2018), Maggetti (2007, 2013), Gilardi and Maggetti (2011), Majone (1994, 2001)	Independence index (Gilardi, 2002, Koop and Hanretty, 2018)
Accountable Risk Assessment (ACCRA)	<i>scientification</i> of politics and politicisation of science, separation vs. integration, Two logics of delegation	Gilardi (2002, 2005), Koop and Hanretty (2018), Maggetti (2007, 2013), Gilardi and Maggetti (2011), Majone (1994, 2001, Busuioc (2009), Maggetti et al. (2013)	Accountability index (Koop & Hanretty, 2018)
Institutional separation of RA from RM (SEP)	Independent Regulatory Agencies IRAs, Regulatory State, <i>agencification</i>	Majone (2001), Weingart (1999), Abels and Kobusch (2015), Levi-Faur (2011), Ansell and Vogel (2006), Borrás <i>et al.</i> (2007)	Condition of a dichotomous nature: present (1), absent (0)
Capacity of Risk Management (CAPRM)	Policy capacity	Howlett and Ramesh (2016), Howlett (2009), Huber and McCarty	Responsiveness of MS to FVO's recommendations on

		(2004), Koop and Hanretty (2018)	monitoring, control, enforcement (RM)
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Next chapter will address in detail the calibration strategies adopted for the outcome and the explanatory conditions. The analyses of necessity and sufficiency will follow (both for effectiveness and ineffectiveness of governance), together with the discussion of results.

CHAPTER SIX

EFFECTIVE GOVERNANCE OF FOOD SAFETY REGULATION

1. INTRODUCTION

Chapter 2 modelled effective food safety governance, identifying the institutional conditions that are expected to play a difference-making role towards effectiveness and considering them in the light of regulatory governance and policy capacity literatures to code them as explanatory conditions. Drawing upon the Institutional Analysis and Development framework (Ostrom, 2005; 2011), this research engaged in theoretical work undertaken at three levels of analysis: first, it identified the institutional elements and the general relationships among them through the IAD framework, then it specified which institutional elements are particularly relevant to address the research question in the light of existing theories, and finally it constructed the explanatory model, involving precise assumptions about a limited set of conditions and deriving precise expectations about the results of combining these conditions (Ostrom, 2011: 8). Chapter 4 and chapter 5 addressed the operationalizations of the outcome and of the explanatory conditions.

This chapter aims to provide a configurational explanation of the effectiveness of food safety regulation, providing empirical evidences from the EU-15. The analyses of necessity and of sufficiency are performed, in order to identify the combinations of conditions associated with high / low effectiveness, and to investigate whether there are alternatives or complementary explanations.

The chapter is structured as follows. Section 2 discusses in detail the calibration adopted for the outcome and for the explanatory conditions, followed by the analysis of necessity (section 3). In section 4 the analysis of sufficiency is performed for the positive outcome, while section 5 presents the analysis of sufficiency for the negative outcome. Eventually, results are discussed (section 6) and the possible limitations addressed (section 7).

2. CALIBRATION OF THE EXPLANATORY CONDITIONS AND OF THE OUTCOME

Chapter 3 introduced the method used in this study (QCA) and described calibration as the process through which the membership of each case is first determined in each set, and then in each logically

possible configuration. The operation transforms the raw numerical data to set membership scores, based on a certain number of qualitative anchors or thresholds. Fuzzy sets can have an infinitely large number of possible values, and elements are not just in or out but more or less included in a given set, starting from the value 0 (completely out) to the value 1 (completely inside). Three anchor points define a set: full membership (membership score equal to 1), full non-membership (membership score equal to 0), and crossover point (membership score of 0.5). Between the extremes of full membership and full non-membership, a set can have more or less fine-grained membership scores, from four-point sets (0, 0.33, 0.67, 1) to continuous sets. Cases on different sides of the crossover point are different in kind, while cases with different memberships on the same side of the crossover point are different in degree (Ragin, 2014: 72).

Calibration has to be based on the combination of theoretical knowledge and empirical evidence (Ragin, 2014: 150; Schneider and Wagemann, 2012: 32).

Ragin (2014) proposed two different strategies for calibration: the so-called direct and indirect methods. The direct method uses a *logistic function* to fit the raw data in-between the three qualitative anchors at 1 (full membership), 0.5 (crossover point), and 0 (full non-membership). The qualitative anchors are established using criteria external to the data. The indirect method, by contrast, requires an initial grouping of cases into set-membership scores. Using a *fractional logit model*, these preliminary set-membership scores are then regressed on the raw data (Schneider and Wagemann, 2012: 35).

First, the fully-in criterion of each condition is defined, then it is discussed what it is meant by fully-out, and finally the crossover point is specified for the concepts of interests (Basurto and Speer, 2012). To calibrate the raw data, this work makes use of the direct method of calibration, and identifies the anchors through both theoretical knowledge and empirical evidence (Ragin, 2014; Schneider and Wagemann, 2012).

2.1 Institutional separation of risk assessment from risk management

The institutional separation of risk assessment from risk management is a condition of a dichotomous nature, which is either present or absent. Therefore, calibration does not apply (it applies only to fuzzy sets) and the condition has been coded with the value of 0 when absent and with the value of 1 when present (see Table 6.1).

Table 6.1 – Institutional separation of risk assessment from risk management in the EU-15

COUNTRY	INSTITUTIONAL SEPARATION
AUSTRIA	1
BELGIUM	0
DENMARK	1
FINLAND	0
FRANCE	1
GERMANY	1
GREECE	0
IRELAND	0
ITALY	0
NETHERLANDS	1
PORTUGAL	0
SPAIN	0
SWEDEN	0
UK	0

2.2 Formal independence of risk assessment

To define the criteria for membership in independent risk assessment the domestic institutions under investigation are clustered with respect to the five dimensions of independence proposed by Gilardi (2002): the stated independence of the agency, the financial and organizational autonomy, the extent of the delegated regulatory competencies, the status of the agency head, and the status of the members of the management board. As highlighted in chapter 4, the items conceptually linked to accountability have been excluded (Koop and Hanretty, 2018).

Gilardi's coding of the items of independence provides for a 4-point ordinal scale (0, 0.33, 0.67, 1) and the output is a fuzzy score which determines the membership into the set of formally independent agency³⁹. As to the responses to the items, the point of maximum ambivalence corresponds to 0,5 and it was assigned either when foreseen by Gilardi's coding, or when the

³⁹ For some responses Gilardi provides for a 6-point ordinal scale (0, 0.2, 0.4, 0.6, 0.8, 1) or a 3-point ordinal scale (0, 0.5, 1). When Gilardi's coding provided for a 4-point ordinal scale with different anchors (0, 0.25, 0.75, 1) it has been changed with the anchors: 0, 0.33, 0.67, 1 in order to guarantee comparability of membership scores across conditions.

available response drawn from data (the statutory provisions or the institutive law) was ambiguous, or no specific provisions were available⁴⁰.

In order to construct the index, there are two possible operations: algebraic and Boolean aggregation. Algebra simply aggregates the items calculating the average, so that different scoring among dimensions always compensate for each other. By contrast, Boolean logic enables us to use AND and OR operations, depending if the dimensions are substitutable or not and, thus, on the contribution of each dimension to the concept of interest. In order to test robustness of the measures, dimensions are first aggregated through algebraic average, and then they are aggregated through Boolean logic, testing for different calibration strategies.

In most of the countries under investigation, risk assessment is coordinated by the national food safety agency and carried out by the agency itself or by the agency together with ministries and/or other independent experts. Therefore, the calibration strategies entail membership of the country to the set of independent risk assessment is given assigning the score of independence to the national food safety agency, as the leading institution in carrying out the regulatory function. This is also coherent with the conceptualization used by scholars in the field of regulation and *agencification* studies, among who Gilardi (2002), Maggetti (2007), Levi-Faur (2011).

The algebraic average led to assign the following membership scores (see Table 6.2).

Table 6.2 – Algebraic calibration of independence

CASE	ALGEBRAIC AGGREGATION
AUS - AGES	0,286
BEL - FASFC	0,419
DEN - DVFA	0,399
FIN - EVIRA	0,416
FRA - ANSES	0,682
GER - BFR	0,861
GRE - EFET	0,613
IRE - FSAI	0,401
ITA - ISS	0,256
NET - NVWA	0,655

⁴⁰ For instance, the item “Is the mandate renewable?” provides for the following coding for the responses: No = 1, Yes once = 0.5, Yes, more than once = 0 (Gilardi 2005). When no specific provisions were found in the data and there was no pre-set coding (in Gilardi 2005) the response was coded 0,5 as point of maximum ambivalence.

POR - ASAE	0,475
SPA - AECOSAN	0,757
SWE - LV	0,917
UK - FSA	0,406

The Boolean aggregation is done drawing upon the *weakest link* theory, according to which a system capacity to function depends on the weakest of a list of underlying building blocks (Lucas, 1988; Williamson, 2005; Camerer and Knez, 1997). The Boolean logic is used to build an intersection (AND operation), assigning the score of the weakest performing dimension of independence to the agency. As outlined in chapter 5, Gilardi's index is composed of five dimensions: status of the agency head, status of the members of the management board, relationship with government and parliament, financial and organizational autonomy, and the extent of delegated regulatory competencies (Gilardi, 2002: 146). After the exclusion of those indicators conceptually linked to accountability, which need a separate investigation (Koop and Hanretty, 2018), the indicators associated to the five dimensions are 18 (see Table 5.1). The dimension of the relationship with government and parliament (first dimension) is made of one indicator of formal status of independence of the agency. The dimension of financial and organizational autonomy (second dimension) is made of 4 indicators which ask the source of the agency's budget, how is the budget controlled, the control over the agency's internal organization and of human resources. The third dimension is made of one indicator which asks the extent of delegated regulatory competencies. Finally, the dimensions related to the status of the agency head (fourth dimension) and of the management board (fifth dimension) are made of 6 indicators (each), asking for term of office, the appointment procedure, dismissal, the renewability of the appointment, the compatibility with other offices and formal requirements of independence (Gilardi, 2002; 2008; Maggetti, 2007; Maggetti, 2009; Maggetti and Gilardi, 2011). The aggregation of the single indicators has been made following Gilardi (2002), who aggregated the items at the level of each dimension through the algebraic average. This is coherent with previous works (Gilardi, 2002; 2008; Maggetti, 2007; Maggetti, 2009; Maggetti and Gilardi, 2011) and draws on the assumption that each indicator composing the dimension have the same weight, namely the same relevance. The Boolean aggregation of the dimensions towards the single independence index enables me to assess the relevance of every dimension for my concept of interest, and of adding the literature with the

consideration that it may be reasonable to assume that the performance of the weakest dimension better reflects the performance of the agency in its entirety (see Table 6.3)⁴¹.

Table 6.3 – Boolean calibration of independence

CASE	DIM 1	DIM 2	DIM 3	DIM 4	DIM 5	BOOLEAN AGGREGATION
AUS - AGES	0	0,125	0,33	0,488	0,488	0,125
BEL - FASFC	0	0,208	1	0,277	0,61	0,208
DEN - DVFA	0	0,583	0,33	0,5	0,583	0,33
FIN - EVIRA	0	0,583	1	0,19	0,305	0,305
FRA - ANSES	1	0,875	1	0,31	0,227	0,227
GER - BFR	1	0,583	1	0,5	0,5	0,583
GRE - EFET	0	0,875	1	0,623	0,567	0,567
IRE - FSAI	1	0,25	0	0,405	0,35	0,25
ITA - ISS	0	0,125	0,33	0,372	0,455	0,125
NET - NVWA	1	0,5	1	0,388	0,388	0,388
POR - ASAE	0	0,625	1	0,305	0,445	0,305
SPA - AECOSAN	1	0,793	1	0,427	0,567	0,427
SWE - LV	1	0,75	1	0,5	0,5	0,75
UK - FSA	0	0,333	1	0,39	0,307	0,333

2.3 Formal accountability of risk assessment

As to accountability, the same reasoning applied in defining membership criteria to calibrate formal independence has been followed. Koop and Hanretty's (2018) accountability index is made of 10 indicators, developed on the basis of the two indicators proposed by Gilardi (2002) with respect to the dimensions of the relationships with government and parliament, which are: what are the formal obligations of the agency vis-à-vis the government and vis-à-vis the parliament? (on a scale which goes from "no formal obligations" to "fully accountable").

⁴¹ Dimension 1 is either present or absent, hence it has be excluded for the Boolean aggregation.

Then, the indicators proposed by Koop and Hanretty (2018) are aggregated with respect to accountability to government and accountability to parliament, as distinct dimensions of accountability. Thus, the indicators related to accountability to government are separated from those related to accountability to parliament. This way, the accountability index comprises two dimensions, which are made of 5 indicators each: send information upon request, is the agency requested to submit an annual plan, submit an annual itemized budget, submit an annual activity report, and submit an annual financial report.

In order to ensure coherence across measures, the coding made by Koop and Hanretty (2018), which provided for a 3-point ordinal scale (0.0, 0.75, 1.0), has been redefined, providing for a 4-point ordinal scale (0.0, 0.33, 0.67, 1.0) as Gilardi's index (2002). The 4-point ordinal scale goes from "no formal obligations" (0.0), "yes, for information" (0.33), "yes, for approval" (0.67), to the agency is "fully accountable" (1.0). The coding output is a fuzzy score which determines the membership into the set of formally accountable attribute. Applying the same calibration strategies applied for formal independence, dimensions have been first aggregated through algebraic average (see Table 6.4), then through Boolean logic, through the AND operation (see Table 6.5).

Table 6.4 – Algebraic aggregation of accountability

CASE	ALGEBRAIC AGGREGATION
AUS - AGES	0,234
BEL - FASFC	0,132
DEN - DVFA	0,198
FIN - EVIRA	0,268
FRA - ANSES	0,334
GER - BFR	0,234
GRE - EFET	0,066
IRE - FSAI	0,233
ITA - ISS	0,201
NET - NVWA	0,166
POR - ASAE	0,8
SPA - AECOSAN	0,201
SWE - LV	0,199

UK - FSA	0,399
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Table 6.5 – Boolean aggregation of accountability

CASE	TO GOVERNMENT	TO PARLIAMENT	BOOLEAN AGGREGATION
AUS - AGES	0,468	0	0
BEL - FASFC	0,198	0,066	0,066
DEN - DVFA	0,264	0,132	0,132
FIN - EVIRA	0,268	0,268	0,268
FRA - ANSES	0,468	0,2	0,2
GER - BFR	0,468	0	0
GRE - EFET	0,132	0	0
IRE - FSAI	0,466	0	0
ITA - ISS	0,268	0,134	0,134
NET - NVWA	0,332	0	0
POR - ASAE	0,8	0,8	0,8
SPA - AECOSAN	0,402	0	0
SWE - LV	0,398	0	0
UK - FSA	0,332	0,466	0,332

2.4 Capacity

As to policy capacity of monitoring and enforcement, this study measured the responsiveness of the Member States under analysis with respect to the recommendations made by the Food and Veterinary Office (FVO), a directorate of the Directorate General for Health and Food Safety of the European Commission. The FVO works to ensure effective control systems and to evaluate compliance of the Member States to the EU standards. To do so, it makes recommendations to Member States to deal with any shortcomings revealed during its audits. Member States have to take appropriate follow-up action in the light of recommendations resulting from FVO's controls (as required by EU Regulation n. 882/2004).

Table 6.6 – Capacity index

	action taken / total	In progress / tot	Closed for other reasons / tot closed	Still required / tot	CODED
AUSTRIA	0,78	0,13	0,09	0,01	0,78
BELGIUM	0,94	0,05	0,00	0,01	0,94
DENMARK	0,86	0,08	0,05	0,01	0,86
FINLAND	0,83	0,10	0,08	0,00	0,83
FRANCE	0,81	0,08	0,12	0,00	0,81
GERMANY	0,78	0,04	0,19	0,00	0,78
GREECE	0,57	0,07	0,38	0,01	0,57
IRELAND	0,87	0,01	0,10	0,02	0,87
ITALY	0,70	0,05	0,26	0,01	0,70
NETHERLANDS	0,80	0,09	0,11	0,01	0,80
PORTUGAL	0,64	0,08	0,30	0,02	0,64
SPAIN	0,74	0,06	0,21	0,00	0,74
SWEDEN	0,91	0,08	0,00	0,01	0,91
UK	0,70	0,06	0,23	0,04	0,70

Calibration is done with the direct method (Ragin, 2014; Schneider and Wagemann, 2012): using the function *threshold setter*⁴² (Duşa, 2007) natural gaps in the distribution of the cases are identified, and the three thresholds for complete exclusion (0.67), complete inclusion (0.845), and crossover point (0.76) are settled.

The second calibration strategy is the result of a *back and forth dialogue with the cases and theory*. The Food and Veterinary Office (FVO)'s reports address in detail the progresses made by the Member States on the implementation of the recommendations FVO made, distinguishing between horizontal and sectoral-specific issues. Horizontal recommendations refer to horizontal provisions of Regulation n. 882/2004 *on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, considered by the FVO more urgent. Sectoral-specific recommendations refer to specific provisions regarding animal health, food of

⁴² Dusa, Adrian (2007) User manual for the QCA(GUI) package in R. Journal of Business Research 60(5), 576-586.

animal origin, imports of animals and food of animal origin, feeding stuffs and animal nutrition, TSE and Animal By-Products ABP, veterinary medicinal products VMP and residues, foodstuffs and food hygiene, imports of food of plant origin, plant protection products PPP and residues, animal welfare, plant health, and quality labelling. Drawing upon this distinction (between responsiveness to horizontal and to sector-specific recommendations) the Boolean logic is applied to build an intersection (AND operation), assigning the score of the weakest performing dimension of responsiveness (see Table 6.7).

Table 6.7 – Boolean aggregation of capacity

	Horizontal action taken / horizontal recommendations	Sectoral action taken / sectoral recommendations	CODED
AUSTRIA	1	0,76	0.76
BELGIUM	1	0,94	0.94
DENMARK	1	0,86	0.86
FINLAND	0,63	0,84	0.63
FRANCE	1	0,81	0.81
GERMANY	1	0,78	0.78
GREECE	1	0,57	0.57
IRELAND	1	0,87	0.87
ITALY	1	0,7	0.7
NETHERLANDS	1	0,8	0.8
PORTUGAL	1	0,64	0.64
SPAIN	0,67	0,74	0.67
SWEDEN	1	0,91	0.91
UK	0	0,7	0.0

2.5 Effectiveness

Chapter 4 conceptualized and operationalized effectiveness of food safety regulation, drawing upon the literature which discriminates between “delivered safety” and “perceived safety”, and suggests that the effectiveness of its regulation can be measured on both dimensions (Righettini, 2015).

My gauge of effectiveness is based on the Rapid Alert System for Food and Feed (RASFF) data. As a tool that ensures “*the flow of information to enabling swift reaction when risks to public health are detected in the food chain*”, the RASFF provides notifications about food safety related risks occurring across its members, recording original notifications together with follow-up notifications. As outlined by the European Commission itself, the effectiveness of RASFF can be assessed in terms of achievement of its main objectives – namely, information exchange between members of the network on (a) direct or indirect risks in relation to food or feed, (b) the follow up to notified direct or indirect risks, (c) measures to contain risk. Among the indicators described by the European Commission as indicators for the effectiveness of RASFF, the indicator of reactivity of the members to the risk identified has been selected, as recognized indicator of the contribution of the member to the safety of food and feed in the EU⁴³.

In order to control for country size, the number of notifications and follow-ups is divided for the population size (per 100000 inhabitants)⁴⁴. Table 6.8 shows the gauges of effectiveness, calculated as the annual average for the period 2014-2016.

Table 6.8 – Delivered food safety across 15 EU Member States (2014-2016)

Indicators	Number of notifications transmitted (2014-2016) per 100000 inhabitants	Number of follow up notifications (2014-2016) per 100000 inhabitants	Number of rejected notifications (2014-2016) per 100000 inhabitants
Austria	0,57	2,309	0,011
Belgium	1,49	2,498	0,062
Denmark	1,59	2,992	0,158
Finland	1,28	1,772	0,018
France	0,35	0,668	0,012
Germany	0,40	0,698	0,032

⁴³ To the extent that a follow up notification signifies a reaction from another member of the network in addressing the risk identified, it can serve as an indicator for the effectiveness of the RASFF not only as a tool for information exchange, but for contributing to the safety of food and feed in the EU (Source: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en)

⁴⁴ Source: <https://ec.europa.eu/eurostat/web/population-demography-migration-projections/population-data>

Greece	0,56	0,764	0,046
Ireland	0,92	2,882	0,148
Italy	0,78	1,076	0,064
Luxembourg*	2,20	6,886	0,174
Netherlands	1,56	2,901	0,029
Portugal	0,33	0,853	0,077
Spain	0,37	1,325	0,075
Sweden	0,80	2,069	0,071
UK	0,49	0,554	0,026

Source: RASFF portal⁴⁵

Calibration is done with the direct method (Ragin, 2014; Schneider and Wagemann, 2012): using the function *threshold setter*⁴⁶ (Duşa, 2007) natural gaps in the distribution of the cases are identified, and the three thresholds for complete exclusion (0.965), complete inclusion (2.19), and crossover point (1.535) are settled.

2.6 Summing up

This section discussed in detail the calibration strategies adopted for the outcome and for the explanatory conditions. Table 6.9 presents the calibrated dataset⁴⁷. In the next sections the analyses of necessity and of sufficiency are performed⁴⁸.

Table 6.9 – Calibrated dataset

CASE	SEP	INDRA	ACCRA	CAPRM	EFF
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⁴⁵ <https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1>

As to Luxembourg, data are presented, even though it is dropped from the analysis because of its dimensional and economic uniqueness.

⁴⁶ Dusa, Adrian (2007) User manual for the QCA(GUI) package in R. Journal of Business Research 60(5), 576-586.

⁴⁷ Here, I present the 'algebraic' calibration of the conditions. This is coherent with previous works (Gilardi, 2002; 2008; Maggetti, 2007; Maggetti, 2009; Maggetti and Gilardi, 2011).

⁴⁸ The R script, outputs, XY plots of individual conditions and all additional materials can be found in the Appendixes. To run the analyses, I relied on: Dusa, Adrian (2007) User manual for the QCA(GUI) package in R. Journal of Business Research 60(5), 576-586.

AUS - AGES	1	0,29	0,23	0,666	0,970
BEL - FASFC	0	0,42	0,13	0,998	0,987
DEN - DVFA	1	0,4	0,2	0,969	0,998
FIN - EVIRA	0	0,42	0,27	0,918	0,742
FRA - ANSES	1	0,68	0,33	0,849	0,011
GER - BFR	1	0,86	0,23	0,666	0,013
GRE - EFET	0	0,61	0,07	0,002	0,017
IRE - FSAI	0	0,4	0,23	0,978	0,997
ITA - ISS	0	0,26	0,2	0,123	0,087
NET - NVWA	1	0,66	0,17	0,799	0,997
POR - ASAE	0	0,48	0,8	0,019	0,028
SPA - AECOSAN	0	0,76	0,2	0,342	0,229
SWE - LV	0	0,92	0,2	0,994	0,917
UK - FSA	0	0,41	0,4	0,123	0,006

3. ANALYSIS OF NECESSITY

First, the directional expectations about isolated effects of each explanatory condition are outlined, as discussed in chapter 2 (see Table 6.10).

Table 6.10 – Directional expectations

Condition	Ceteris paribus, condition produces effective governance when...	Ceteris paribus, condition produces ineffective governance when...
Institutional separation of RA from RM	Present	Absent
Independence of RA	High	Low
Accountability of RA	High	Low
Policy capacity of RM	High	Low

Directional expectations are based on theoretical and empirical knowledge and help to distinguish between plausible (easy) from implausible (difficult) counterfactuals (Ragin, 2008). This study focuses on the three main aspects of complex causation, which are conjunctural causation, asymmetrical causation, and equifinality (Schneider and Wagemann, 2012). Conjunctural causation implies that conditions will unfold their effect only in combination: H1 claims that $IND * ACC \rightarrow EFF$ and expects that independence and accountability of the agencies carrying out risk assessment will produce effective governance in combination. Moreover, H2 expects the institutional separation of risk assessment from risk management, as explanatory condition of institutional design, will contribute to the occurrence of a positive response. Indeed, H2 claims that $SEP \rightarrow EFF$. As to equifinality, it allows for different, mutually non-exclusive explanations of the same phenomenon: H3 claims that $CAP \rightarrow EFF$ and expects capacity to play a prominent role for effectiveness of food safety regulation.

This study wants to assess whether the explanatory conditions related to institutional designs (i.e. independence, accountability, and separation of regulatory aims) will unfold their effect in combination with the explanatory condition of policy capacity, or whether the two explanations will be mutually non-exclusive for the occurrence of effectiveness.

Finally, effectiveness is expected to have a different explanation than ineffectiveness. Indeed, asymmetrical causation implies that appropriate performance can have a different explanation than deficient performance.

Table 6.11 – Analysis of necessity

Condition	Effective food safety governance EFF			Ineffective food safety governance ~EFF		
	Consistency	RoN	Coverage	Consistency	RoN	Coverage
SEP	0.427	0.818	0.598	0.287	0.751	0.402
~SEP	0.573	0.501	0.446	0.713	0.555	0.554
INDRA	0.557	0.637	0.515	0.636	0.673	0.588
~INDRA	0.554	0.748	0.604	0.475	0.709	0.517
ACCRA	0.256	0.847	0.490	0.374	0.909	0.716
~ACCRA	0.851	0.455	0.577	0.733	0.413	0.496
CAPRM	0.918	0.733	0.761	0.360	0.483	0.298
~CAPRM	0.152	0.654	0.192	0.711	0.936	0.896

Necessity is identified by two measures: consistency, which quantifies the strength of the relation, and coverage, which indicates the empirical relevance of the relationship to cases. A condition is necessary when the consistency of necessity is higher than 0.95 (Schneider and Wagemann, 2012). The analysis of necessity reveals that none of the conditions is necessary, even though it emerges that non-accountability of risk assessment (\sim ACCRA) and capacity of risk management (CAPRM) prove to be of some necessity for the explanation of EFF, thus playing a prominent role for an effective response. As to ineffectiveness, none of the conditions are strictly necessary.

4. SUFFICIENT CONDITIONS FOR EFFECTIVE FOOD SAFETY GOVERNANCE

For the analysis of sufficiency, a truth table is constructed (see Table 6.12). The rows of the truth table describe all possible combinations of conditions. This allows us to attribute the cases accordingly to the truth table and to identify empirically unobserved configurations (so-called logical remainders).

Table 6.12 – Truth table for effective food safety governance

	SEP	INDRA	ACCRA	CAPRM	OUT	n	incl	PRI	cases
2	0	0	0	1	1	3	0.930	0.901	BEL, FIN, IRE
6	0	1	0	1	1	1	0.900	0.864	SWE
10	1	0	0	1	0	2	0.789	0.783	AUS, DEN
14	1	1	0	1	0	3	0.512	0.501	FRA, GER, NET
3	0	0	1	0	0	1	0.300	0.018	POR
5	0	1	0	0	0	2	0.213	0.011	GRE, SPA
1	0	0	0	0	0	2	0.211	0.011	ITA, UK
4	0	0	1	1	?	0	-	-	
7	0	1	1	0	?	0	-	-	
8	0	1	1	1	?	0	-	-	
9	1	0	0	0	?	0	-	-	
11	1	0	1	0	?	0	-	-	
12	1	0	1	1	?	0	-	-	
13	1	1	0	0	?	0	-	-	
15	1	1	1	0	?	0	-	-	

16	1	1	1	1	?	0	-	-	
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The analyses of sufficiency can operate three kinds of *minimizations*. This operation – i.e. logical minimization - is a procedure based on basic set theory: $A*B*C + A*B*\sim C$ can be *minimized* to $A*B$. The first minimization treats only the configurations of the *empirically true* cases, finding *complex* solutions. The second makes use of both true configurations and the ones *empirically unobserved* that are still logically possible (i.e. logical remainders), regardless their plausibility. Doing so, it finds the *parsimonious* solution. The third also minimizes both true configurations and logical remainders, but only the *plausible* ones – namely those which are consistent with the theoretical expectations about the contribution of the condition to the occurrence of the outcome. Here, logical remainders “truly act as counterfactuals and provide ‘intermediate’ solutions detailed enough to allow understanding and learning, but also general enough to transcend the singularity of cases” (Damonte, 2014: 34).

To evaluate the results, we use consistency and coverage measures. The values of these fit measures can range from 0 (low) to 1 (high). Consistency is the extent to which the results are in line with the statements of necessity or sufficiency. For sufficient conditions, consistency is described for single truth table rows (raw consistency), for single configurations, or for the entire solution term. The proportional reduction in inconsistency (PRI) describes the degree to which a given configuration is not simultaneously sufficient for both the occurrence and the non-occurrence of the outcome.

Coverage sufficiency features how well the model explains the available empirical information. Raw coverage describes how much a single configuration covers, and unique coverage indicates how much it uniquely covers. Low coverage means that the model has a limited capacity to explain the outcome. For necessary conditions, coverage expresses their relevance in terms of the condition set not much larger than the outcome set, and the relevance of necessity (RoN) in terms of the condition close to a constant.

Setting raw consistency thresholds is decisive for determining which conditions are sufficient. Since consistency values strongly depend on the specific dataset, truth table, and case distributions, there are no fixed anchors for setting these thresholds (Thomann *et al.*, 2018). However, Schneider and Wagemann (2010) set anchors at 0.95 for necessity and 0.85 for sufficiency. In this study, in order to evaluate the accuracy of the explanatory model - i.e. the degree to which observations correspond to set relation – I set the necessity threshold at least ≥ 0.95 and the sufficiency threshold at least ≥ 0.85 .

The analysis finds one path explaining the positive outcome: $\sim\text{SEP}*\text{CAPRM} \Rightarrow \text{EFF}$ with a consistency score of 0.882, a PRI equal to 0.860, and a coverage of 0.567 for the parsimonious solution. The cases explained by the solution are Belgium, Finland, Ireland, and Sweden.

The complex solution describes $\sim\text{SEP}*\sim\text{ACCRA}*\text{CAPRM} \Rightarrow \text{EFF}$ as the sufficient path to effectiveness, with a consistency score of 0.930, a PRI equal to 0.914 and a coverage of 0.502.

For the purpose of constructing the intermediate solution, directional expectations are specified, assuming that the presence of the explanatory conditions contributes to the effectiveness of governance. The intermediate solution finds $\sim\text{SEP}*\text{CAPRM} \Rightarrow \text{EFF}$ as sufficient path, with a consistency score of 0.882, a PRI equal to 0.860, and a coverage of 0.567.

The final test for the explanatory capacity of the model requires verifying how the cases under analysis scatter in the XYplot (Schneider and Grofman, 2006). The XYplot shows the distribution of cases by their fuzzy membership scores to the outcome and to the condition or the solution. The main diagonal, where $y = x$, is where cases fall for which the presence of the condition x is together necessary and sufficient to the occurrence of the outcome y . Below ($y < x$), x is necessary to y and sufficient above ($y > x$). A good solution has to result in: (a) all the positive cases ($y > 0.5$) also displaying the solution ($x > 0.5$) and lying above the diagonal ($y > x$) and (b) all the negative cases ($y < 0.5$) not displaying the solution ($x < 0.5$).

Figure 6.1 – XY plot of cases by positive outcome and parsimonious solution

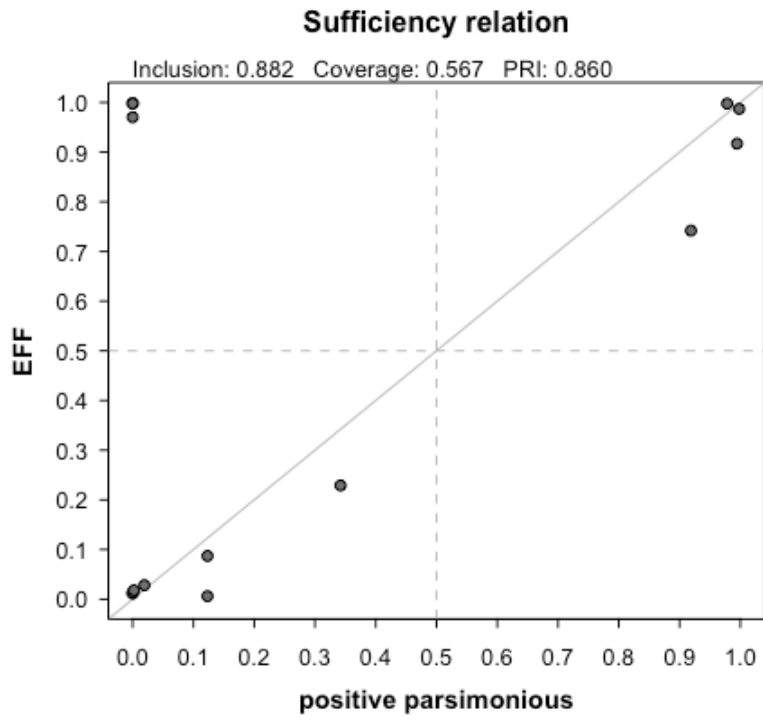
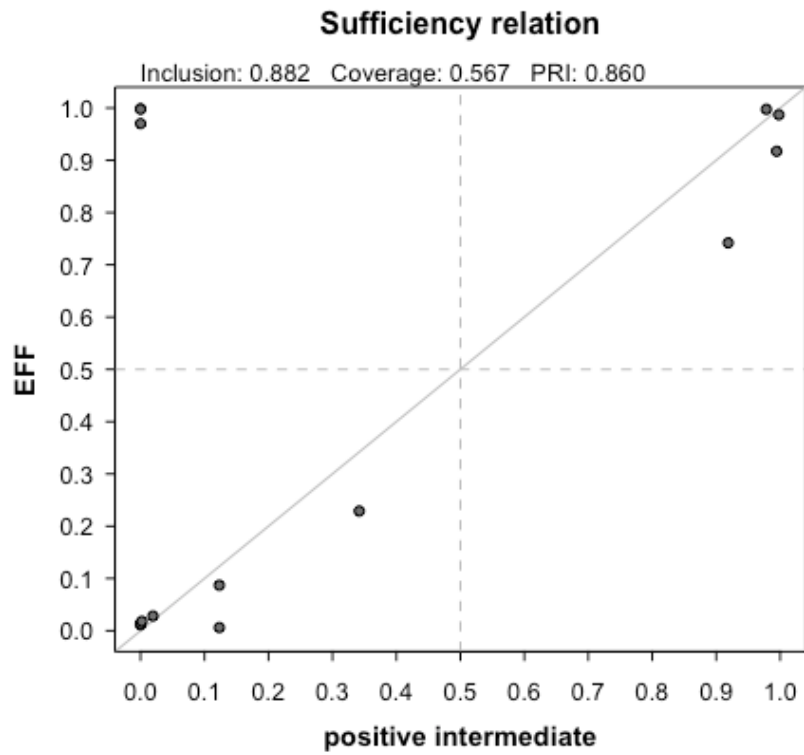


Figure 6.2 – XY plot of cases by positive outcome and intermediate solution



5. SUFFICIENT CONDITIONS FOR INEFFECTIVE FOOD SAFETY GOVERNANCE

The analysis of sufficiency for ineffective food safety governance is performed here. Table 6.13 shows the truth table for ineffectiveness.

Table 6.13 – Truth table for ineffective food safety governance

	SEP	INDRA	ACCRA	CAPRM	OUT	n	incl	PRI	cases
1	0	0	0	0	1	2	0.992	0.989	ITA, UK
5	0	1	0	0	1	2	0.991	0.989	GRE, SPA
3	0	0	1	0	1	1	0.987	0.982	POR
14	1	1	0	1	0	3	0.510	0.499	FRA, GER, NET
2	0	0	0	1	0	3	0.367	0.099	BEL, FIN, IRE
6	0	1	0	1	0	1	0.364	0.136	SWE
10	1	0	0	1	0	0	0.239	0.217	AUS, DEN
4	0	0	1	1	?	0	-	-	
7	0	1	1	0	?	0	-	-	
8	0	1	1	1	?	0	-	-	
9	1	0	0	0	?	0	-	-	
11	1	0	1	0	?	0	-	-	
12	1	0	1	1	?	0	-	-	
13	1	1	0	0	?	0	-	-	
15	1	1	1	0	?	0	-	-	
16	1	1	1	1	?	0	-	-	

The analysis of sufficiency identifies $\sim\text{CAPRM} \Rightarrow \sim\text{EFF}$ with a consistency score of 0.896, a PRI equal to 0.886 and a coverage of 0.711 for the parsimonious solution. The cases explained by the solution are Italy, UK, Portugal, Greece, and Spain.

The complex solution describes $\sim\text{SEP} * \sim\text{INDRA} * \sim\text{CAPRM} + \sim\text{SEP} * \sim\text{ACCRA} * \sim\text{CAPRM} \Rightarrow \sim\text{EFF}$ as the sufficient paths to ineffectiveness, with a consistency score of 0.995, a PRI equal to 0.994 and a coverage of 0.514.

For the purpose of constructing the intermediate solution, directional expectations are specified, assuming that the absence of the explanatory conditions contributes to the ineffectiveness of governance. The intermediate solution finds $\sim\text{SEP}^*\sim\text{INDRA}^*\sim\text{CAPRM} + \sim\text{SEP}^*\sim\text{ACCRA}^*\sim\text{CAPRM} \Rightarrow \sim\text{EFF}$ as sufficient paths with a consistency score of 0.995, a PRI equal to 0.994 and a coverage of 0.514.

Figures 6.3 and 6.4 show the XY plots of cases by negative outcome and parsimonious solution (Figure 6.3) and intermediate solution (Figure 6.4).

Figure 6.3 – XY plot of cases by negative outcome and parsimonious solution

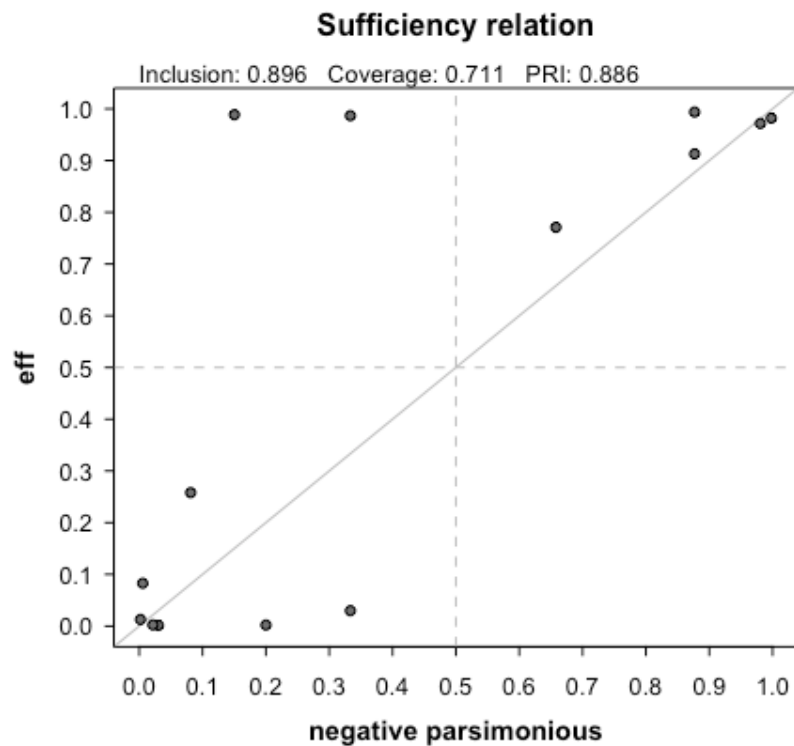
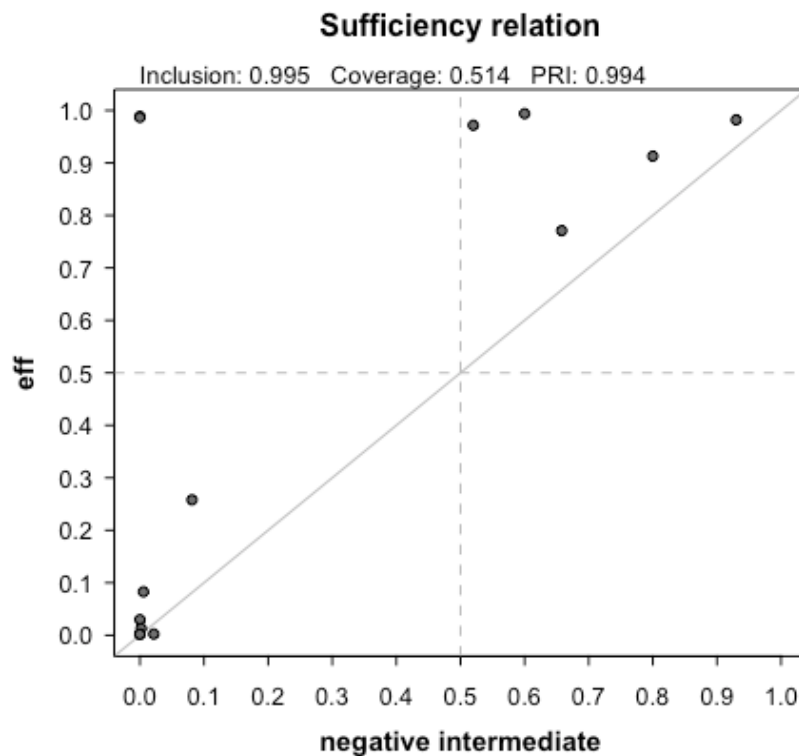


Figure 6.4 – XY plot of cases by negative outcome and intermediate solution



6. DISCUSSION OF THE RESULTS

As to the analysis of sufficiency for the positive outcome, the solutions identify \sim SEP*CAPRM as path for effective food safety governance, revealing the prominent role of capacity in producing an effective response. This is in line with the theoretical expectations: H3 claims CAPRM \rightarrow EFF and this is also proved by the high consistency of the necessity of capacity (which is equal to 0.918).

As to the assumption on conjunctural causation, capacity unfolds its effect on the occurrence of the outcome in combination with an integrated model of distribution of regulatory aims. This explanation of effectiveness reveals that capacity can unfold its effect only in combination with some type of institutional arrangement, providing insights on the complementarity of institutional design's theory and policy capacity's theory. Indeed, as claimed by Howlett, capacity is a factor affecting effectiveness and efficiency of any single governance mode (Howlett, 2009; Howlett and Ramesh, 2016) and "*governance is intimately linked to policy success and, therefore, to policy capacity*" (Howlett and Ramesh, 2016: 302). This understanding of capacity of risk management allows also to investigate the possible implication of the risk of capture. As highlighted in chapter 1, in the debate about why regulatory agencies fail monitoring, control, and enforcement, capture is an influential concept. According to a narrow conceptualisation, regulatory capture is the process

through which *regulatees* end up manipulating the agencies that are supposed to control them (Dal Bò, 2006). One way to understand this phenomenon is to think of a three-tier hierarchy comprising a political principal, a regulator, and the target. This understanding enables me to consider also how the political principal might want to respond to the risk that the regulator may be captured by the target. As highlighted by Huber and McCarty (2004), the incentives of civil servants to comply with legislation are diminished by reduction in capacity. This means that capacity is a feature of the system as a whole, but it is affecting all parts of the bureaucracy, including food safety regulation, and it enhances incentives of civil servants to comply with legislation, reducing the risk of capture and contributing to effectiveness of governance. Results show that in Member States where capacity of monitoring, control, and enforcement is high, the incentives of civil servants to comply with legislation are higher, and therefore the risk of capture is reduced. Literature widely explored success and failure of monitoring, control, and enforcement by regulatory agencies, and this study contributes to the debate in proving that how the regulatory functions are distributed among the institutions matters for effectiveness of governance, and it does so only in combination with a capable system of monitoring, control, and enforcement.

As to the question of whether integrated versus separated regulatory aims contribute to effectiveness of governance, this study contributes to the debate. On one hand, a separated model may cause problem with coordination and communication, while on the other, a coordinated one may facilitate a prompt response to food-related risks and, thus, to their minimization. However, a separated model could also enhance credibility of scientific expertise, while a coordinated one may lead to the discussed issues of *scientification* of politics and *politicization* of science (Weingart, 1999). As stressed by some authors, it is precisely through the full institutional separation of risk assessment from risk management that it has increasingly become clear that scientific activities cannot be carried out in complete isolation and in a political vacuum (Ansell and Vogel, 2006). The National Research Council's Red Book has already pointed out a central criticism of full organizational separation which states that "*simply separating risk assessment from the regulatory agencies would not separate science from policy*" (NRC 1983: 139). Results prove this linkage between science and policy, and the necessity to preserve an integrate system to ensure a positive outcome.

Moreover, the question of whether a separated model or an integrated model contribute to effectiveness of governance is strictly related to the other institutional conditions of independence and accountability. Results prove that when the regulatory aims are integrated and assigned to the

same agencies, independence and accountability become irrelevant for the occurrence of the outcome. This is due to the fact that if the regulatory functions of risk assessment and risk management are both assigned to the national food safety agency, or to the agency together with the competent ministry, for the agency being independent or accountable to its principal becomes irrelevant for ensuring effectiveness of governance, and thus for delivering food safety to citizens and consumers. Hence, the distribution of the regulatory tasks is what determines the level of cooperation between the regulators, or within the same agency, and leads to an effective response (or hinders it), in combination with high capacity of monitoring, control, and enforcement.

Food safety governance is proved to be a very complex action-situation, where different regulators interact, and results show that how rules are monitored and enforced do matter for the effectiveness of the results, as well as the aggregation of different regulators around specific sets of regulatory tasks.

As to the analysis of sufficiency for the negative outcome, the solutions identify low capacity as contributing to ineffective food safety governance ($\sim\text{CAPRM} \Rightarrow \sim\text{EFF}$). Making use of directional expectations, the intermediate solution identifies $\sim\text{SEP} * \sim\text{INDRA} * \sim\text{CAPRM} + \sim\text{SEP} * \sim\text{ACCRA} * \sim\text{CAPRM} \Rightarrow \sim\text{EFF}$. Here, the conjunctural effects of both institutional design's elements and of policy capacity are proved to contribute to ineffective response. The two paths provide insights for different mutually non-exclusive explanations of the phenomenon under investigation and enable us to contribute to the debate about governance failures. Results are coherent with our theoretical expectations, identifying both low independence and low accountability as contributing to ineffectiveness of governance, as well as low capacity. As to the institutional separation of the regulatory aims, an integrated model appears to contribute to an ineffective response, but only in combination with low independence and low capacity in one path, and with low accountability and low capacity in the other path. When institutional arrangements provide the agency carrying out risk assessment with low formal independence or low accountability and assign both risk assessment and risk management functions to the same institution, in combination with low capacity of monitoring, control, and enforcement, these produce unsatisfactory performances.

7. LIMITATIONS

Thomann and Maggetti (2017) provided a conceptual map that systematizes the different approaches and related tools surrounding research that applies QCA. Drawing upon their work, this research is situated in the traditional case-oriented approach, characterized by the close analysis of particular cases using deep contextual knowledge. In addition to cross-case inference, in-depth knowledge plays a crucial role in establishing operationalization and internal validity. Here, QCA is employed to generate new insights, engaging in a back and forth dialogue between prior knowledge, cases, and theory.

This study specifies the empirical scope, being coherent with the case selection rationale, and defines scope conditions, which provide evidence about the explanatory conditions of both positive and negative outcomes. Finally, it sets the context in which the explanation applies. Furthermore, it justifies whether assumptions about logical remainders are made, together with directional expectations and simplifying assumptions applied.

As to measurement errors, collocating this study in a case-oriented approach, an in-depth knowledge of cases and concepts is developed, thus minimizing ex ante measurement error (Schneider and Wagemann, 2012: 11). Potential condition errors can be identified by comparing conservative, intermediate, and parsimonious solutions across different model specifications. This enables the detection of conditions and solution terms that are more or less robust, indicating potential measurement issues. Errors related to model specifications can be addressed through robustness tests (Skaaning, 2011), by adding or dropping conditions, trying different raw consistency thresholds, and testing for different calibration strategies. The latter is particularly advisable if strong conceptual criteria are absent, especially for determining the crossover point (Sager and Thomann, 2016). For this reason, in the calibration section the different calibration strategies adopted are addressed, testing for both algebraic and Boolean aggregation of conceptual dimensions and using the threshold setter function to determine the anchors.

As to limited diversity, parsimonious solutions reliably reveal a redundancy-free set of causal factors. Moreover, my model includes 4 explanatory conditions for 14 cases.

Directional expectations, based on theoretical and empirical knowledge, help to distinguish plausible (*easy*) from implausible (*difficult*) counterfactuals (Ragin, 2008). To ensure validity of the

explanation, one way of enhancing transparency about different solution terms is inspecting these solutions. This is why all the solutions are presented – complex, parsimonious and intermediate – and contradictory simplifying assumptions have been checked (see Appendix A6.2).

As to skewedness, becoming aware of how results are affected by case distribution is crucial. It is possible to detect simultaneous subset relations using the proportional reduction in inconsistency (PRI) measure. The relevance of necessity (RoN) indicates the irrelevance of necessary conditions that approximate a constant. Schneider and Wagemann (2012) propose XY plots as a diagnostic tool. Calculating the Boolean intersections of different solution terms equally helps to detect simultaneous subset relations, which exist if the results for the positive and negative outcomes overlap (Thomann and Maggetti, 2017).

The strategies to address errors and evaluate models are summarized in Table 6.14, as presented by Thomann (Thomann *et al.*, 2018) for large-N applications. It was deemed necessary to address some of them in this limitation section, though this study is a small-N application of QCA (N = 14).

Table 6.14: Strategies to address errors and evaluate models

	Issue	Definition	Strategy	Application
Possible error sources	Deviant case and measurement errors	Errors related to sensitivity to one or more flawed cases	Frequency thresholds robustness test	Use three different frequency thresholds; configurations without a certain frequency are treated as logical remainders
		Sensitivity to changes in raw consistency levels	Raw consistency robustness test	Use of three different raw consistency thresholds (criterion: PRI)

	Plausibility and tenability	Limited diversity and contradictions can trigger inferences that are implausible and/or contradictory	Enhanced standard analysis	Intermediate solution based on directional expectations and exclusion of contradictory rows and untenable assumptions
Criteria for model evaluation	Accuracy	Degree to which observations correspond to set relation	Consistency	Necessity > 0.9 Sufficiency > 0.75
		Simultaneous subset relations: degree to which the same condition is not simultaneously sufficient for the negated outcome	Proportional Reduction in Inconsistency (PRI)	No fixed threshold
	Explanatory power	Empirical relevance of model	Coverage and relevance of necessity	Necessity > 0.6 RoN > 0.6 (direct calibration) Low coverage indicates low explanatory power
	Random errors	Errors that are unpredictable and inconsistent	Probabilistic criteria	Right-handed Z-test for proportion of

		in their magnitude or direction		cases with $X > Y$ (necessity) / $X < Y$ (sufficiency) 0.8: “almost always”
	Limited empirical diversity	Presence of logical remainders, that is, truth table rows without enough cases with membership > 0.5	Limited diversity index % remainders / logically possible configurations	Models with less limited diversity have a stronger empirical basis
	Ambiguity	Patterns in data are unclear: several equally nonredundant solutions can be derived	Ambiguity index (Nr of equally plausible models)	Unambiguous models are preferred (row dominance applied)
	Robustness	Terms of enhanced parsimonious solution remain robust across different models that pass consistency threshold 0.75	Robustness index Average % of models in which (a subset of) a term appears	More robust models are preferred
	Skewness	Skewed distributions can produce simultaneous	Skewness statistics	Skewness is problematic if the vast majority (>85%) of the

		subset relations, exacerbate limited diversity, and strongly distort parameters of fit		case cluster in only one of the four possible intersecting areas of the XY plots with two diagonals
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Source: Thomann et al., 2018 based on Baumgartner and Thiem, 2017; Fiss, 2011; Maggetti and Levi-Faur, 2013; Ragin, 2000; Schneider and Wagemann, 2012; Skaaning, 2011; Thomann and Maggetti, 2017.

CONCLUSION

This study aimed at investigating differences in effectiveness of food safety regulation across 15 EU countries and explaining them by differences in domestic governance design. The focus is justified by a pragmatic consideration, inspired by the Institutional Analysis and Development framework (IAD: Ostrom 2005, 2011): although regulatory effectiveness more directly depends on a wide array of non-institutional factors, the institutional dimension of governance is the one which shapes individual actors' strategies and behaviours (Ostrom, 2005; 2011) and achieves the desired outcome.

Drawing upon the Institutional Analysis and Development framework (Ostrom, 2005; 2011), this study engaged in theoretical work, undertaken at three levels of analysis: (1) first, it identified the institutional elements and the general relationships among them through the IAD framework; (2) then, it specified which institutional elements are particularly relevant to address the research question in the light of existing theories, and (3) finally, it construed the explanatory model, involving precise assumptions about a limited set of conditions and deriving precise expectations about the results of combining these conditions (Ostrom, 2011:8). Specifically, the assumption that regularities in actions cannot occur if rules are not enforced (Ostrom, 2011: 20), enabled me to select those institutional features of regulatory designs of monitoring and enforcement in order to investigate the impact they exert over effectiveness of governance (i.e. the extent to which they ensure predicted results in actions and, thus, behaviours). Moreover, the assumption that institutions are intentional constructions that structure information (Ostrom, 1999: 5) enabled me to identify the quality of regulatory designs as one of those institutional features, being the agencies operating in the collective-choice action-situation those who exert control over information which is circulated in the operational action-situation. Finally, in light of the assumption of the configurational nature of institutions, it has been possible to argue that the institutional arrangements of monitoring and enforcement activities and of control of information – jointly given – exert an impact on the effectiveness of operational outcomes.

Regulatory governance and design theories have always been concerned with achieving effectiveness in regulatory instruments, and institutional theories suggest that institutional structures and arrangements significantly shape regulation and its effectiveness. Specifically, the

institutional design theory identifies in information asymmetries the main regulatory failure-mechanism: agency drift on one hand and industry drift on the other are particularly contributing to the failure of regulation, and several scholars identify in the quality of regulatory design the response to this effectiveness challenge (Gilardi, 2008; Maggetti, 2007; Levi-Faur, 2010). Debates about quality of regulatory designs bring together discussion of independence and accountability (Gilardi, 2002; 2005; 2008; Maggetti, 2008; Hanretty and Koop, 2012; Enns-Jedenastik, 2015; Maggetti and Gilardi, 2011; Maggetti, 2009; 2007; Biela and Papadopoulos, 2014; Koop, 2015; Busuioc, 2009; Majone, 1999; Quintyn and Taylor, 2007; Koop and Hanretty, 2018), and recent design literature extensively discussed policy (and regulatory) capacity, highlighting their fundamental nature to produce effective outcomes (Peters *et al.*, 2018; Considine, 2012; Ramesh and Howlett, 2015; Bullock *et al.*, 2001; Wu *et al.*, 2010; Rotberg, 2014; Howlett and Ramesh, 2014; Howlett and Ramesh, 2016). Drawing upon the IAD as general framework of institutional analysis, I tested the explanatory power of complementary or competing theories and models (Ostrom, 2006: 26). This way, this research contributed substantially to enriching the debate about quality of regulatory designs on one hand, and of policy capacity on the other. The explanatory model for effectiveness of regulation developed in this research derived hypotheses from regulatory governance theories, providing insights on the complementarity of institutional design's theory and policy capacity's theory. This study focused on the three features of causal complexity: equifinality, asymmetric causation, and conjunctural causation (Rihoux & Ragin 2009, Schneider & Wagemann 2012), proving that qualities of regulatory designs unfold their effect in combination with policy capacity, and that effectiveness of regulation can have a different explanation than ineffectiveness. As to effectiveness of regulation, this work contributes to the debate about the institutional separation of the regulatory functions, providing insights about whether an integrated model works better than a separated model in producing an effective response. As to ineffectiveness of regulation, this research contributed to the literature on regulatory failure, providing an institutional explanation that unfolds its effect in combination with low policy capacity.

By drawing upon Levi-Faur's definition of regulation, which includes continuous action of monitoring, assessment, and enforcement of rules⁴⁹, this study identifies in the control's dimension of regulation the difference-making role it plays towards effectiveness (and ineffectiveness) of the

⁴⁹ "The promulgation of prescriptive rules as well as the monitoring and enforcement of these rules by social, business, and political actors on other social, business, and political actors" (Levi-Faur, 2010: 9).

substantial dimension. The Institutional Analysis and Development (IAD) constitutes the theoretical framework that makes the strongest claims with respect to the impact monitoring and enforcement activities exert over regulatory effectiveness, by identifying the coercive power of rules as the crucial element for the desired outcomes to occur.

Recently, much of the scholarly development of the IAD has offered a systematic approach to analyse policy designs, generating a considerable body of work (Carter *et al.*, 2015; Ostrom, 2005; Basurto *et al.*, 2010; Crawford and Ostrom, 1995; Crawford and Ostrom, 2005; Siddiki *et al.*, 2012; Siddiki *et al.*, 2011). However, not all elements in the framework are yet fully investigated and developed. So far, contributions focusing on the impact that monitoring and enforcement activities exert on operational outcomes are still missing. Hence, this study substantially contributed to the development of this literature, by establishing a connection between the IAD framework and acknowledged regulation theories. Moreover, it contributed to the literature that applies configurational analyses of institutional designs making use of the Institutional Analysis and Development framework (IAD: Ostrom 2005, 2011).

The area of food governance has generated an extensive body of work, drawing the attention of several scholars, from a wide range of disciplines and perspectives. Over the years, political scientists and policy scholars have drawn their attention in studying food and agriculture policy-making as a *generative empirical example in the theoretical development of policy studies* (Daugbjerg and Feindt, 2017:1566). The regulation of food safety constitutes a particularly important dimension of public policy, and the issue provides a lens into a set of contemporary questions (Ansell and Vogel, 2006: 5): multi-level governance of regulation, European integration and customization (Thomann, 2018), trade globalization, politicization of risk assessment and regulatory science, regulation of new technologies, hybrid forms of governance (and the shifting balance between public and private regulation), the agricultural protectionism phenomenon, consumer and public health protection, regulatory quality and the risk of capture, failing monitoring and enforcement systems, the control over information that is circulated among regulators, regulatees, and consumers. Recently, literature has increasingly investigated how the resulting multiple and conflicting actor rationalities and the overlap of several regulatory roles affect the effectiveness and legitimacy of the decision-making and implementation of food safety policy (Thomann, 2018). By highlighting issues such as regulatory capture and deficient enforcement systems, Thomann (2018) suggested that more research is needed to identify the conditions under

which the regulatory structures ensure effective food safety (Thomann, 2018; Scharff *et al.*, 2009). This study attempted to fill this gap and to enriching the academic debate about the impact monitoring and enforcement activities exert over regulatory effectiveness. Evidence suggests that the conditions required to effectively protect the public interest include effective monitoring and enforcement; control over information; responsiveness to recommendations and reactivity to food-related risks.

Finally, the present research substantially contributed to answer some empirical questions. First, how can we conceptualize and measure effectiveness of governance of food safety regulation? Building on policy design and regulatory governance literatures, chapter 4 proposed a new measure of food safety delivered. The gauge is based on the Rapid Alert System for Food and Feed (RASFF) data. As a tool that ensures *“the flow of information to enabling swift reaction when risks to public health are detected in the food chain”*, the RASFF provides notifications about food safety related risks occurring across its members, recording original notifications together with follow-up notifications. As outlined by the European Commission itself, the effectiveness of RASFF can be assessed in terms of achievement of its main objectives – namely, information exchange between members of the network on (a) direct or indirect risks in relation to food or feed, (b) the follow up to notified direct or indirect risks, (c) measures to contain risk. The new metrics understands delivered food safety as the quality of the response of the domestic system to food-related risks about which they get information through the RASFF network – exchanged information, quality of notifications transmitted, and reaction to the risk.

Second, in order to investigate under which conditions food safety regulation is effective, chapter 5 contributes to the existing empirical literature by developing a measure of food safety policy capacity and by gauging formal independence and accountability of the 15 domestic food safety agencies of the EU countries under scrutiny. As to policy capacity, my gauge is based on the evaluation reports released by the FVO on the monitoring-control-enforcement systems of each member state. Evaluations draw upon the audits conducted by the FVO on a 5-year period, and they report the progresses made by the member states implementing recommendations made by the FVO. Data have been cross checked with the legal provisions regarding food safety and statutory provisions of the domestic institutions carrying our monitoring, control, and enforcement activities. Thus, an index of responsiveness to recommendations is constructed - as a proxy of capacity - calculating the ratio between the number of actions taken by the member states in response to the

recommendations made by the FVO, over the number of total recommendations received. As to independence and accountability, previous studies ranked only 7 food safety national agencies and data is no longer up to date (Gilardi, 2002). This study contributed to the existing empirical literature providing formal independence and accountability measures on food safety agencies across 15 EU Member States, drawing upon acknowledged indexes and coding procedures (Gilardi, 2002; 2005; Hanretty and Koop, 2018).

To conclude, I would like to highlight three particularly promising areas for future research: the further development of the IAD in analysing regulatory designs; the development of a conjunctural theory of policy capacity; the further investigation of control as causal mechanism.

Recently, much of the scholarly development of the IAD has offered a systematic approach to analyse policy designs, generating a considerable body of work (Carter *et al.*, 2015; Ostrom, 2005; Basurto *et al.*, 2010; Crawford and Ostrom, 1995; Crawford and Ostrom, 2005; Siddiki *et al.*, 2012; Siddiki *et al.*, 2011). To analyse the *rules*, Ostrom (Crawford and Ostrom, 1995) provides for a sophisticated analytical tool, the Institutional Grammar Tool. The purpose of the IGT is to unravel the components of formal institutions, such as policies, legislation, and regulations (Siddiki *et al.*, 2011). The grammar tool comes into play in the identification of actions (required, permitted, forbidden), actors assigned to specific tasks, temporal and spatial boundaries in which actions take place, and sanctions associated with noncompliance. Future systematic and detailed investigations could employ the Institutional Grammar Tool to analyse the content of the regulatory designs as they are written in the procedural rules. The comparison across different cases could be done by integrating the use of the IGT with the elements of the IAD (collective-choice action-situations, rule types, monitoring and enforcement, operational outcomes).

Future systematic and detailed applications of the IAD and the IGT could enable to turn the textual contents of the regulatory designs into comparable information, by developing a sophisticated coding of some institutional features that could be modelled through the IAD. This research constituted an effort to analyse the impact that formal independence and formal accountability of the national food safety agencies have with respect to effectiveness of regulation. The investigation of these institutional features through the IGT could provide for a systematic coding procedure and for the extrapolation of comparable information with respect of required, permitted and forbidden

actions, actors assigned to specific tasks, temporal and spatial boundaries in which actions take place, and sanctions associated with noncompliance.

Moreover, a computational approach to the application of the grammar tool could help the institutional analyst to identify and code the corpus of institutional statements that are shaping a certain action-situation (i.e. governance structure). Automatic text-analysis is a growing set of methods that automatically extract statistically manipulable information about the presence, frequency, intensity, of some characteristics of textual material (Shapiro and Markoff, 1997). An interesting development could be the use of the ADICO syntax of the IGT as instruction to automatically extract comparable information from written action-situations (Carter *et al.*, 2015).

The analysis conducted in this study reveals the prominent role of capacity in producing an effective response, and it unfolds its effects in combination with an integrated model of distribution of the regulatory functions. This explanation provides insights on the complementarity of the institutional design's theory and the policy capacity's theory. As claimed by Howlett (2016), capacity is a factor affecting effectiveness of any single governance mode, and governance is linked to policy success and, therefore, to policy capacity. As to regulatory failure, the conjunctural effects of both institutional design's elements (low accountability or low independence) and of low policy capacity are proved to contribute to ineffective response, in line with the theoretical expectations. Future research could further develop a conjunctural theory of policy capacity, by investigating complementary and competing explanatory factors for improved capacity.

Third, this research constituted an effort to conduct a configurational analysis of the impact the control dimension of regulation exerts over operational outcomes. In doing so, this study undertakes empirical work by employing Qualitative Comparative Analysis, which provides a range of institutional configurations of causal conditions and explores the links of the institutional configurations to the outcome (i.e. effective governance of food safety regulation) through (combinations of) necessary and sufficient conditions. Future research could further investigate control as causal mechanism. Specifically, this research focused on formal monitoring and enforcement activities carried out by agencies within formal collective-choice action-situations. However, investigations of informal monitoring and enforcement activities carried out within informal action-situations are still missing. As discussed earlier, hybrid forms of governance (and the shifting balance between public and private regulation) are gaining the attention of food policy

scholars and future research could investigate the relationship between formal and informal monitoring and enforcement activities carried out in formal and informal collective-choice action-situations, in order to assess the impact both formal and informal activities exert over operational outcomes.

Several challenges have been faced while conducting this research, from the research design, to the data collection and the analysis. The first challenge was found in the measurement of the outcome, i.e. effectiveness of food safety regulation. A systematic review of the existing empirical literature has been conducted in order to assess existing conceptualizations and measures of effectiveness. However, none of the existing measures were suitable to answer the research question. Therefore, a new measure of *delivered food safety* has been developed based on RASFF data, facing challenges related to comparability and reliability of the measure.

The second main challenge was the reliability of the coding of the statutory provisions of the national food safety agencies, that was done to measure formal independence and accountability. Lack of resources prevented from relying on a second coder. To solve this problem, the coding scheme adopted is provided, as well as the literal transcription of the responses that have been drawn from the statutory provisions, in the attempt of being as much transparent as possible in justifying the coding operations.

The third main challenge was both theoretical and methodological. This work focused on the institutional design's approach to success and failures of food safety regulation, modelling the control dimension of regulation (i.e. monitoring and enforcement) and the impact it exerts on the substantial dimension. In doing so, it contributed to the literature that applies configurational analyses of institutional designs making use of the Institutional Analysis and Development framework (IAD: Ostrom 2005, 2011). Yet, it has been challenging to formalize the analysis, from the modelling of the food safety nested action-situations to the identification of the explanatory conditions, their measurement and calibration, as well as the analyses of necessity and of sufficiency. To test robustness of the explanatory model, different calibration strategies have been explored, and the analyses have been performed both with the QMC algorithm and the CCubes algorithm, to prove the same end results.

APPENDIX A5.1 – Coding of formal independence

		AUS - AGES		BELGIUM - FASFC		DENMARK		FINLAND - EVIRA		FRANCE - ANSES	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Relationship with government and parliament			0		0		0		0		1
Is the independence of the agency formally stated?	1 = Yes 0 = No	The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.	0	Art. 13.§ 1st. The agency is subject to the hierarchical authority of the minister.	0	The Danish Veterinary and Food Administration is part of the Ministry of Environment and Food. An annual performance plan between the Ministry and the DVFA sets out the annual targets and performance indicators, which are reviewed the following year.	0	The Food Agency is administratively under the Ministry of Agriculture and Forestry. The Ministry of Agriculture and Forestry, the Ministry of Trade and Industry and the Ministry of Social Affairs and Health are responsible for co-ordinating the performance management of the Agency as stipulated by the Government Decree.	0	It implements an independent and pluralistic scientific expertise.	1
Financial and organizational autonomy			0,125		0,2075		0,5825		0,5825		0,875
What is the source of the agency's budget?	fees levied on the regulatees = 1 both government and fees levied on regulatees = 0.5 government = 0	(5) ... The registered capital of the Agency amounts to € 1 000 000 and must be paid in full by the Federal Minister of Health and Women as well as by the Federal Minister of Agriculture, Forestry, Environment and Water Management. Federal funds § 12. (1) The Confederation [...] to provide a base grant of EUR 55.2313 million for 2006 and a base grant of EUR 54.5046 million per	0,5	Art. 10.The agency is financed by: 1 ° the product of the rights, royalties and fees included in the laws referred to in article 5, insofar as the benefit of these provisions has been transferred to the agency by the royal decrees taken in execution of the same article 5; (2) the appropriations entered in the estimates; 3 ° donations and legacies; 4 ° occasional income; 5 ° the product of administrative fines;	0,5	The Danish Veterinary and Food Administration is part of the Ministry of Environment and Food. An annual performance plan between the Ministry and the DVFA sets out the annual targets and performance indicators, which are reviewed the following year.	0,5	Source: https://www.evira.fi/tietoa- evirasta/esittely/toiminnan- suunnittelu-ja-seuranta/tulosohjaus/ The budgets decided by Parliament: Parliament decides on state budget. The document contains estimates and appropriations approved by Parliament.	0	" Article L. 1313-7 - The resources of the agency consist in particular of: "1o Grants from public authorities, their public establishments, the European Union or international organizations; "2o the proceeds of taxes and payments instituted for his benefit; "3o The product of fees for services	0,5

		<p>year from 2007 onwards [...] (3) Half of the amounts referred to in paragraphs 1, 2 and 8 shall be borne by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and by the Federal Ministry of Health and Women by the end of December 31, 2006. As of 1 January 2007, 40% of these amounts are to be borne by the Federal Ministry of Agriculture, Forestry, Environment and Water Management and 60% by the Federal Ministry of Health and Women. [...]</p> <p>[...] (8) The tariff rates are hedged on the basis of the consumer price index (CPI 2010) published by the Federal Statistical Office or the index replacing it and are annual, for the first time from 1 January 2016, with effect from 1 January to adapt to each calendar year. [...]</p>		<p>6 ° with the agreement of the Minister responsible for Finance, the proceeds of the investment of the financial reserves;</p> <p>7 ° a single transfer of resources from existing funds under programs 54.1, 54.2 and 55.2 of the budget of the Ministry of Agriculture and Middle Classes, insofar as they concern the activities to be taken over by the agency;</p> <p>8 ° the royalties and the payments imposed by the King by deliberate decree in the Council of Ministers, in charge of the physical and legal persons participating in the food chain. These fees must be fixed in particular according to the health risks related to the activities of the natural and legal persons targeted in the food chain, as well as the importance of these activities;</p> <p>9 ° the fees imposed by the King by order deliberated in the Council of Ministers, for the activities of the agency within the framework of this law;</p> <p>10 ° revenue from the European Union relating to activities falling within the scope of this Law;</p> <p>11 ° voluntary or contractual contributions.</p>						<p>rendered;</p> <p>"4o Miscellaneous products, gifts and legacies;</p> <p>"5o Loans."</p>	
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<p>How is the budget controlled?</p>	<p>by the agency = 1 by the accounting office or court = 0.67 by both the agency and the government = 0.33 by the government only = 0</p>	<p>The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year [...]</p>	<p>0</p>	<p>Art. 13. § 1st. The agency is subject to the hierarchical authority of the minister. § 2. The agency shall submit to the Minister quarterly reports on its activities, within one month of the period covered by the report, as well as an annual report on its activities, including a summary of the results achieved with regard to its activities. missions, which it also submits to Parliament.</p> <p>The agency submits to the Minister and the Minister responsible for the Quarterly Situation Budget in the month of the end of the reporting period. It draws up by 30 April at the latest, the annual account for the implementation of its budget, as well as an active and passive situation on 31 December of the year in question.</p>	<p>0,33</p>	<p>"The Danish Veterinary and Food Administration is part of the Ministry of Environment and Food. An annual performance plan between the Ministry and the DVFA sets out the annual targets and performance indicators, which are reviewed the following year."</p>	<p>0,33</p>	<p>Source: https://www.evira.fi/en/about-evira/about-us/planning-and-monitoring/ PLANNING AND MONITORING OF EVIRA'S OPERATIONS The key plans of State performance management are performance agreements and the budget decided upon by Parliament. A performance agreement is an agreement between a government agency and Ministry of Agriculture and Forestry concerning the operating objectives for the new year within the framework of granted appropriations. Of central importance in monitoring data are the financial statements, in particular the annual that forms part of them, and the ministry's opinion of these documents.</p>	<p>0,33</p>	<p>Article R. 1313-14 - The Board of Directors sets by its deliberations the general guidelines of the agency. It adopts its rules of procedure. It deliberates on: 1 ° The multi-year strategic orientations; 2 ° The annual work program; 3 ° the performance contract concluded with the State; 4 ° The activity report; 5 ° The investment program; 6 ° The initial budget and the amending decisions; 7 ° the financial account;</p>	<p>1</p>
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<p>Which body decides on the agency's internal organisation?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.</p>	<p>0</p>	<p>§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel.</p>	<p>0</p>	<p>In March 2012, DVFA was restructured, resulting in a centralised/decentralised organisation, with operations/business processes harmonised throughout the country. Under the new structure, each manager is responsible for the quality, output and economic/financial aspects of operations. The 2017-2021 MANCP contains the overall DVFA mission, vision and strategy, which provide a foundation for the performance contract between DVFA and the Ministry of Environment and Food. The performance contract, to which the MANCP provides a link, serves as a basis for reviewing the performance of the entire organisation.</p>	<p>0,5</p>	<p>Management and decision-making The Food Safety Authority is headed by a Director General. The Director-General decides on cases that come to the Food Safety Authority, unless it has been prescribed or stipulated in the Rules of Procedure that any other official at the work shall determine them. The work's rules of procedure are laid down by the Director-General.</p>	<p>1</p>	<p>Article R. 1313-14 - The Board of Directors sets by its deliberations the general guidelines of the agency. It adopts its rules of procedure. It deliberates on: 9 ° The general organization of the agency, including the creation of specialized committees of experts; 10 ° The internal regulations of the agency; 11 ° The general conditions of employment and recruitment of the personnel and the conditions of remuneration of the other persons who assist the agency;</p>	<p>1</p>
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<p>Which body is in charge of the agency's personnel policy (hiring and firing staff, deciding on its allocation and composition)?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>The Federal Office for Food Safety is a subordinate department of the Federal Ministry of Agriculture, Forestry, Environment and Water Management. The Federal Minister of Agriculture, Forestry, Environment and Water Management is authorized to issue upper authority.</p>	<p>0</p>	<p>§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel.</p>	<p>0</p>	<p>Each manager is responsible for the quality, output and economic/financial aspects of operations. The 2017-2021 MANCP contains the overall DVFA mission, vision and strategy, which provide a foundation for the performance contract between DVFA and the Ministry of Environment and Food. The performance contract, to which the MANCP provides a link, serves as a basis for reviewing the performance of the entire organisation.</p>	<p>1</p>	<p>Section 4 - Appointment and employment of staff The Director-General is appointed by the Government. The Director General appoints the Heads of Department or the Head of Research, the Heads of Unit, or the Head of Research, the Research Director, the Research Professors, and the Head of an Activity Whole Unit that exceeds the Division and Division. Personnel other than the above mentioned personnel in terms of employment or employment relationship are appointed or employed by the Director General or any other person belonging to the workforce staff as required by the Rules of Procedure. A research professorship can be added by calling.</p>	<p>1</p>	<p>Article R. 1313-14 - The Board of Directors sets by its deliberations the general guidelines of the agency. It adopts its rules of procedure. It deliberates on: 9 ° The general organization of the agency, including the creation of specialized committees of experts; 10 ° The internal regulations of the agency; 11 ° The general conditions of employment and recruitment of the personnel and the conditions of remuneration of the other persons who assist the agency;</p>	<p>1</p>
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<p>Regulatory competencies</p>	<p>the agency only = 1 the agency and another independent authority = 0.67 the agency and the parliament = 0.5 the agency and the government = 0.33 the agency has only consultative competencies = 0</p>	<p>Tasks of the agency § 8. (1) The Agency shall carry out the research required to fulfill its tasks and provide relevant scientific knowledge. (2) In order to achieve the objective stated in § 1 and § 1 and to protect the health of humans and livestock, the Agency shall in particular fulfill the following tasks [...]</p> <p>(2a) In order to achieve the objectives set out in the International Treaty on Plant Genetic Resources for Food and Agriculture, Federal Law Gazette III No. 98/2006, the Agency must fulfill the following tasks, other than subordinate departments of the Federal Ministry of Agriculture, Forestry, Environment and Forestry Water management are responsible for [...]</p>	<p>0,33</p>	<p>§ 3. In the interest of public health, the agency is competent to: 1 ° the control, examination and expertise of food products and their raw materials at all stages of the food chain, and this in the interest of public health; 2 ° the control and expertise of production, processing, conservation, transport, trade, import, export and production, processing, packaging, trading, storage and sale of food products and their materials first; 3 ° the granting of authorizations and authorizations related to the execution of its mission; 4 ° the integration and development of identification and tracing systems for food products and their raw materials in the chain food and the control of it; 5 ° the collection, classification, management, archiving and distribution of any information about his mission. 6 ° the development and implementation of a policy of prevention, sensitization and information, in consultation with communities and areas; 7 ° the supervision of the respect of the legislation relating to all the links of</p>	<p>1</p>	<p>The Danish Veterinary and Food Administration is part of the Ministry of Environment and Food. An annual performance plan between the Ministry and the DVFA sets out the annual targets and performance indicators, which are reviewed the following year.</p>	<p>0,33</p>	<p>The Food Agency directs, designs and develops, as well as contributes to the monitoring of food and food contact materials and related risk management.</p> <p>Food Act Section 30 – Central competent authority (352/2011) (1) The Finnish Food Safety Authority is responsible for planning, steering, developing and undertaking food control nationally as laid down in this Act, in addition to which it: 1) steers the Regional State Administrative Agencies in assessing municipal food control; 2) sees to food control in slaughterhouses, game handling establishments and establishments connected to them; 3) is responsible for the planning and implementation of the national control of contaminants in food; 4) is responsible nationally for other food control duties requiring special expertise; 5) assesses the guides to good practice referred to in Article 8 of the General Food Hygiene Regulation; 6) functions as the national contact point for the rapid alert system under the General Food Regulation; 7) approves the training of hunters in health and hygiene referred to in Annex III, Section IV of the Foodstuffs of Animal Origin Hygiene Regulation; 8) sees to the national information and communication activities, communication about risks and consumer information; 9) assesses the meat inspection of</p>	<p>1</p>	<p>Art. L. 1313-1. - The National Agency for Food Safety, Food Safety and the environment and work is a public state institution of an administrative nature. "It implements an independent and pluralistic scientific expertise."</p>
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				the food chain. § 4. Within the framework of its mission, the agency shall give the competent authorities opinions on existing and future regulations, including transposition of international regulations into Belgian law. § 5. By deliberate decision in the Council of Ministers, the King determines within the framework of skills of the agency the tasks for which the agency can be assist by third parties or that the agency may have third parties perform and determines the related conditions.				reindeer organised by the Regional State Administrative Agency and the related control.			
Status of the agency head			0,4883		0,2767		0,5		0,1933		0,31
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0	The term of office is five years.	0,6	Art. 6.§ 1st. The management of the agency is entrusted by an employment contract of indefinite duration to a managing director who preferably provides proof of knowledge of the two national languages, in accordance with article 43, § 3, paragraph 3, of the coordinated laws. of 16 July 1966 on the use of languages in administrative matters.	0		0,5	No fixed term	0	The term of office of chairman of the board of directors, appointed for three years, is renewable once	0,2

Who appoints the agency head?	members of management board = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0	The management of the agency consists of up to three members who are to be appointed in accordance with the provisions of the Staffing Act, Federal Law Gazette I No. 26/1998	0	<p>§ 2. The managing director is selected by a selection committee composed by the minister and the minister responsible for the civil service.</p> <p>The Selection Committee presents a candidate on the basis of detailed and duly motivated reports. The selection procedure must in any case include the competence aspect regarding organizational changes and safety of the food chain. § 3. The managing director is appointed by the King, on the proposal of the Minister, after deliberation by the Council of Ministers. The King determines by deliberate decree in the Council of Ministers the methods of application, the conditions of appointment and exercise of the function as well as the contractual conditions and the pecuniary status to which the managing director will be subject. § 4. The day-to-day management is entrusted to the managing director.</p> <p>The King can also assign specific skills.</p>	0,33		0,5	The Director-General is appointed by the Government.	0,33	"Art. L. 1313-5. - The institution is headed by a director general appointed by decree.	0,33
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Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33	0,5	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33
May the agency head hold other offices in government?	no = 1 only with permission of the government = 0.5 yes = 0	If a federal official enters into an employment relationship with the agency as managing director, then this federal official is granted leave of absence for the duration of this employment relationship.	1	§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel. § 6. Before taking up his duties, any member of the statutory or contractual staff of the agency shall declare the interests he has in any establishment or enterprise falling within the competence of the agency and undertake to inform that agency and any changes to the declared interest. The King determines by royal decree deliberated in the Council of Ministers the conditions in which the agency organizes the service with a view to preventing any conflict of interest.	1	0,5	No specific provisions	0,5	The duties of Chairman of the Board of Directors are incompatible with those of the Chief Executive Officer of the Agency.	0,5

Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0	The term of office is five years.	1	Art. 6.§ 1st. The management of the agency is entrusted by an employment contract of indefinite duration to a managing director who preferably provides proof of knowledge of the two national languages, in accordance with article 43, § 3, paragraph 3, of the coordinated laws. of 16 July 1966 on the use of languages in administrative matters.	0	0,5	No fixed term	0	The term of office of chairman of the board of directors, appointed for three years, is renewable once	0,5
Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0	No specific requirements for the appointment	0	0,5	No specific requirements for the appointment	0	No specific requirements for the appointment	0
Status of the members of the management board			0,4883		0,61	0,5833		0,305		0,2267
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0	The term of office is five years.	0,6	No specific provision	0,5	0,5	No fixed term	0	Art. R. 1313-5. - The term of office of the members of the board of directors is three years. It is renewable.	0,2

<p>Who appoints the members of the management board?</p>	<p>agency's head = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0</p>	<p>The management of the agency consists of up to three members who are to be appointed in accordance with the provisions of the Staffing Act, Federal Law Gazette I No. 26/1998</p>	<p>0</p>	<p>§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel. § 6. Before taking up his duties, any member of the statutory or contractual staff of the agency shall declare the interests he has in any establishment or enterprise falling within the competence of the agency and undertake to inform that agency and any changes to the declared interest. The King determines by royal decree deliberated in the Council of Ministers the conditions in which the agency organizes the service with a view to preventing any conflict of interest. § 7. The King determines by royal decree deliberated in the Council of Ministers the framework and the administrative and pecuniary status of the personnel, as well as the system of voluntary and ex officio mobility to, from or in the agency, with the modalities related thereto. The other executive functions will be entrusted by mandate whose terms will be fixed by a decree deliberated in the Council of Ministers.</p>	<p>0,33</p>		<p>0,5</p>	<p>The Director General appoints the Heads of Department or the Head of Research, the Heads of Unit, or the Head of Research, the Research Director, the Research Professors, and the Head of an Activity Whole Unit that exceeds the Division and Division.</p>	<p>1</p>	<p>The agency is administered by a board of directors composed, in addition to the president, appointed by decree, and staff representatives, five colleges respectively comprising: "1o Representatives of the State; "2o Representatives of approved associations for the protection of the environment, of approved associations having an activity in the field of quality of health and care of patients and associations consumer protection associations as well as national associations of victims of occupational accidents and occupational diseases mentioned in Article L. 1313-3; "3o Representatives of interested professional organizations; "4o Representatives of inter-professional organizations of</p>	<p>0,33</p>
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										employers and trade unions representative of employees at the national level; "50 Elected and qualified personalities chosen because of their competence in the fields under the missions of the agency.	
Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33	Management ensures that members of staff do not engage in activities which are in conflict with their employment at the DVFA. Staff in the DVFA must inform their manager of potential situations of conflict of interest. The manager decides on any necessary actions in such cases.	0	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33

May the members of the management board hold other offices in government?	no = 1 only with permission of the government = 0.5 yes = 0	If a federal official enters into an employment relationship with the agency as managing director, then this federal official is granted leave of absence for the duration of this employment relationship.	1	§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel. § 6. Before taking up his duties, any member of the statutory or contractual staff of the agency shall declare the interests he has in any establishment or enterprise falling within the competence of the agency and undertake to inform that agency and any changes to the declared interest. The King determines by royal decree deliberated in the Council of Ministers the conditions in which the agency organizes the service with a view to preventing any conflict of interest	1	Employees of the DVFA have the right to other employment aside from the main job, but the second job must be exercised within the limits imposed by the Civil Servants Law § 17, which means that the second job: - Must not involve any risk of conflicts of interest in relation to his or her main job; - Must not occupy the employee's time to the detriment of his or her main job; - Must not be incompatible with the decorum required of his or her main job.	1	No specific provisions	0,5	The duties of Chairman of the Board of Directors are incompatible with those of the Chief Executive Officer of the Agency.	0,5
Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0	The term of office is five years.	1	No specific provision	0,5		0,5	No fixed term	0	Art. R. 1313-5. - The term of office of the members of the board of directors is three years. It is renewable.	0

Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0	§ 5. The King determines by decree deliberated in the Council of Ministers the conditions of recruitment of the statutory staff as well as the contractual staff, in order to ensure the objectivity, the independence and the competence of the personnel.	1	Management ensures that members of staff do not engage in activities which are in conflict with their employment at the DVFA. Staff in the DVFA must inform their manager of potential situations of conflict of interest. The manager decides on any necessary actions in such cases.	1	No specific requirements for the appointment	0	No specific requirements for the appointment	0
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		GERMANY - BFR		GREECE - EFET		IRELAND - FSAI		ITALY - ISS		LUXEMBOURG - OSQCA	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Relationship with government and parliament			1		0		1		0		0
Is the independence of the agency formally stated?	1 = Yes 0 = No	<p>§ 2 Activities and task execution (1) Within the scope of its competence, the BfR independently addresses issues in particular Improving consumer health protection and conducting research according to § 2 Abs. 1 Nr. 4 BfRG. (2) In its scientific assessments and research BfR is subject to the § 8 Abs. 1 BfRG independent of instructions.</p>	1	<p>1. A legal entity governed by public law is appointed under the name of the Uniform Body of Food Control (EFET), headquartered in Athens and under the supervision of the Ministry of Development.</p>	0	<p>10.—The Authority shall, subject to this Act, be independent in the exercise of its functions.</p>	1	<p>1. The ISS, hereinafter referred to as an Institute, is the technical-scientific body of the National Health Service and pursues the protection of public health, in particular through development of the functions of research, control, consultancy, regulation and training. The Minister of Health, the Regions and the Authorities avail themselves of this Autonomous provinces of Trento and Bolzano. 2. For the purposes referred to in paragraph 1, the Institute operates as a public body research with scientific, organizational, administrative autonomy and accountant, supervised by the Minister of Health.</p>	0	<p>Art. 2. (1) There is hereby established an agency responsible for the safety and quality of the food chain (OSQCA), hereinafter referred to as the "body", which is under the authority of the Ministers respectively with Health and Agriculture in their attributions.</p>	0

Financial and organizational autonomy			0,5825		0,875		0,25		0,125		0,25
What is the source of the agency's budget?	fees levied on the regulatees = 1 both government and fees levied on regulatees = 0.5 government = 0	(2) The budget shall be determined by the President. He needs to his effectiveness of the approval of the Federal Ministry. The Federal Institute receives to compensate the approved federal budget subsidies in accordance with the relevant budgetary law.	0	"7. Resources of HFF They are: a) Annual subsidy from the State Budget. b) Funding from the European Union or other international organizations. c) Countervailing fees for the provision of services, imposed by a joint decision of the Ministers of Finance and Development. d) The proceeds of any financial penalties imposed for breaches of the present. e) Grants, sponsorships, inheritances, legacies, grants from third parties."	0,5	"(2) The determination of the amounts of charges referred to in subsection (1) shall be subject to the approval of the Minister following consultations with the Minister for Finance." 24.—The Minister may, from time to time, with the consent of the Minister for Finance, advance to the Authority out of moneys provided by the Oireachtas, such sums as the Minister may determine for the purposes of expenditure by the Authority in the performance of its functions.	0	Article 20. Economic-financial resources (sources of funding) 1. The Institute provides for the performance of institutional functions with the financial means deriving from: a) from the state financial contribution; b) contributions to be paid by the special supplementary research fund referred to in Article 1, paragraph 3, of the Legislative Decree of 5 June 1998, n. 204, and subsequent amendments; c) from its patrimony; d) from the sums referred to in Article 1 of the Legislative Decree of 30 December 1992, n. 502, and subsequent amendments; e) contributions from national or foreign bodies, the European Union and	0,5	https://budget.public.lu/lb/budget2016/am-detail.html?chpt=depenses&dept=14&sect=105# Ministère de la Santé - Budget Organisme pour la Sécurité et la Qualité de la Chaîne Alimentaire (OSQCA): frais de fonctionnement - Cnl 2014: 5.903 € 2015: 11.000 € 2016: 11.000 € 2017: 15.000 € 2018: 15.000 € 2019: 15.000 € Administration de Service Veterinaires Budget Frais de fonctionnement de l'Organisme pour la Sécurité et la Qualité de la Chaîne Alimentaire (OSQCA) (part du département de l'agriculture) - Csde 2013: 1.483 € 2014: 7.000 € 2015: 7.000 € 2016: 7.200 € 2017: 7.400 € 2018: 7.600 €	0

							<p>other international organizations;</p> <p>f) income from protocols, conventions, agreements and contracts stipulated with administrations, institutions, institutes, associations and other persons legal, public or private, national or international;</p> <p>g) income from the formation of associations, consortia, foundations or companies or by participation in associations, consortia, foundations or companies;</p> <p>h) any other income related to the activities performed;</p> <p>i) donations and bequests from public or private entities;</p> <p>j) from paid services.</p>		
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<p>How is the budget controlled?</p>	<p>by the agency = 1 by the accounting office or court = 0.67 by both the agency and the government = 0.33 by the government only = 0</p>	<p>(2) The budget shall be determined by the President. He needs to his effectiveness of the approval of the Federal Ministry. The Federal Institute receives to compensate the approved federal budget subsidies in accordance with the relevant budgetary law.</p>	<p>0,33</p>	<p>9. The Board of Directors decides on any matter concerning the administration, operation and management of the NBG. In this context it exercises in particular the following competencies: [...] b) Approves the budget of the Hellenic Public Broadcaster, the necessary adjustments and modifications during its execution, as well as the balance sheet and the financial report of each year</p>	<p>1</p>	<p>"(2) The determination of the amounts of charges referred to in subsection (1) shall be subject to the approval of the Minister following consultations with the Minister for Finance." 24.—The Minister may, from time to time, with the consent of the Minister for Finance, advance to the Authority out of moneys provided by the Oireachtas, such sums as the Minister may determine for the purposes of expenditure by the Authority in the performance of its functions.</p>	<p>0</p>	<p>2. Staff regulations are approved by the Minister of health, in agreement with the Minister for Public Administration and simplification; the regulations relating to administration, finance and accounting are approved by the Minister of Health, in agreement with the Minister for the Economy and Finance.</p>	<p>0</p>	<p>No specific provisions</p>	<p>0,5</p>
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Which body decides on the agency's internal organisation?	the agency = 1 both the agency and the government = 0.5 the government = 0	(2) The Board of Directors has the task of informing the President of the management of the Federal Institute to support; in particular, it contributes to this 1. the treatment of scientific issues of particular importance, 2. the planning and awarding of research projects, 3. the establishment of commissions and the coordination of their activities with each other, 4. the establishment of the budget, 5. the principles of organization, personnel management and personnel management.	1	9. The Board of Directors decides on any matter concerning the administration, operation and management of the NBG. In this context it exercises in particular the following competencies: (a) take all necessary decisions to carry out the EFET mission [...] j) decides on the recruitment of personnel, where and as provided by the applicable provisions,	1	(1) The Board may appoint such and such number of persons to be members of the staff of the Authority as it may determine with the consent of the Minister and the Minister for Finance. (2) The grades of the staff of the Authority and the numbers of staff in each grade and the appropriate level of remuneration for each grade shall be determined by the Board with the consent of the Minister and the Minister for Finance.	0,5	2. Staff regulations are approved by the Minister of health, in agreement with the Minister for Public Administration and simplification; the regulations relating to administration, finance and accounting are approved by the Minister of Health, in agreement with the Minister for the Economy and Finance.	0	No specific provisions	0,5
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<p>Which body is in charge of the agency's personnel policy (hiring and firing staff, deciding on its allocation and composition)?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>(2) The Board of Directors has the task of informing the President of the management of the Federal Institute to support; in particular, it contributes to this</p> <ol style="list-style-type: none"> 1. the treatment of scientific issues of particular importance, 2. the planning and awarding of research projects, 3. the establishment of commissions and the coordination of their activities with each other, 4. the establishment of the budget, 5. the principles of organization, personnel management and personnel management. 	<p>1</p>	<p>[...] j) decides on the recruitment of personnel, where and as provided by the applicable provisions,</p>	<p>1</p>	<p>(1) The Board may appoint such and such number of persons to be members of the staff of the Authority as it may determine with the consent of the Minister and the Minister for Finance.</p> <p>(2) The grades of the staff of the Authority and the numbers of staff in each grade and the appropriate level of remuneration for each grade shall be determined by the Board with the consent of the Minister and the Minister for Finance.</p>	<p>0,5</p>	<p>"2. Staff regulations are approved by the Minister of health, in agreement with the Minister for Public Administration and simplification; the regulations relating to administration, finance and accounting are approved by the Minister of Health, in agreement with the Minister for the Economy and Finance."</p>	<p>0</p>	<p>(4) The body may appoint experts. (5) The secretariat of the organization shall be provided by a full-time officer of the Ministry of Health.</p>	<p>0</p>
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<p>Regulatory competencies</p>	<p>the agency only = 1 the agency and another independent authority = 0.67 the agency and the parliament = 0.5 the agency and the government = 0.33 the agency has only consultative competencies = 0</p>	<p>§ 2 Activities and task execution (1) Within the scope of its competence, the BfR independently addresses issues in particular Improving consumer health protection and conducting research according to § 2 Abs. 1 Nr. 4 BfRG.</p>	<p>1</p>	<p>2. Purpose of the HFF is to protect the consumer by ensuring the import, production and movement of healthy food, certification of fitness, quality control and quality improvement of food, as well as protecting the consumer's financial interests and ensuring that consumers are prevented its misleading in relation to hygiene, composition, labeling and the price of food.</p>	<p>1</p>	<p>15.—The Authority shall at the request of the Minister or of another Minister of the Government, provide to the Minister or that other Minister of the Government advice on issues relating to all or any of the matters listed in this section or may, on its own initiative, provide such advice on— [...]</p>	<p>0</p>	<p>1. The Higher Institute of Health, hereinafter referred to as an Institute, is the technical-scientific body of the National Health Service and pursues the protection of public health, in particular through development of the functions of research, control, consultancy, regulation and training. The Minister of Health, the Regions and the Authorities avail themselves of this Autonomous provinces of Trento and Bolzano.</p>	<p>0,33</p>	<p>Art. 4. The organization is responsible for carrying out on behalf of the Ministers having respectively Health and Agriculture in their attributions, the following missions: - the development, integration, management and updating of the integrated multiannual control plan according to the provisions of Articles 41 to 44 of Regulation (EC) No 882/2004; - to be the point of contact for Luxembourg of the rapid alert system for feed and feed foodstuffs established under Article 50 of Regulation (EC) No 178/2002, including the management of system; - the development, management and updating of the crisis management plan provided for in Article 13 of Regulation (EC) No. 882/2004; - the communication, subject to the rules of confidentiality laid down in Article 52 of Regulation (EC) No 178/2002, information intended for the general public pursuant to Article 7 of the abovementioned Community Regulation and Article 10 of Regulation (EC) No 178/2002; - the coordination of the in-service training of officials responsible for carrying out official controls in application of Article 6 of Regulation (EC) No 882/2004; - the carrying out and / or evaluation of audits carried out pursuant to Article 4 of Regulation (EC) No 882/2004; - the coordination of the registers of establishments in the food sector; - advise on all scientific and technical issues related to food security are submitted by the Ministers having respectively Health and Agriculture in their attributions; - to study and propose on its own initiative any measure or improvement in the field of food safety that he will judge useful; - to ensure the coordination of meetings concerning the official control of products covered by this Regulation, organized at the level of the institutions of the European Community;</p>	<p>1</p>
<p>Status of the agency head</p>			<p>0,5</p>		<p>0,6233</p>		<p>0,405</p>		<p>0,3717</p>		<p>0,305</p>

Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0		0,5	The term of office of the Chairman and the members of the Board of Directors is four years.	0,4	(1) The term of office of the chairperson of the Board shall be 5 years.	0,6	a) the President, whose position has a duration of four years and can be confirmed only once;	0,4	No specific provisions	0,5
Who appoints the agency head?	members of management board = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0		0,5	The Chairman and the Vice-Chairman of the Board of Directors are appointed by the Council of Ministers, on a proposal of the Minister of Development and the opinion of the Hellenic Parliament, as defined in this Regulation.	0,67		0,5	Article 4. President 1. The President of the Institute is chosen from among personalities to the scientific community, endowed with high and recognized professionalism documented through the presentation of curricula, in the field of research and experimentation in the fields of activity of the Institute itself, and is appointed by decree of the President of the Council of Ministers, on the proposal of the Minister of Health	0	(3) The Minister of Health together with the Minister in charge of Agriculture appoints a President and a vice-president among these members.	0

Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0		0,5 7. By a decision of the Cabinet of Ministers and upon recommendation of the Minister of Development, a member of the Board of Directors shall decline from it if he no longer fulfills the conditions set out in paragraph 3 of this article or in performing his duties prejudiced his behavior purposes of HEPA. 8. The replacement of a member of the Board of Directors who has passed away, resigns or is forfeited for the remainder of the term of the Board of Directors.	0,67 (3) The chairperson of the Board may at any time resign his or her office as chairperson by letter sent to the Minister and the resignation shall, unless previously withdrawn in writing, take effect at the commencement of the meeting of the Board held next after the Board has been informed by the Minister of the resignation.	0,33	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33
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<p>May the agency head hold other offices in government?</p>	<p>no = 1 only with permission of the government = 0.5 yes = 0</p>		<p>0,5</p>	<p>The Chairman and the members of the Board of Directors in the performance of their duties must abstain from any business activity directly or indirectly related to the object of NBG.</p>	<p>1</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>if he is a university professor, he is placed on leave in accordance with article 12 of the President's decree of the Republic of 11 July 1980, n. 382, and subsequent amendments, if he is employee of public administrations he is placed in expectation without checks, with recognition of seniority of service. For maximum organizational transparency, the Institute adopts a code of ethics, as well as a special regulation to prevent, identify and resolve any conflicts of interest.</p>	<p>1</p>	<p>No specific provisions</p>	<p>0,5</p>
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Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0		0,5	The term of office of the Chairman and the members of the Board of Directors is four years.	1	(4) The chairperson of the Board shall, unless he or she sooner dies or otherwise ceases to be chairperson by virtue of subsection (2) or (3), hold office until the expiration of his or her period of membership of the Board and, if he or she is re-appointed as a member of the Board, he or she shall be eligible for re-appointment as chairperson of the Board.	0,5	a) the President, whose position has a duration of four years and can be confirmed only once;	0,5	No specific provisions	0,5
Is independence a formal requirement for the appointment?	yes = 1 no = 0		0,5	No specific requirements for the appointment	0	No specific requirements for the appointment	0	No specific requirements for the appointment	0	No specific requirements for the appointment	0
Status of the members of the management board			0,5		0,5667		0,35		0,455		0,2217

Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0		0,5	The term of office of the Chairman and the members of the Board of Directors is four years.	0,4	(4) The Minister, when appointing an ordinary member of the Board, shall fix such member's period of membership which shall not exceed 5 years and, subject to this section, membership shall be on such terms as the Minister determines. (5) Four of the ordinary members of the Board appointed under subsection (2) shall hold office for a period not exceeding three years from the date of their appointment as determined by the Minister.	0,6	b) the Board of Directors, whose term has a duration of four years;	0,4	No specific provisions	0,5
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<p>Who appoints the members of the management board?</p>	<p>agency's head = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0</p>		<p>0,5</p>	<p>1. EFET. is managed by a seven-member Board of Directors. 2. The members of the Board of Directors are appointed by decision of the Council of Ministers upon proposal of the Minister of Development.</p>	<p>0,33</p>	<p>(2) The Minister shall, as soon as may be after the establishment of day, appoint persons to be members of the Board.</p>	<p>0</p>	<p>Article 5. Board of Directors 1. Board of directors is appointed by the Minister of Health and is composed of five members: the President and four experts from high and recognized professionalism documented through the presentation of curricula, professionalism in technical-scientific subjects e laws that fall within the scope of the Institute's powers, like this identified: a) an expert appointed by the Minister of Health; b) two experts designated by the Unified Conference referred to in Article 8 of the legislative decree of 28 August 1997, n. 281; c) an expert appointed by the Minister of Education, of the University and research.</p>	<p>0</p>	<p>(2) This body shall consist of six members, each of whom shall be appointed three times by the Minister of Health and by the Minister in charge of Agriculture. Two members are seconded on a full-time basis and four part-time members of their respective administrations to carry out their duties in the framework of the body.</p>	<p>0</p>
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Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0		0,5	"7. By a decision of the Cabinet of Ministers and upon recommendation of the Minister of Development, a member of the Board of Directors shall decline from it if he no longer fulfills the conditions set out in paragraph 3 of this article or in performing his duties prejudiced his behavior purposes of HEPA. 8. The replacement of a member of the Board of Directors who has passed away, resigns or is forfeited for the remainder of the term of the Board of Directors."	0,67	0	No specific provisions for dismissal	0,33	No specific provisions for dismissal	0,33
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					<p>cease to be and shall be disqualified from being a member of that Board where such member—</p> <p>(a) is adjudicated bankrupt, (b) makes a composition or arrangement with creditors, (c) is sentenced by a court of competent jurisdiction to a term of imprisonment, or</p> <p>(d) is disqualified or restricted from being a director of any company (within the meaning of the Companies Acts, 1963 to 1990).</p> <p>(9) If a member of the Board dies, resigns, retires, becomes disqualified or is removed from office, the Minister may appoint a person to be a member of the Board to fill the casual vacancy so occasioned and the person so appointed shall be appointed in the same manner as the member of</p>				
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					the Board who occasioned the casual vacancy. The person so appointed shall be appointed within 2 months of the Minister being notified of the vacancy.					
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<p>May the members of the management board hold other offices in government?</p>	<p>no = 1 only with permission of the government = 0.5 yes = 0</p>		<p>0,5</p>	<p>The Chairman and the members of the Board of Directors in the performance of their duties must abstain from any business activity directly or indirectly related to the object of NBG.</p>	<p>1</p>	<p>40.—(1) Where a member of the Board— (a) is nominated as a member of Seanad Éireann, (b) is elected as a member of either House of the Oireachtas or as a representative in the European Parliament, (c) is regarded pursuant to section 19 of the European Parliament Elections Act, 1997, as having been elected to the European Parliament to fill a vacancy, (d) becomes a member of a local authority, or (e) becomes a member of the board of a health board, he or she shall thereupon cease to be a member of the Board</p>	<p>1</p>	<p>3. For maximum organizational transparency, the Institute adopts a code ethics, as well as a special regulation to prevent, identify and resolve any conflicts of interest.</p>	<p>1</p>	<p>No specific provisions</p>	<p>0,5</p>
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Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0		0,5	The term of office of the Chairman and the members of the Board of Directors is four years.	1	(10) A member of the Board whose period of membership expires by the effluxion of time shall be eligible for re-appointment as a member of the Board.	0,5	b) the Board of Directors, whose term has a duration of four years;	1	(2) This body shall consist of six members, each of whom shall be appointed three times by the Minister of Health and by the Minister in charge of Agriculture. Two members are seconded on a full-time basis and four part-time members of their respective administrations to carry out their duties in the framework of the body.	0
Is independence a formal requirement for the appointment?	yes = 1 no = 0		0,5	No specific requirements for the appointment	0	No specific requirements for the appointment	0	No specific requirements for the appointment	0	No specific requirements for the appointment	0

		NETHRLANDS - NVWA		PORTUGAL - ASAE		SPAIN - AECOSAN		SWEDEN - LV		UK - FSA	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Relationship with government and parliament			1		0		1		1		0
Is the independence of the agency formally stated?	1 = Yes 0 = No	NVWA is an independent agency commissioned by the VWS and the EZ. It is under the administrative responsibility of EZ but functions as an executive delivery body for both Ministries.	1	Article 2 Legal nature and mission 1 - The ASAE is a service of the direct administration of the State endowed with administrative autonomy, in the hierarchical dependence of the minister who supervises the area of the economy. 2 - ASAE is the national administrative authority specialized in food safety and economic surveillance. 3. The ASAE shall be the national authority responsible for coordinating the official control of foodstuffs and the national liaison body with other Member States. It shall be responsible for assessing and communicating risks in the food chain and for disciplining economic activities in the sectors food and non-food, through the supervision and prevention of compliance with the legislation regulating them.	0	1. It is created, under the name of the Spanish Agency for Food Safety, a public body with the character of an autonomous body, in accordance with the provisions of articles 41, 43, 61 and 62 of Law 6/1997 on Organization and Operation of the General Administration of the State, with different legal and public personality and full capacity to act, which shall be governed by this law and other applicable provisions.	1	In Sweden, the National Food Administration, an autonomous government agency reporting to the Ministry of Agriculture, Food and Fisheries, is the central administrative authority for matters concerning food.	1	1.—(1) There shall be a body to be called the Food Standards Agency The Food or, in Welsh, yr Asiantaeth Safonau Bwyd (referred to in this Act as “the Standards Agency”) for the purpose of carrying out the functions conferred on it by Agency or under this Act.	0
Financial and organizational autonomy			0,5		0,625		0,7925		0,75		0,3325

<p>What is the source of the agency's budget?</p>	<p>fees levied on the regulatees = 1 both government and fees levied on regulatees = 0.5 government = 0</p>	<p>The Ministry of Health, Welfare and Sports (VWS) The Ministry provides approximately one third of the NVWA budget.</p>	<p>0,5</p>	<p>Recipes The revenues of ASAE are: a) The appropriations coming from the State Budget; b) The product of services rendered; c) The proceeds from the sale of publications; d) The proceeds of fines imposed in administrative offenses, in the same proportion as they revert to services that are extinct or restructured; (e) the proceeds from the levying of fees for non-wine spirit drinks; f) Any other revenues that are attributed to it by law, contract or other title.</p>	<p>0,5</p>	<p>Article 6. Financing and patrimony. 1. The economic resources of the Agency shall consist of: a) The allocations that are established annually with charge to the General Budgets of the State. b) Contributions from community funds destined to fulfill their purposes. c) Taxes or other public income arising from their activity. d) The subsidies, as well as the income obtained as a result of concerts or agreements with public entities. e) Any other resource not foreseen in the previous sections and that may legally correspond to it.</p>	<p>0,5</p> <p>The work of the NFA is financed partly by an annual appropriation from the Government (ca. 145 million Swedish crowns, SEK, for 2004), partly by fees paid by slaughterhouses and the food industry and trade (ca. 188 million SEK in 2004) and to a small extent by research grants, etc (17 million SEK in 2004) – in all ca 350 million SEK. The meat inspection service is financed entirely by fees collected from the slaughterhouse operators. Municipal food control is financed partly by local taxes and partly by fees collected from the food industry and trade for sampling and analysis. All establishments producing or handling foods (except very small operations) are required to pay an annual food control fee to the supervisory authority, i.e. the</p>	<p>0,5</p> <p>39.—(1) There shall be paid out of money provided by Parliament—provisions. (a) any expenditure incurred by a Minister of the Crown by virtue of this Act; (b) any increase attributable to this Act in the sums payable out of money so provided under any other Act. (2) Any expenditure incurred by the Agency shall be paid out of money provided by Parliament unless it is met from money paid or appropriated under subsection (3) (or from money which the Agency is authorised by virtue of any relevant provision to apply for the purpose). (3) Sums may be— (a) paid by the National Assembly for Wales; (b) paid out of the Scottish Consolidated Fund; or (c) appropriated by Act of the Northern Ireland Assembly, for the purpose of meeting any of the</p>	<p>0</p>
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								<p>NFA or the municipal food control authority.</p>	<p>expenditure of the Agency.</p> <p>(4) Any sums received by the Agency, other than—</p> <p>(a) money provided by Parliament or paid or appropriated under subsection (3);</p> <p>(b) receipts which are, by virtue of provision made by or under any enactment, payable—</p> <p>(i) to the National Assembly for Wales;</p> <p>(ii) into the Scottish Consolidated Fund; or</p> <p>(iii) into the Consolidated Fund of Northern Ireland,</p> <p>or which would be so payable but for any relevant provision relating to those receipts; and</p> <p>(c) other receipts specified, or of a description specified, in a determination under subsection (5), shall be paid into the Consolidated Fund.</p>	
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<p>How is the budget controlled?</p>	<p>by the agency = 1 by the accounting office or court = 0.67 by both the agency and the government = 0.33 by the government only = 0</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>Article 16 Directorate General Services DSG promotes and ensures the administration and management of human, financial, property, computer, library, documentation and expedient resources, in particular: [...] e) To elaborate the draft budgets and their alterations, as well as all the elements necessary for the social management; (f) to exercise budgetary control and evaluation of the allocation of financial resources to the activities of bodies and services; (g) promote and ensure all procedures relating to the settlement of expenditure and the efficient collection of revenue; h) To elaborate and instruct the processes of acquisition of equipment, goods and services;</p>	<p>1</p>	<p>Article 9. Intervention and accounting. 1. The Agency will be subject to control by the General Comptroller of the State Administration, in the manner foreseen in the General Budgetary Law for the Autonomous Bodies. 2. The Agency will be subject to the public accounting system.</p>	<p>0,67</p>	<p>The Board of the NFA, which consists of 11 members, with the Director-General of the NFA as chairman, meets about eight times a year. It makes decisions on regulations issued by the NFA, budget proposals and the annual report submitted to the Government.</p>	<p>1</p>	<p>Accounts of Agency relating to sums paid or appropriated under s.39(3) 3.—(1) The Agency shall prepare separate accounts for each year of its expenditure in relation to each of the following descriptions of sums, that is to say— (a) the sums paid by the National Assembly for Wales under section 39(3)(a); (b) the sums paid out of the Scottish Consolidated Fund under section 39(3)(b); or (c) sums appropriated by Act of the Northern Ireland Assembly under section 39(3)(c). (2) Any sum received by the Agency which it applies by virtue of any relevant provision (within the meaning of section 39) shall be regarded as falling within paragraph (a), (b) or (c) of subparagraph (1), as the case may require. (3) Accounts required under</p>	<p>0,33</p>
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<p>Which body decides on the agency's internal organisation?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>	<p>The organization is headed by an Inspector-General (IG). The Inspector General has overall responsibility and is assisted by the Deputy IG. Three divisions are led by chief inspectors. The other sectors are led by a Director. Three divisions are responsible for enforcing.</p>	<p>0,5</p>	<p>Article 25 Principles of management 1 - The functioning of the ASAE is based on the structure defined in this decree-law and on the articulation with the central services in order to achieve the common objectives of the ministries.</p>	<p>0</p>	<p>Article 26. General Subdirections and basic units. The Spanish Agency for Food Safety is structured in the following units and centers, under the dependence of the Executive Director of said agency: a) General Secretariat, with an organic level of the General Subdirectorate, which carries out functions of support to the Executive Director in administrative, financial, legal and human resources management matters and, specifically, in the development of the functions included in paragraphs a), d), h) and u) of article 2.2 of Law 11/2001, as well as the Secretariat of the Interministerial Commission for Food Management (CIOA). b) Subdirectorate General of Food Risk Management, which assumes the development of functions related to the management of food risk in the production, transformation, processing, transportation, distribution and sale or service to final consumers and communities, as well as those of the same nature that had been assigned to the units or pre-existing services that are integrated in this Subdirectorate General. Specifically: [...]</p>	<p>1</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>"Staff 8.—(1) The Agency may, with the approval of the Minister for the Civil Service as to numbers and terms and conditions of service, appoint such staff as it may determine. (2) Sub-paragraph (1) is subject to section 3 in the case of the chief executive and the directors for Wales, Scotland and Northern Ireland."</p>	<p>0,5</p>
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<p>Which body is in charge of the agency's personnel policy (hiring and firing staff, deciding on its allocation and composition)?</p>	<p>the agency = 1 both the agency and the government = 0.5 the government = 0</p>		<p>0,5</p>	<p>Article 16 Directorate General Services DSG promotes and ensures the administration and management of human, financial, property, computer, library, documentation and expedient resources, in particular: a) To elaborate the studies necessary for the allocation and management of human resources; b) Study the application of updated methods of human resources management and promote the implementation of the actions necessary for the implementation of the annual training plan, taking into account the objectives of administrative modernization and the general and specific needs of the various departments and organizational units; c) Collect and organize information related to human resources for optimized management and prepare the social report; d) To ensure the processing of salaries and allowances related to personnel, as well as the record related to the social benefits to which they are entitled;</p>	<p>1</p>	<p>Article 5. Staff regime. The staffing regime of the Agency shall comply with the following criteria: 1. The management of the Agency, which will be determined in its Statute, will be appointed in accordance with the provisions of Law 6/1997 on the Organization and Functioning of the General State Administration. 2. The processing of the calls for selection and provision of jobs will be carried out by the Agency, adjusting its bases to the general principles established in Law 30/1984, on Measures for the Reform of Public Function.</p>	<p>1</p>	<p>The Director General and the five heads of department are responsible for the day-to-day running of the NFA, which has a staff of about 300 at its headquarters in Uppsala.</p>	<p>1</p>	<p>Staff 8.—(1) The Agency may, with the approval of the Minister for the Civil Service as to numbers and terms and conditions of service, appoint such staff as it may determine. (2) Sub-paragraph (1) is subject to section 3 in the case of the chief executive and the directors for Wales, Scotland and Northern Ireland.</p>	<p>0,5</p>
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<p>Regulatory competencies</p>	<p>the agency only = 1 the agency and another independent authority = 0.67 the agency and the parliament = 0.5 the agency and the government = 0.33 the agency has only consultative competencies = 0</p>	<p>The three main tasks of NVWA are supervision, risk assessment and risk communication in the areas of food and product safety. It is also responsible for: incident and crisis management, including animal health and disease control issues, and policy advice to the EZ and VWS. A significant part of its work involves liaising with other ministries and maintaining international contacts. Furthermore, the NVWA has three core tasks and two other tasks:</p> <ul style="list-style-type: none"> • enforcement (core task) • risk assessment (core task) • risk communication (core task) • policy advice • performance 	<p>1</p>	<p>1 - The ASAE is a service of the direct administration of the State endowed with administrative autonomy, in the hierarchical dependence of the minister who supervises the area of the economy. 2 - ASAE is the national administrative authority specialized in food safety and economic surveillance. 3. The ASAE shall be the national authority responsible for coordinating the official control of foodstuffs and the national liaison body with other Member States. It shall be responsible for assessing and communicating risks in the food chain and for disciplining economic activities in the sectors food and non-food, through the supervision and prevention of compliance with the legislation regulating them.</p>	<p>1</p>	<p>2. The functions of the Agency are: a) Coordinate the actions of the Administrations with competences that directly or indirectly affect food security and nutrition. b) Scheduling and coordinating the actions related to the sanitary aspects of the official control of food products provided by current regulations. c) Urge executive actions and, where appropriate, regulations, from the competent authorities, especially in situations of crisis or emergency. d) Identify and coordinate intersectoral and interterritorial forums with competencies in food security and nutrition. e) Censing and updating resources, public or private, related to food security and nutrition, favoring relations between them. f) Prepare and promote studies and research. g) Design annual programs of prospective studies on food security and nutrition to be developed, where appropriate, by the competent authorities. h) Report on the position of Spain and, where appropriate, represent it, in matters of food security and nutrition dealt with in the European Union and in international organizations, especially the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the "Codex Alimentarius" and the Council of Europe. i) Provide a technical support that, for the whole of the Administrations with competences, guarantees the use of the best scientific evidence. j) Advise public administrations in the planning and development of</p>	<p>1</p>	<p>[...] In order to achieve these goals, the NFA - issues food standards and other food regulations; - carries out supervision according to the Food Act and leads and coordinates food control in Sweden; - keeps the Government informed about developments in the food sector; - assists the Government with and participates in EU work and other international activities in the food area; - carries out investigations and practical scientific studies on foods and dietary habits and develops methods for food control; - informs consumers and other interested parties in the food chain about current legislation and other important matters related to food; - participates in the implementation of the regional development policy;</p>	<p>1</p>	<p>General functions in relation to food 6.—(1) The Agency has the function of— Development of (a) developing policies (or assisting in the development by any food policy and provision of public authority of policies) relating to matters connected with advice, etc. to food safety or other interests of consumers in relation to food; public authorities. and (b) providing advice, information or assistance in respect of such matters to any public authority. [...]</p>	<p>1</p>
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					<p>their food policies.</p> <p>k) Advise the economic and social sectors involved in food security and nutrition, with which they will establish permanent communication channels.</p> <p>l) Disseminate the reports and technical criteria prepared by the scientific committee.</p> <p>m) Promote as many information actions as are necessary for consumers and users.</p> <p>n) Develop a general action procedure for food crisis and emergency situations.</p> <p>ñ) Coordinate the functioning of the existing warning networks in the field of food safety in the Spanish territory and their integration into community and international warning systems.</p> <p>o) Develop certified food control procedures, processes and establishments, which serve as reference for accreditation purposes by the competent authorities.</p> <p>p) Promote the simplification and unification of standards in matters of food security and nutrition, as well as formulate proposals for new regulatory developments.</p> <p>q) Inform, where appropriate, the authorizations that correspond to the General State Administration in this area.</p> <p>r) Identify the needs of continuing training of food control professionals and design framework programs to meet those needs.</p> <p>s) To establish the databases that can collaborate in the harmonious development of the functions entrusted to the authorities.</p> <p>t) Prepare an annual report that reflects the actions of official control in the whole of the State and that analyzes the general</p>	<p>- works for the development of the country's school meals;</p> <p>- co-ordinates questions concerning infant nutrition, including breastfeeding.</p>			
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						situation of food security and nutrition in Spain, indicating the priority fields of action and, in particular, the emerging risks. u) Establish and maintain the necessary mechanisms to act in an integrated manner in the European network of food security and nutrition agencies or agencies. v) Carry out any others attributed to it by legal or regulatory standards, as well as those corresponding to the bodies and units integrated into the structures of the Agency.				
Status of the agency head			0,3883		0,305		0,4267		0,5	0,39
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0		0,5	No specific provisions	0,5	c) The appointment of the members of the Board of Directors shall fall on persons of recognized professional competence in any of the areas relevant to the operation of the Agency. His term will be four years. Said mandate shall be renewable in the manner determined by the Statute.	0,4	No specific provisions	0,5	No specific provisions 0,5

Who appoints the agency head?	<p>members of management board = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0</p>		0,5	<p>1 - The ASAE is headed by a president, appointed by joint order of the Prime Minister and the member of the Government responsible for the area of the economy, who is assisted by four vice presidents, one of whom acts as scientific director for the risks of the food chain, appointed by order of the member of the Government responsible for the area of the economy.</p>	0	<p>d) The President shall be appointed by the Council of Ministers, at the proposal of the head of the Department of Health and Consumption and may appoint up to two Vice Presidents in the manner determined by regulation.</p>	0,33		<p>2.—(1) The Agency shall consist of a chairman and deputy chairman Appointment of and not less than eight or more than twelve other members, of whom— members etc. (a) one member shall be appointed by the National Assembly for Wales; (b) two members shall be appointed by the Scottish Ministers; (c) one member shall be appointed by the Department of Health and Social Services for Northern Ireland; and (d) the others shall be appointed by the Secretary of State. (2) The chairman and deputy chairman shall be appointed by the appropriate authorities acting jointly and, before appointing a person as one of the other members of the Agency the authority making the appointment shall consult the other appropriate</p>	0,67
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										<p>authorities.</p> <p>(3) Before appointing a person as chairman, deputy chairman or member of the Agency, the authorities or authority making the appointment shall—</p> <p>(a) have regard to the desirability of securing that a variety of skills and experience is available among the members of the Agency (including experience in matters related to food safety or other interests of consumers in relation to food); and</p> <p>(b) consider whether any person it is proposed to appoint has any financial or other interest which is likely to prejudice the exercise of his duties.</p>	
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Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0	No specific provisions for dismissal	0,33	No specific provision for dismissal	0,33	No specific provision for dismissal	0,33		0,5	3.—(1) The person holding office as chairman or deputy chairman— (a) may resign his office by giving notice to any of the appropriate authorities (and on doing so ceases to be a member of the Agency); and (b) may be removed from office by the appropriate authorities acting jointly if they are satisfied that he is eligible to be removed under paragraph 4.	0,67
May the agency head hold other offices in government?	no = 1 only with permission of the government = 0.5 yes = 0	No specific provisions	0,5	No specific provisions	0,5	No specific provisions	0,5		0,5	No specific provisions	0,5
Is the appointment renewable?	no = 1 yes once = 0.5 yes more than once = 0	No specific provisions	0,5	No specific provisions	0,5	c) The appointment of the members of the Board of Directors shall fall on persons of recognized professional competence in any of the areas relevant to the operation of the Agency. His term will be four years. Said mandate shall be renewable in the manner determined by the Statute.	0		0,5	2.—(1) A person appointed as chairman or deputy chairman or as one of the other members shall hold and vacate office in accordance with the terms of his appointment and, on ceasing to hold that office, is eligible for re-appointment.	0

Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0	No specific requirements for the appointment	0	f) The members of the Board of Directors in the exercise of the functions that correspond to them will act with full autonomy.	1		0,5	No specific requirements for the appointment	0
Status of the members of the management board			0,3883		0,445		0,5667		0,5		0,3067
Term of office	over 8 years = 1 6 to 8 years = 0.8 5 years = 0.6 4 years = 0.4 fixed term under 4 years or under discretion of the appointer = 0.2 no fixed term = 0	No specific provisions	0,5	No specific provisions	0,5	His term will be four years.	0,4		0,5		0,5

<p>Who appoints the members of the management board?</p>	<p>agency's head = 1 a complex mix of the parliament and government = 0.67 parliament = 0.5 government collectively = 0.33 one or two ministries = 0</p>		<p>0,5</p>	<p>1 - The ASAE is headed by a president, appointed by joint order of the Prime Minister and the member of the Government responsible for the area of the economy, who is assisted by four vice presidents, one of whom acts as scientific director for the risks of the food chain, appointed by order of the member of the Government responsible for the area of the economy.</p>	<p>0</p>	<p>b) The Board of Directors will be composed of: 1) The President of the Board of Directors of the Agency that will hold the presidency of the Agency. 2) The Vice President (s). 3) Four members appointed by the Government of the Nation at the proposal of the Ministers of Health and Consumer Affairs, of Agriculture, Fisheries and Food, of Environment, as well as of Science and Technology. 4) Four members appointed by the Autonomous Communities. 5) Two members appointed by local entities at the proposal of the association of local entities with the greatest presence in Spain. 6) Two members, appointed on the proposal of the Council of Consumers and Users and another on the proposal of the most representative economic organizations of the production, transformation, distribution and restoration sectors in the terms determined by regulation. c) The appointment of the members of the Board of Directors shall fall on persons of recognized professional competence in any of the areas relevant to the operation of the Agency. His term will be four years. Said mandate shall be renewable in the manner determined by the Statute.</p>	<p>0,33</p>		<p>2.—(1) The Agency shall consist of a chairman and deputy chairman Appointment of and not less than eight or more than twelve other members, of whom— members etc. (a) one member shall be appointed by the National Assembly for Wales; (b) two members shall be appointed by the Scottish Ministers; (c) one member shall be appointed by the Department of Health and Social Services for Northern Ireland; and (d) the others shall be appointed by the Secretary of State. (2) The chairman and deputy chairman shall be appointed by the appropriate authorities acting jointly and, before appointing a person as one of the other members of the Agency the authority making the appointment shall consult the other appropriate</p>	<p>0,67</p>
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										<p>authorities.</p> <p>(3) Before appointing a person as chairman, deputy chairman or member of the Agency, the authorities or authority making the appointment shall—</p> <p>(a) have regard to the desirability of securing that a variety of skills and experience is available among the members of the Agency (including experience in matters related to food safety or other interests of consumers in relation to food); and</p> <p>(b) consider whether any person it is proposed to appoint has any financial or other interest which is likely to prejudice the exercise of his duties.</p>	
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Dismissal	dismissal is impossible = 1 possible, but only for reasons not related to policy = 0.67 no specific provisions for dismissal = 0.33 possible at the appointer's discretion = 0	No specific provisions for dismissal	0,33	3 - Without prejudice to civil or criminal liability resulting therefrom, breach of professional secrecy established in this article when committed by one of the members of the ASAE organs or by their personnel implies to the offender disciplinary sanctions corresponding to their seriousness, which may go to the dismissal, dismissal or termination of the respective employment contract, and when practiced by a person or entity linked to the ASAE by a service agreement or agreement grants the President the right to terminate immediately that contract.	0,67	Article 11. Declaration of incompatibility by the members of the Board of Directors. If in the course of the term of office of the members of the Board of Directors, there were causes that could create a situation of incompatibility for the performance of their management, in accordance with the provisions of Article 4.6.d) of Law 11/2001, the those affected by them will carry out, before the President of the Agency, immediate declaration of the same, which will be evaluated by the Board of Directors. If, as from said evaluation, it concludes that the declarant's independence to exercise his mandate as a member of the Board may be compromised, the incompatibility will have eight days to choose between his status as Director and the incompatible position. If the option is not exercised within the aforementioned period, the Council will formulate, through the President of the Agency, a proposal for removal and replacement before the establishment that appointed it.	0,67		0,5	(2) A member other than the chairman or deputy chairman— (a) may resign his office by giving notice to the authority by which he was appointed; and (b) may be removed from office by that authority if it is satisfied that he is eligible to be removed under paragraph 4. A person may be removed from office as chairman, deputy chairman or other member only if— (a) he has been adjudged bankrupt, has had his estate sequestered or has made a composition or arrangement with, or granted a trust deed for, his creditors; or (b) he is failing to carry out the duties of his office or is otherwise unable or unfit to carry out those duties.	0,67
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<p>May the members of the management board hold other offices in government?</p>	<p>no = 1 only with permission of the government = 0.5 yes = 0</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>4. Without prejudice to legal provisions on incompatibilities, the personnel of the inspection careers in service and the members of the Scientific Council and the Technical Committees shall not hold management, administration or any other functions, whether paid or unpaid, to the entities whose activity is within the scope of the duties of the ASAE.</p>	<p>1</p>	<p>Article 11. Declaration of incompatibility by the members of the Board of Directors. If in the course of the term of office of the members of the Board of Directors, there were causes that could create a situation of incompatibility for the performance of their management, in accordance with the provisions of Article 4.6.d) of Law 11/2001, the those affected by them will carry out, before the President of the Agency, immediate declaration of the same, which will be evaluated by the Board of Directors. If, as from said evaluation, it concludes that the declarant's independence to exercise his mandate as a member of the Board may be compromised, the incompatibility will have eight days to choose between his status as Director and the incompatible position. If the option is not exercised within the aforementioned period, the Council will formulate, through the President of the Agency, a proposal for removal and replacement before the establishment that appointed it.</p>	<p>1</p>	<p>0,5</p>	<p>No specific provisions</p>	<p>0</p>
<p>Is the appointment renewable?</p>	<p>no = 1 yes once = 0.5 yes more than once = 0</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>No specific provisions</p>	<p>0,5</p>	<p>1. In accordance with article 4.1.c) of Law 11/2001, the term of office of the members of the Board of Directors will be four years, renewable for periods of equal duration, which will begin to be computed from the day following the of the publication in the "Official State Gazette" of the appointment of the same.</p>	<p>0</p>	<p>0,5</p>	<p>2.—(1) A person appointed as chairman or deputy chairman or as one of the other members shall hold and vacate office in accordance with the terms of his appointment and, on ceasing to hold that office, is eligible for re-appointment.</p>	<p>0</p>

Is independence a formal requirement for the appointment?	yes = 1 no = 0	No specific requirements for the appointment	0	No specific requirements for the appointment	0	f) The members of the Board of Directors in the exercise of the functions that correspond to them will act with full autonomy.	1		0,5	No specific requirements for the appointment	0
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APPENDIX A5.2 – Coding of formal accountability

		AUS - AGES		BELGIUM - FASFC		DENMARK		FINLAND		FRANCE - ANSES	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Is the agency required to send information upon request to government?	1 = Yes, 0 = No	(6) Within the scope of the tasks entrusted to it, the Agency shall, at the request of the Federal Minister for Health and Women or the Federal Minister for Agriculture, Forestry, Environment and Water Management, carry out the following activities: [...] The members of the Supervisory Board are obliged to provide comprehensive information to the respective appointing Federal Minister.	1	No formal obligations	0	No formal obligations	0	No formal obligations	0	No formal obligations	0
Is the agency required to send information upon request to parliament?	1 = Yes, 0 = No	No formal obligations	0	No formal obligations	0	No formal obligations	0	No formal obligations	0	No formal obligations	0

<p>Is the agency required to submit an annual plan to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>§ 8a. (1) The Agency shall submit an annual work program to the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management. The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year as proposed by the Agency and submitted to the management for budget preparation. The content of the work program, including any key topics in the work program, must be agreed in good time with the owners' ministries. Work program and budgeting must cover the strategic orientation of the Agency.</p>	<p>0,67</p>	<p>No formal obligations</p>	<p>0</p>	<p>The performance contract between MEF and DVFA is reviewed annually. Overall performance is measured inter alia against key Performance Indicators (KPIs) contained in the performance contract. The Danish MANCP contains an overall strategy map as a basis for reviewing the performance of DVFA. The strategy map contains desired outcomes, frontline activities and management and development initiatives, which are reviewed at management meetings; certain of these are monitored using key performance indicators (KPIs). Progress in achieving the desired outcomes and in implementing</p>	<p>0,33</p>	<p>The Food Agency is administratively under the Ministry of Agriculture and Forestry. The Ministry of Agriculture and Forestry, the Ministry of Trade and Industry and the Ministry of Social Affairs and Health are responsible for co-ordinating the performance management of the Agency as stipulated by the Government Decree. Ministries' cooperation in the field of food inspection The Ministry of Agriculture and Forestry, together with the Food Safety Authority, signs an action concerning the performance targets pursuant to Section 11 of the Government Budget Regulation (1243/1992) and issues a position as set out in section 66 of that regulation. The action regarding the performance targets and the statement of accounts shall be prepared in cooperation with the Ministry of Trade and Industry and the Ministry of Social Affairs and Health.</p>	<p>0,67</p>	<p>No formal obligations</p>	<p>0</p>
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						front line activities and initiatives contained in the strategy maps is monitored through regular management meetings at various levels, including less measurable elements (e.g. good resource management, effective methods and IT support) for which no KPI are available.					
Is the agency required to submit an annual plan to parliament?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	No formal obligations	0	No formal obligations	0	"Source: https://www.evira.fi/en/about-evira/about-us/planning-and-monitoring/PLANNING AND MONITORING OF EVIRA'S OPERATIONS The key plans of State performance management are performance agreements and the budget decided upon by Parliament. A performance agreement is an agreement between a government agency and Ministry of Agriculture and Forestry concerning the operating objectives for the new year within the framework of granted appropriations. Of central importance in monitoring data are the financial statements, in particular the annual that forms part of them, and the ministry's opinion of these documents."	0,67	No formal obligations	0

<p>Is the agency required to submit an annual itemized budget to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>§ 8a. (1) The Agency shall submit an annual work program to the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management. The work program shall refer to the funds made available pursuant to § 12 and shall be determined by the Federal Minister of Health and the Federal Minister of Agriculture, Forestry, Environment and Water Management in due time each year as proposed by the Agency and submitted to the management for budget preparation. The content of the work program, including any key topics in the work program, must be agreed in good time with the owners' ministries. Work program and budgeting must cover the strategic orientation of the Agency.</p>	<p>0,67</p>	<p>The agency submits to the Minister and the Minister responsible for the Quarterly Situation Budget in the month of the end of the reporting period. It draws up by 30 April at the latest, the annual account for the implementation of its budget, as well as an active and passive situation on 31 December of the year in question.</p>	<p>0,33</p>	<p>The performance contract between MEF and DVFA is reviewed annually. Overall performance is measured inter alia against key Performance Indicators (KPIs) contained in the performance contract. The Danish MANCP contains an overall strategy map as a basis for reviewing the performance of DVFA. The strategy map contains desired outcomes, frontline activities and management and development initiatives, which are reviewed at management meetings; certain of these are monitored using key performance indicators (KPIs). Progress in achieving the desired outcomes and in implementing</p>	<p>0,33</p>	<p>The Food Agency is administratively under the Ministry of Agriculture and Forestry. The Ministry of Agriculture and Forestry, the Ministry of Trade and Industry and the Ministry of Social Affairs and Health are responsible for co-ordinating the performance management of the Agency as stipulated by the Government Decree.</p> <p>Ministries' cooperation in the field of food inspection</p> <p>The Ministry of Agriculture and Forestry, together with the Food Safety Authority, signs an action concerning the performance targets pursuant to Section 11 of the Government Budget Regulation (1243/1992) and issues a position as set out in section 66 of that regulation. The action regarding the performance targets and the statement of accounts shall be prepared in cooperation with the Ministry of Trade and Industry and the Ministry of Social Affairs and Health.</p>	<p>0,67</p>	<p>Art. R. 1313-36. - The agency is subject to the financial control of the State under the conditions provided by Decree No. 2005-757 of 4 July 2005 on financial control in public administrative institutions of the State.</p>	<p>0,67</p>
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						front line activities and initiatives contained in the strategy maps is monitored through regular management meetings at various levels, including less measurable elements (e.g. good resource management, effective methods and IT support) for which no KPI are available.					
Is the agency required to submit an annual itemized budget to parliament?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	No formal obligations	0	No formal obligations	0	"Source: https://www.evira.fi/en/about-evira/about-us/planning-and-monitoring/PLANNING AND MONITORING OF EVIRA'S OPERATIONS The key plans of State performance management are performance agreements and the budget decided upon by Parliament. A performance agreement is an agreement between a government agency and Ministry of Agriculture and Forestry concerning the operating objectives for the new year within the framework of granted appropriations. Of central importance in monitoring data are the financial statements, in particular the annual that forms part of them, and the ministry's opinion of these documents."	0,67	No formal obligations	0

Is the agency required to submit an annual activity report to government?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	§ 2. The agency shall submit to the Minister quarterly reports on its activities, within one month of the period covered by the report, as well as an annual report on its activities, including a summary of the results achieved with regard to its activities, which it also submits to Parliament.	0,33	DVFA publish the MANCP and annual reports on their websites.	0,33	No formal obligations	0	"He shall send each year to the Prime Minister, to the ministers concerned and to the presidents of the two parliamentary assemblies and to the Economic, Social and Environmental Council the activity report of the agency and shall ensure its publicity."	1
Is the agency required to submit an annual activity report to parliament?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	§ 2. The agency shall submit to the Minister quarterly reports on its activities, within one month of the period covered by the report, as well as an annual report on its activities, including a summary of the results achieved with regard to its activities. missions, which it also submits to Parliament.	0,33	DVFA publish the MANCP and annual reports on their websites.	0,33	No formal obligations	0	"He shall send each year to the Prime Minister, to the ministers concerned and to the presidents of the two parliamentary assemblies and to the Economic, Social and Environmental Council the activity report of the agency and shall ensure its publicity."	1
Is the agency required to submit an annual financial report to government?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	The agency submits to the Minister and the Minister responsible for the Quarterly Situation Budget in the month of the end of the reporting period. It draws up by 30 April at the latest, the annual account for the implementation of its budget, as well as an active and passive situation on 31 December of the year in question.	0,33	DVFA publish the MANCP and annual reports on their websites.	0,33	No formal obligations	0	Art. R. 1313-36. - The agency is subject to the financial control of the State under the conditions provided by Decree No. 2005-757 of 4 July 2005 on financial control in public administrative institutions of the State.	0,67

<p>Is the agency required to submit an annual financial report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information, 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>DVFA publish the MANCP and annual reports on their websites.</p>	<p>0,33</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>
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		GERMANY - BFR		GREECE - EFET		IRELAND - FSAI		ITALY - ISS		LUXEMBOURG - OSCQA	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Is the agency required to send information upon request to government?	1 = Yes, 0 = No	(2) The Federal Institute is obliged to inform the Federal Ministry at any time about its activities To give. (3) Representatives of the Federal Ministry are authorized to participate in the deliberations of the Executive Board; them is always available to listen to.	1	No formal obligations	0	15.—The Authority shall at the request of the Minister or of another Minister of the Government, provide to the Minister or that other Minister of the Government advice on issues relating to all or any of the matters listed in this section or may, on its own initiative, provide such advice on— (3) The Authority shall, whenever so requested by the Minister, furnish to the Minister information in relation to such matters as he or she may specify concerning or relating to the scope of its activities generally, or in respect of any account prepared by the Authority or any report specified in subsection (1) or the policy or activities, other than day to day activities, of the Authority.	1	No formal obligations	0	No formal obligations	0

Is the agency required to send information upon request to parliament?	1 = Yes, 0 = No	No formal obligations	0	No formal obligations	0	No formal obligations	0	No formal obligations	0	No formal obligations	0
Is the agency required to submit an annual plan to government?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	(f) draw up and submit to the Minister for Development at the end of each year an annual report on the activity of the Single Food Authority, as well as planning its activities for the following year	0,33	No formal obligations	0	2. The Institute adopts a three-year activity plan, updated annually, in accordance with the aims and objectives assigned to it and in coherence also with the relative guidelines and programming lines at the National Center for Transplantation and at the National Blood Center by the Minister of Health, in agreement with the Permanent Conference for the relations between the State, the regions and the autonomous provinces of Trento and of Bolzano. 3. The plan referred to in paragraph 1 establishes the general directions of the activity, determines objectives, priorities and resources for the programming period, defines the expected scientific and socio-economic results, as well as the related personnel, instrumental and financial resources provided for each of the programs and projects in which it is structured. The plan includes the three-year planning of human resources needs in compliance with current regulations.	0,67	No formal obligations	0

								4. The plan referred to in paragraph 1, prepared by the Chairman, after consultation with i responsible for the structures of the technical-scientific operating area, is rendered public for at least thirty days, at the end of the formulation by the staff of the Institute for any observations. The plan is approved by the Board of Directors, subject to the opinion of the Scientific Committee, ed it is approved by the Minister of Health, also for identification purposes and the development of general system objectives and coordination with the research program identified by the National Health Plan.			
Is the agency required to submit an annual plan to parliament?	1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations	No formal obligations	0	No formal obligations	0	No formal obligations	0	6. The Minister of Health presents one to the Parliament every three years report on the activities carried out by the Institute and on the results achieved and on the program for the next three years.	0,67	No formal obligations	0

<p>Is the agency required to submit an annual itemized budget to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>(2) The budget shall be determined by the President. He needs to his Effectiveness of the approval of the Federal Ministry. The Federal Institute receives to compensate the approved federal budget subsidies in accordance with the relevant budgetary law.</p>	<p>0,67</p>	<p>No formal obligations</p>	<p>0</p>	<p>26.—(1) The chief executive, following the agreement of the Board, shall submit estimates of income and expenditure to the Minister in such form, in respect of such periods, and at such times as may be required by the Minister and shall furnish to the Minister any information which the Minister may require in relation to such estimates, including proposals and future plans relating to the discharge by the Authority of its functions over a period of years, as required.</p> <p>(2) The determination of the amounts of charges referred to in subsection (1) shall be subject to the approval of the Minister following consultations with the Minister for Finance.</p>	<p>0,67</p>	<p>the regulations relating to administration, finance and accounting are approved by the Minister of Health, in agreement with the Minister for the Economy and Finance.</p>	<p>0,67</p>	<p>No formal obligations</p>	<p>0</p>
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<p>Is the agency required to submit an annual itemized budget to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual activity report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>(f) draws up and submit to the Minister for Development at the end of each year an annual report on the activity of the Single Food Authority, as well as planning its activities for the following year g) draws up and submits to the Minister of Development, at the end of each quarter, reports of audits carried out by the services of EFET</p>	<p>0,33</p>	<p>25.—(1) As soon as may be after the end of the financial year of the Authority in which the establishment day falls and of each subsequent financial year of the Authority, but not later than 6 months thereafter, the Authority shall make a report to the Minister of its activities during that year and the Minister shall cause copies of the report to be laid before each House of the Oireachtas. (2) Each report under subsection (1) shall include information in such form and regarding such matters as the Minister may direct.</p>	<p>0,33</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>

<p>Is the agency required to submit an annual activity report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>
<p>Is the agency required to submit an annual financial report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>(3) The financial year is the calendar year. After the end of the financial year, an invoice for the To raise revenue and expenditure. The invoice has to be checked by the Federal Ministry.</p>	<p>0,67</p>	<p>No formal obligations</p>	<p>0</p>	<p>26.—(1) The chief executive, following the agreement of the Board, shall submit estimates of income and expenditure to the Minister in such form, in respect of such periods, and at such times as may be required by the Minister and shall furnish to the Minister any information which the Minister may require in relation to such estimates, including proposals and future plans relating to the discharge by the Authority of its functions over a period of years, as required.</p>	<p>0,33</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>

<p>Is the agency required to submit an annual financial report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>
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		NETHERLANDS - NVWA		PORTUGAL - ASAE		SPAIN - AECOSAN		SWEDEN - LV		UK - FSA	
		TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE	TEXT	CODE
Is the agency required to send information upon request to government?	1 = Yes, 0 = No	The main implementing agencies [carrying out official controls] reporting to the Ministries [- the Ministry of Economic Affairs (Ministerie van Economische Zaken – EZ), and - the Ministry of Health, Welfare and Sports (Ministerie van Volksgezondheid, Welzijn en Sport – VWS)] are: the Netherlands Food and Consumer Products Safety Authority and the Netherlands Enterprise Agency	1	No formal obligations	0	No formal obligations	0	The NFA - keeps the Government informed about developments in the food sector; - informs consumers and other interested parties in the food chain about current legislation and other important matters related to food;	1	6.—(1) The Agency has the function of (a) developing policies (or assisting in the development by any provision of public authority of policies) relating to matters connected with advice, etc. to food safety or other interests of consumers in relation to food; public authorities. and (b) providing advice, information or assistance in respect of such matters to any public authority. (2) A Minister of the Crown or government department, the National Assembly for Wales, the Scottish Ministers or a Northern Ireland Department may request the Agency to exercise its powers under this section in relation to any matter. (3) It is the duty of the Agency, so far as is reasonably practicable, to comply with any such request.	1

<p>Is the agency required to send information upon request to parliament?</p>	<p>1 = Yes, 0 = No</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>6.—(1) The Agency has the function of (a) developing policies (or assisting in the development by any provision of public authority of policies) relating to matters connected with advice, etc. to food safety or other interests of consumers in relation to food; public authorities. and (b) providing advice, information or assistance in respect of such matters to any public authority. (2) A Minister of the Crown or government department, the National Assembly for Wales, the Scottish Ministers or a Northern Ireland Department may request the Agency to exercise its powers under this section in relation to any matter. (3) It is the duty of the Agency, so far as is reasonably practicable, to comply with any such request.</p>	<p>1</p>
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<p>Is the agency required to submit an annual plan to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>Activities carried out by NVWA, including delegated tasks, are the subject of internal reporting to NVWA management and external reporting to the EZ on the implementation of its tasks for the specific year.</p>	<p>0,33</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>1. The Executive Director shall prepare, on an annual basis, a draft program of activities, including the annual and, where appropriate, multi-year forecasts. For this, it will collect the contributions of the Institutional Commission, the Advisory Board and the Scientific Committee. This project will be submitted to the Board of Directors, for the purpose of approval. 2. The programs of activities, approved in accordance with the previous section, will be the subject of the dissemination foreseen in section 6.g) of article 4 of Law 11/2001. g) The programs of activities, as well as the report of activities of the Agency, once approved by the Board of Directors, will be presented to the Cortes Generales, to the Government of the Nation and to the Governments of the Autonomous Communities.</p>	<p>0,67</p>	<p>12 a § By 30 September of each year, the Authority shall submit to the Government an account of how food control can be developed and improved. The report should also include the shortcomings in the control identified by the work and describe how they can be addressed. Regulation (2015: 294).</p>	<p>0,33</p>	<p>No formal obligations</p>	<p>0</p>
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<p>Is the agency required to submit an annual plan to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>
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<p>Is the agency required to submit an annual itemized budget to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>1. The Spanish Food Safety Agency will prepare annually a preliminary draft budget with the structure indicated by the Ministry of Finance, and will send it to the Ministry of Health and Consumption for its elevation to the Government and its subsequent referral to the Cortes Generales, as part of the General Budgets of the State. 2. The budgetary regime of the Spanish Agency for Food Security shall be that established in the General Budgetary Law for autonomous agencies.</p>	<p>0,67</p>	<p>The Board of the NFA, which consists of 11 members, with the Director-General of the NFA as chairman, meets about eight times a year. It makes decisions on regulations issued by the NFA, budget proposals and the annual report submitted to the Government.</p>	<p>0,33</p>	<p>(3) Accounts required under this paragraph relating to sums of any description mentioned in sub-paragraph (1)— (a) shall be prepared in such form, and (b) shall be sent to the Comptroller and Auditor General, and to the relevant authority for the accounts, before such time, as the relevant authority for the accounts may direct after consulting the Agency and the other relevant authorities. (4) The Comptroller and Auditor General shall examine any accounts sent to him under sub-paragraph (3) on behalf of the National Assembly for Wales, the Scottish Parliament or the Northern Ireland Assembly (according to the description of sums to which the accounts relate). (5) In carrying out his examination of any such accounts the Comptroller and Auditor General shall, among other things, satisfy himself that the money expended by the Agency has been applied to the purpose or purposes for which the sums in question were intended to provide.</p>	<p>0,33</p>
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<p>Is the agency required to submit an annual itemized budget to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>(3) Accounts required under this paragraph relating to sums of any description mentioned in sub-paragraph (1)— (a) shall be prepared in such form, and (b) shall be sent to the Comptroller and Auditor General, and to the relevant authority for the accounts, before such time, as the relevant authority for the accounts may direct after consulting the Agency and the other relevant authorities. (4) The Comptroller and Auditor General shall examine any accounts sent to him under sub-paragraph (3) on behalf of the National Assembly for Wales, the Scottish Parliament or the Northern Ireland Assembly (according to the description of sums to which the accounts relate). (5) In carrying out his examination of any such accounts the Comptroller and Auditor General shall, among other things, satisfy himself that the money expended by the Agency has been applied to the purpose or purposes for which the sums in question were intended to provide.</p>	<p>0,33</p>
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											<p>(6) When the Comptroller and Auditor General has certified and reported on any accounts under this section, he shall— (a) send the accounts and report to the relevant authority for the accounts; and (b) send copies to the other relevant authorities.</p> <p>(7) The Treasury shall present documents received under sub-paragraph (6) to the House of Commons, the Scottish Ministers shall present such documents to the Scottish Parliament and the Department shall present such documents to the Northern Ireland Assembly.</p> <p>(8) In this paragraph “the relevant authority for the accounts” is—</p> <p>(a) in the case of accounts relating to sums within sub-paragraph (1)(a), the National Assembly for Wales;</p> <p>(b) in the case of accounts relating to sums within sub-paragraph (1)(b), the Scottish Ministers; and</p> <p>(c) in the case of accounts relating to sums within sub-paragraph (1)(c), the Department.</p>
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<p>Is the agency required to submit an annual activity report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>Activities carried out by NVWA, including delegated tasks, are the subject of internal reporting to NVWA management and external reporting to the EZ on the implementation of its tasks for the specific year.</p>	<p>0,33</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; (c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; (g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>t) Prepare an annual report that reflects the actions of official control in the whole of the State and that analyzes the general situation of food security and nutrition in Spain, indicating the priority fields of action and, in particular, the emerging risks. Article 29. Activities report. 1. The Executive Director will request from the other bodies of the Agency, as well as from the units thereof, all the information necessary to prepare, on an annual basis, the report of activities of the Agency. 2. This report, in the project phase, will be submitted to the Board of Directors, for the purpose of approval. 3. The annual report will be disseminated in accordance with section 6.g) of article 4 of Law 11/2001."</p>	<p>0,67</p>	<p>The Board of the NFA, which consists of 11 members, with the Director-General of the NFA as chairman, meets about eight times a year. It makes decisions on regulations issued by the NFA, budget proposals and the annual report submitted to the Government.</p>	<p>0,33</p>	<p>No formal obligations</p>	<p>0</p>
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<p>Is the agency required to submit an annual activity report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>4.—(1) The Agency shall prepare a report on its activities and performance during each financial year. (2) The Agency shall, as soon as possible after the end of each financial year, lay its report for that year before Parliament, the National Assembly for Wales, the Scottish Parliament and the Northern Ireland Assembly.</p>	<p>0,33</p>
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<p>Is the agency required to submit an annual financial report to government?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>(3) Accounts required under this paragraph relating to sums of any description mentioned in sub-paragraph (1)— (a) shall be prepared in such form, and (b) shall be sent to the Comptroller and Auditor General, and to the relevant authority for the accounts, before such time, as the relevant authority for the accounts may direct after consulting the Agency and the other relevant authorities. (4) The Comptroller and Auditor General shall examine any accounts sent to him under sub-paragraph (3) on behalf of the National Assembly for Wales, the Scottish Parliament or the Northern Ireland Assembly (according to the description of sums to which the accounts relate). (5) In carrying out his examination of any such accounts the Comptroller and Auditor General shall, among other things, satisfy himself that the money expended by the Agency has been applied to the purpose or purposes for which the sums in question were intended to provide.</p>	<p>0,33</p>
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<p>Is the agency required to submit an annual financial report to parliament?</p>	<p>1 = fully accountable, 0.67 = for approval, 0.33 = for information 0 = no obligations</p>	<p>No formal obligations</p>	<p>0</p>	<p>Article 26 Management tools The activity of the ASAE complies with the general rules established for the financial regime of the services with administrative autonomy, and the following management instruments are used: a) Medium-term strategic plan, updated annually, contemplating the guidelines of the ASAE; b) Annual plan of activities; c) annual budget, drawn up on the basis of the business plan, and its updates; d) Annual activity report; e) Annual management account; f) Social balance sheet; g) other documents regularly accompanying the activity and budget implementation.</p>	<p>1</p>	<p>No formal obligations</p>	<p>0</p>	<p>No formal obligations</p>	<p>0</p>	<p>4.—(1) The Agency shall prepare a report on its activities and performance during each financial year. (2) The Agency shall, as soon as possible after the end of each financial year, lay its report for that year before Parliament, the National Assembly for Wales, the Scottish Parliament and the Northern Ireland Assembly. (3) Accounts required under this paragraph relating to sums of any description mentioned in sub-paragraph (1)— (a) shall be prepared in such form, and (b) shall be sent to the Comptroller and Auditor General, and to the relevant authority for the accounts, before such time, as the relevant authority for the accounts may direct after consulting the Agency and the other relevant authorities. (4) The Comptroller and Auditor General shall examine any accounts sent to him under sub-paragraph (3) on behalf of the National Assembly for Wales, the Scottish Parliament or the Northern Ireland Assembly (according to the description of sums to</p>	<p>0,67</p>
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										<p>which the accounts relate).</p> <p>(5) In carrying out his examination of any such accounts the Comptroller and Auditor General shall, among other things, satisfy himself that the money expended by the Agency has been applied to the purpose or purposes for which the sums in question were intended to provide.</p> <p>(6) When the Comptroller and Auditor General has certified and reported on any accounts under this section, he shall— (a) send the accounts and report to the relevant authority for the accounts; and (b) send copies to the other relevant authorities.</p> <p>(7) The Treasury shall present documents received under subparagraph (6) to the House of Commons, the Scottish Ministers shall present such documents to the Scottish Parliament and the Department shall present such documents to the Northern Ireland Assembly.</p> <p>(8) In this paragraph “the relevant authority for the accounts” is—</p> <p>(a) in the case of accounts relating to sums</p>
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APPENDIX A6.1 – Output of analyses performed with R software, QCA package, QMC algorithm

```
> ### BAZZAN GIULIA QCA ANALYSIS ###
> library(QCA)

> ### DATASET BAZZAN QMC ALGORITHM ###
> datafile_bazzan <- read.table("/Users/GiuliaB/Desktop/datafile_bazzan.csv", sep = ";", header =
TRUE, dec = ",", row.names = "ID")
> datafile_bazzan
  SEP INDRA ACCRA CAPRM EFF
AUS  1 0.29 0.23 0.78 2.31
BEL  0 0.42 0.13 0.94 2.50
DEN  1 0.40 0.20 0.86 2.99
FIN  0 0.42 0.27 0.83 1.77
FRA  1 0.68 0.33 0.81 0.67
GER  1 0.86 0.23 0.78 0.70
GRE  0 0.61 0.07 0.57 0.76
IRE  0 0.40 0.23 0.87 2.88
ITA  0 0.26 0.20 0.70 1.08
NET  1 0.66 0.17 0.80 2.90
POR  0 0.48 0.80 0.64 0.85
SPA  0 0.76 0.20 0.74 1.30
SWE  0 0.92 0.20 0.91 2.07
UK   0 0.41 0.40 0.70 0.55

> ##### CALIBRATION #####
> #calibration algebraic strategy
> #direct method threshold setter
> datafile_bazzan$CAPRM <- calibrate(datafile_bazzan$CAPRM, thresholds = "e=0.67, c=0.76,
i=0.845")
```

```

> #direct method threshold setter
> datafile_bazzan$EFF <- calibrate(datafile_bazzan$EFF, thresholds = "e=0.965, c=1.535, i=2.19")

> ##### ANALYSIS OF NECESSITY #####
> pofind(datafile_bazzan, outcome = "EFF", conditions = "SEP, INDRA, ACCRA, CAPRM", relation =
"nec")

```

```

      inclN  RoN  covN
-----
1 sep  0.573 0.501 0.446
2 SEP  0.427 0.818 0.598
3 indra 0.554 0.748 0.604
4 INDRA 0.557 0.637 0.515
5 accra 0.851 0.455 0.577
6 ACCRA 0.256 0.847 0.490
7 caprm 0.152 0.654 0.192
8 CAPRM 0.918 0.733 0.761
-----

```

```

> pofind(datafile_bazzan, outcome = "~EFF", conditions = "SEP, INDRA, ACCRA, CAPRM", relation =
"nec")

```

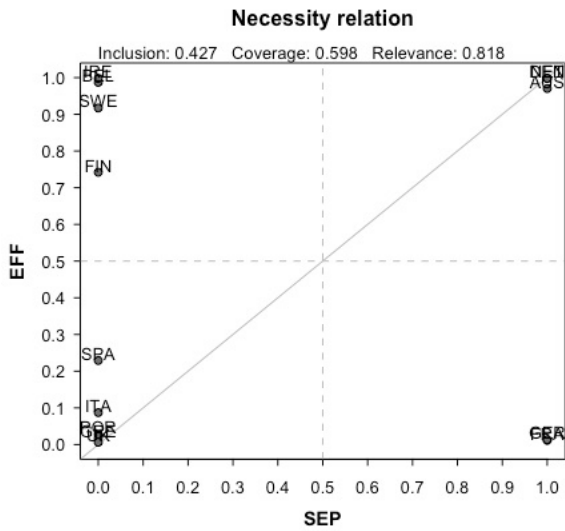
```

      inclN  RoN  covN
-----
1 sep  0.713 0.555 0.554
2 SEP  0.287 0.751 0.402
3 indra 0.475 0.709 0.517
4 INDRA 0.636 0.673 0.588
5 accra 0.733 0.413 0.496
6 ACCRA 0.374 0.909 0.716
7 caprm 0.711 0.936 0.896
8 CAPRM 0.360 0.483 0.298
-----

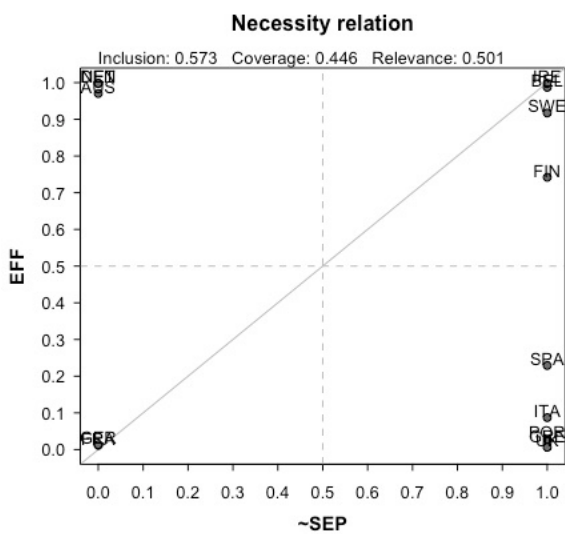
```

> ##### XYPLOT #####

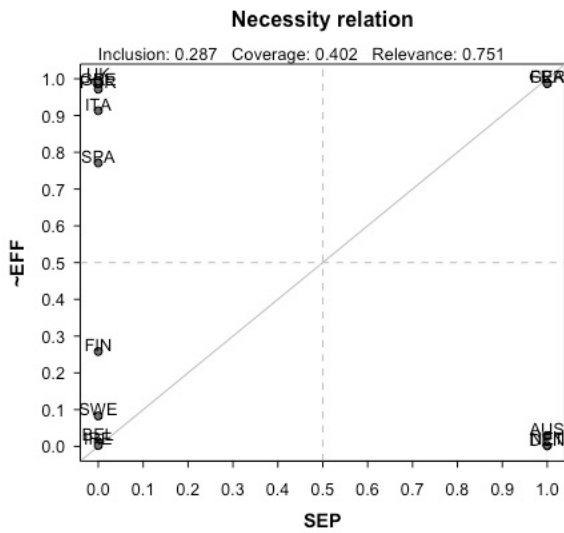
> XYplot(SEP, EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))



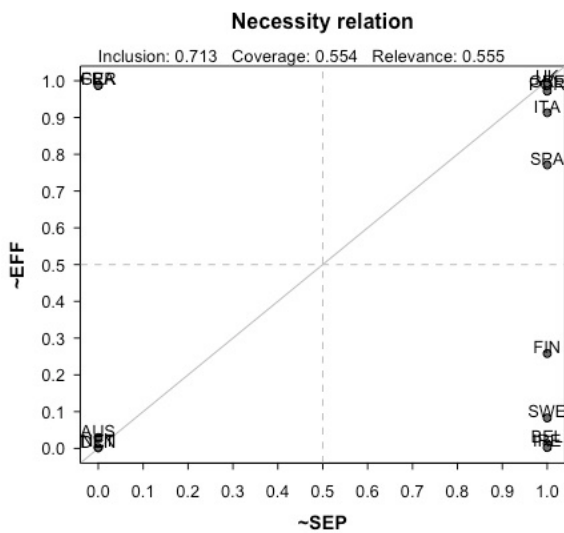
> XYplot(~SEP, EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))



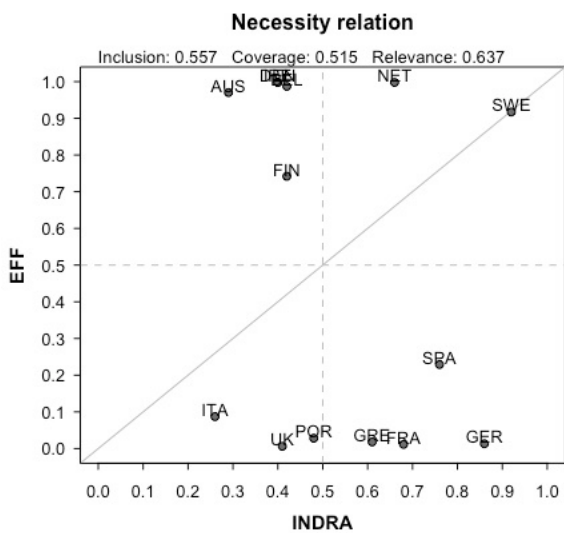
> XYplot(SEP, ~EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))



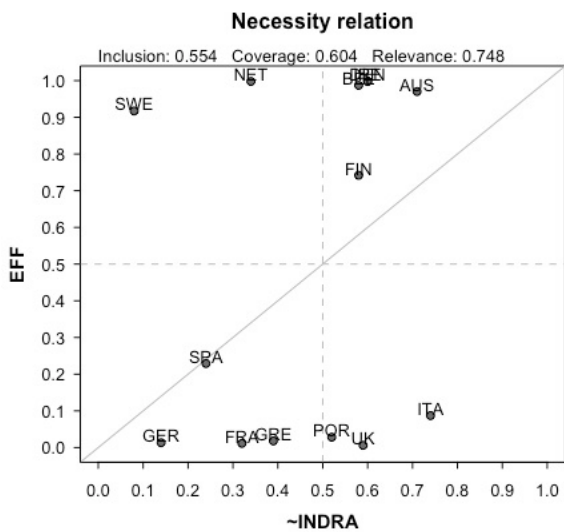
```
> XYplot(~SEP, ~EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))
```



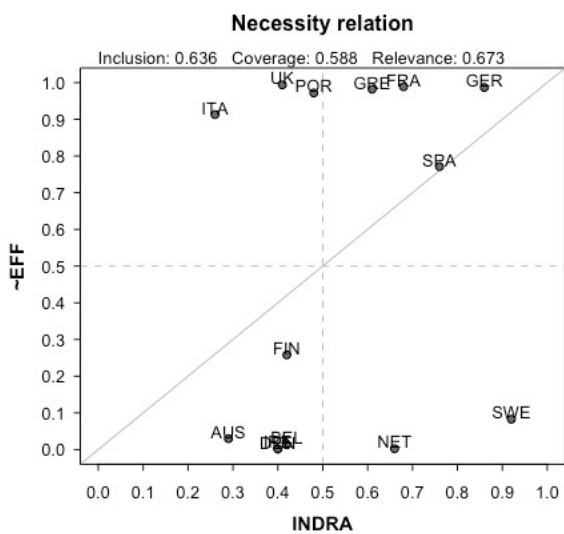
```
> XYplot(INDRA, EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))
```



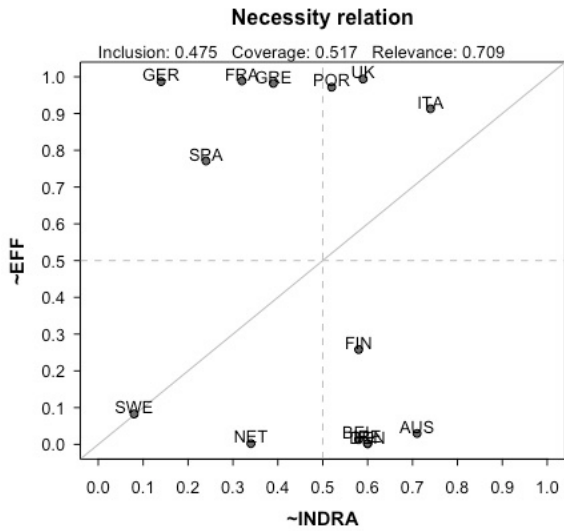
```
> XYplot(~INDRA, EFF, data = datafile_bazzan, relation = "nec", labels
=rownames(datafile_bazzan))
```



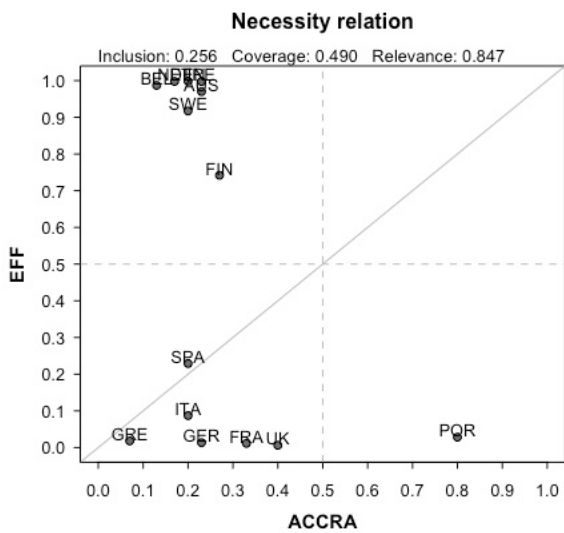
```
> XYplot(INDRA, ~EFF, data = datafile_bazzan, relation = "nec", labels
=rownames(datafile_bazzan))
```



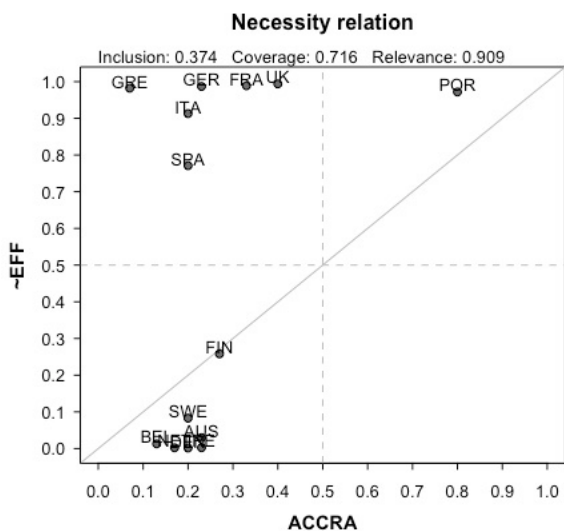
```
> XYplot(~INDRA, ~EFF, data = datafile_bazzan, relation = "nec", labels
=rownames(datafile_bazzan))
```



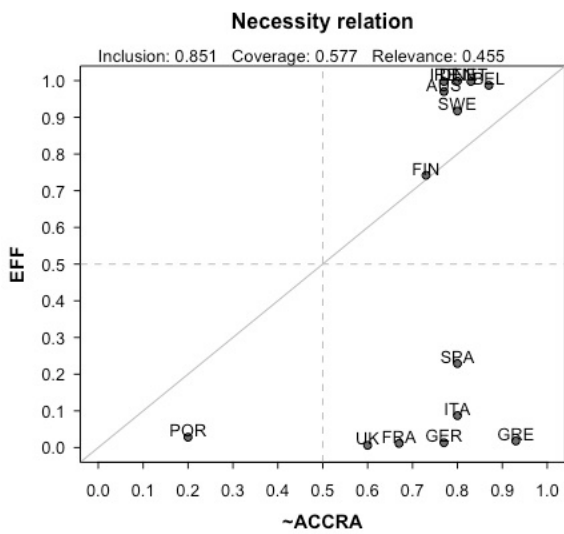
> XYplot(ACCRA, EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))



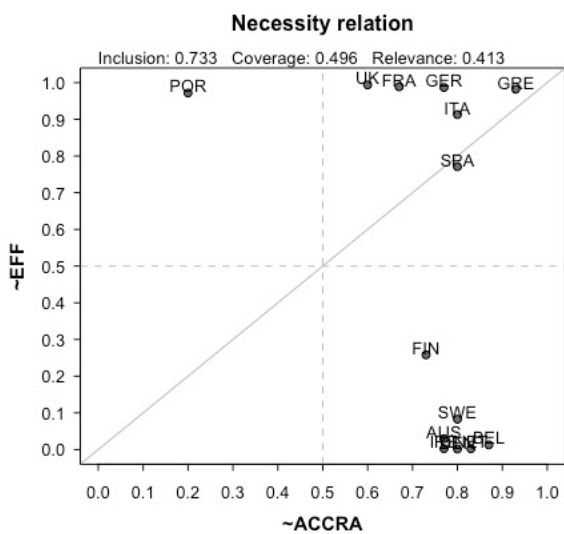
> XYplot(ACCRA, ~EFF, data = datafile_bazzan, relation = "nec", labels = rownames(datafile_bazzan))



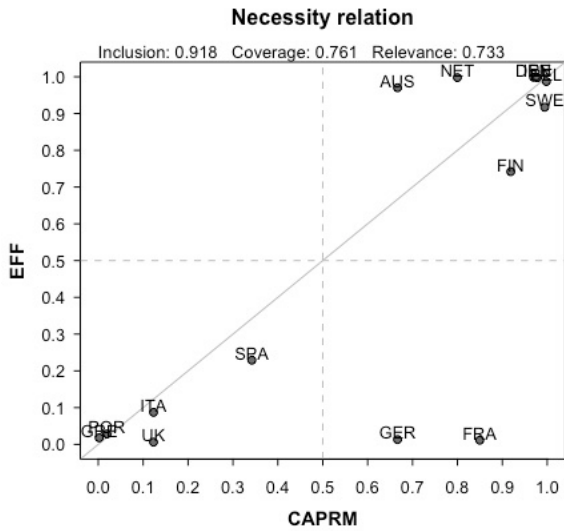

```
> XYplot(~ACCRA, EFF, data =datafile_bazzan, relation = "nec", labels =
rownames(datafile_bazzan))
```



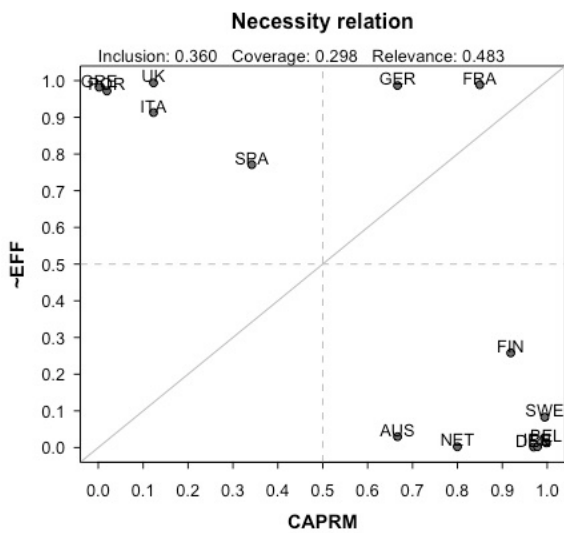
```
> XYplot(~ACCRA, ~EFF, data =datafile_bazzan, relation = "nec", labels =
rownames(datafile_bazzan))
```



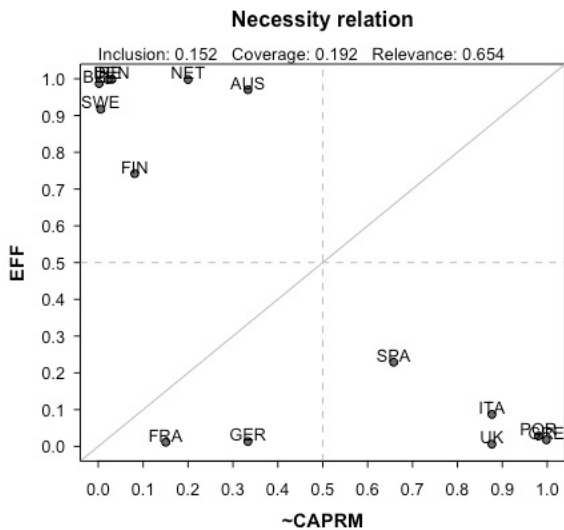
```
> XYplot(CAPRM, EFF, data = datafile_bazzan, relation = "nec", labels =rownames(datafile_bazzan))
```



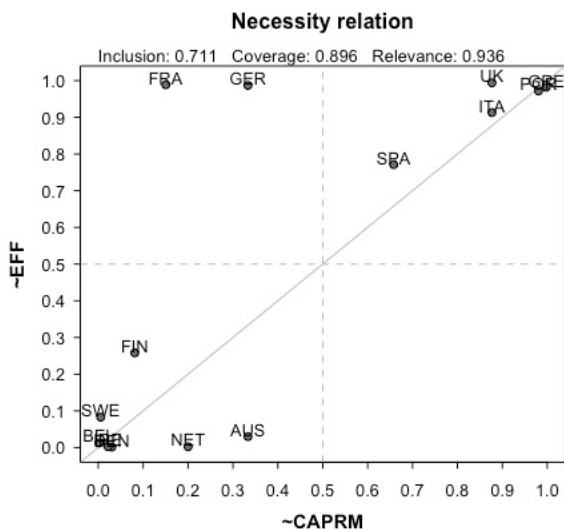
```
> XYplot(CAPRM, ~EFF, data =datafile_bazzan, relation = "nec", labels =
rownames(datafile_bazzan))
```



```
> XYplot(~CAPRM, EFF, data =datafile_bazzan, relation = "nec", labels =
rownames(datafile_bazzan))
```



```
> XYplot(~CAPRM, ~EFF, data =datafile_bazzan, relation = "nec", labels =
rownames(datafile_bazzan))
```



```
> ##### ANALYSIS OF SUFFICIENCY #####
```

```
> #TT positive
```

```
> TTP <- truthTable(datafile_bazzan, outcome = "EFF", conditions = "SEP, INDRA, ACCRA, CAPRM",
incl.cut = 0.85, n.cut = 1, complete = FALSE, show.cases = TRUE, sort.by = "incl, n")
```

```
> TTP
```

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

	SEP	INDRA	ACCRA	CAPRM	OUT	n	incl	PRI	cases
2	0	0	0	1	1	3	0.930	0.901	BEL,FIN,IRE
6	0	1	0	1	1	1	0.900	0.864	SWE
10	1	0	0	1	0	2	0.789	0.783	AUS,DEN
14	1	1	0	1	0	3	0.512	0.501	FRA,GER,NET
3	0	0	1	0	0	1	0.300	0.018	POR
5	0	1	0	0	0	2	0.213	0.011	GRE,SPA
1	0	0	0	0	0	2	0.211	0.011	ITA,UK

> #TT negative

```
> TTN <- truthTable(datafile_bazzan, outcome = "~EFF", conditions = "SEP, INDRA, ACCRA, CAPRM",  
incl.cut = 0.85, n.cut = 1, complete = FALSE, show.cases = TRUE, sort.by = "incl, n")
```

> TTN

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

	SEP	INDRA	ACCRA	CAPRM	OUT	n	incl	PRI	cases
1	0	0	0	0	1	2	0.992	0.989	ITA,UK
5	0	1	0	0	1	2	0.991	0.989	GRE,SPA
3	0	0	1	0	1	1	0.987	0.982	POR
14	1	1	0	1	0	3	0.510	0.499	FRA,GER,NET
2	0	0	0	1	0	3	0.367	0.099	BEL,FIN,IRE
6	0	1	0	1	0	1	0.364	0.136	SWE
10	1	0	0	1	0	2	0.239	0.217	AUS,DEN

> #solution positive QMC algorithm

> #complex solution

```
> SCP <- minimize(TTP, include = "", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol =
TRUE, details = TRUE, use.tilde = TRUE, method = "QMC")
> SCP
```

n OUT = 1/0/C: 4/10/0

Total : 14

Number of multiple-covered cases: 0

M1: ~SEP*~ACCRA*CAPRM <=> EFF

	inclS	PRI	covS	covU	cases
1	~SEP*~ACCRA*CAPRM	0.930	0.914	0.502	- BEL,FIN,IRE; SWE
M1		0.930	0.914	0.502	

```
> SPP <- minimize(TTP, include = "?", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol
= TRUE, details = TRUE, use.tilde = TRUE, method = "QMC")
> SPP
```

n OUT = 1/0/C: 4/10/0

Total : 14

Number of multiple-covered cases: 0

M1: ~SEP*CAPRM <=> EFF

	inclS	PRI	covS	covU	cases
1	~SEP*CAPRM	0.882	0.860	0.567	- BEL,FIN,IRE; SWE

M1 0.882 0.860 0.567

> #prime implicant parsimonious

> SPP\$PIchart

2 6

~SEP*CAPRM x x

> SPP\$SA

\$M1

SEP INDRA ACCRA CAPRM

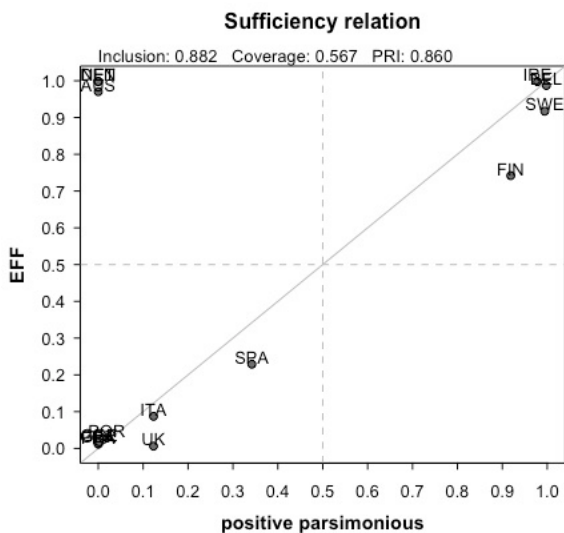
4 0 0 1 1

8 0 1 1 1

> SPP\$DCC

NULL

> XYplot(SPP\$solution[[1]], EFF, xlab = "positive parsimonious", ylab = "EFF", clabels = rownames(datafile_bazzan))



> SPI <- minimize(TTP, include = "?", dir.exp = "1,1,1,1", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol = TRUE, details = TRUE, use.tilde = TRUE, method = "QMC")

> SPI

n OUT = 1/0/C: 4/10/0

Total : 14

From C1P1:

Number of multiple-covered cases: 0

M1: ~SEP*CAPRM <=> EFF

inclS PRI covS covU cases

1 ~SEP*CAPRM 0.882 0.860 0.567 - BEL,FIN,IRE; SWE

M1 0.882 0.860 0.567

> #prime implicant intermediate

> SPI\$PIchart

2 6

~SEP*CAPRM x x

> SPI\$SA

\$M1

SEP INDRA ACCRA CAPRM

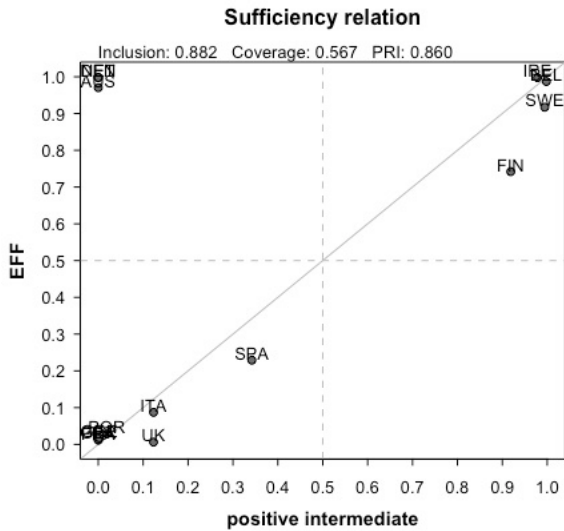
4 0 0 1 1

8 0 1 1 1

> SPI\$DCC

NULL

> XYplot(SPI\$i.sol\$C1P1\$solution[[1]], EFF, xlab = "positive intermediate", ylab = "EFF", clabels = rownames(datafile_bazzan))



```
> SNC <- minimize(TTN, include = "", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol = TRUE, details = TRUE, use.tilde = TRUE, method = "QMC")
```

> SNC

n OUT = 1/0/C: 5/9/0

Total : 14

Number of multiple-covered cases: 2

M1: ~SEP*~INDRA*~CAPRM + ~SEP*~ACCRA*~CAPRM <=> ~EFF

inclS PRI covS covU cases

```
-----
```

1	~SEP*~INDRA*~CAPRM	0.993	0.991	0.367	0.046	ITA,UK; POR
2	~SEP*~ACCRA*~CAPRM	0.994	0.993	0.469	0.147	ITA,UK; GRE,SPA

```
-----
```

M1 0.995 0.994 0.514

```
> SNP <- minimize(TTN, include = "?", dir.exp = "",
+            sol.cons = 0, sol.cov = 0,
+            row.dom = TRUE, all.sol = TRUE,
+            details = TRUE, use.tilde = TRUE, method = "QMC")
```

> SNP

n OUT = 1/0/C: 5/9/0

Total : 14

Number of multiple-covered cases: 0

M1: ~CAPRM <=> ~EFF

inclS PRI covS covU cases

1 ~CAPRM 0.896 0.886 0.711 - ITA,UK; POR; GRE,SPA

M1 0.896 0.886 0.711

> #prime implicant parsimonious

> SNP\$Pchart

1 3 5

~CAPRM x x x

> SNP\$SA

\$M1

SEP INDRA ACCRA CAPRM

7 0 1 1 0

9 1 0 0 0

11 1 0 1 0

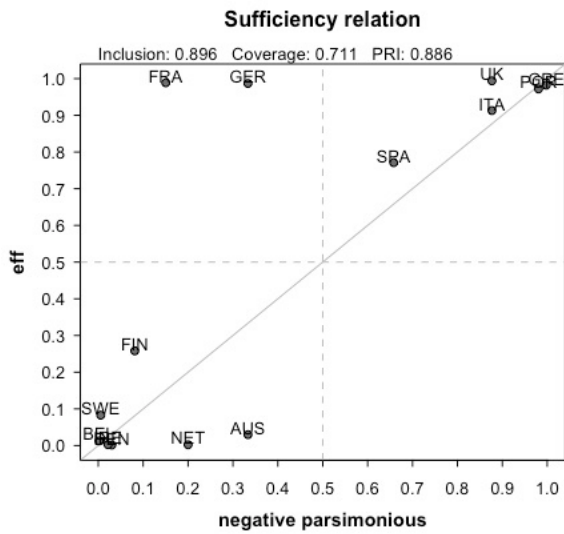
13 1 1 0 0

15 1 1 1 0

> SNP\$DCC

NULL

```
> XYplot(SNP$solution[[1]], ~EFF, xlab = "negative parsimonious", ylab = "eff", labels
=rownames(datafile_bazzan))
```



```
> #intermediate solution
> SNI <- minimize(TTN, include = "?", dir.exp = "0,0,0,0",
+ sol.cons = 0, sol.cov = 0,
+ row.dom = TRUE, all.sol = TRUE,
+ details = TRUE, use.tilde = TRUE, method = "QMC")
> SNI
```

```
n OUT = 1/0/C: 5/9/0
Total : 14
```

From C1P1:

Number of multiple-covered cases: 2

```
M1: ~SEP*~INDRA*~CAPRM + ~SEP*~ACCRA*~CAPRM <=> ~EFF
```

```
inclS PRI covS covU cases
```

```
-----
1 ~SEP*~INDRA*~CAPRM 0.993 0.991 0.367 0.046 ITA,UK; POR
2 ~SEP*~ACCRA*~CAPRM 0.994 0.993 0.469 0.147 ITA,UK; GRE,SPA
```

M1 0.995 0.994 0.514

> #prime implicant intermediate

> SNI\$PIchart

1 3 5

~CAPRM x x x

> SNI\$SA

\$M1

SEP INDRA ACCRA CAPRM

7 0 1 1 0

9 1 0 0 0

11 1 0 1 0

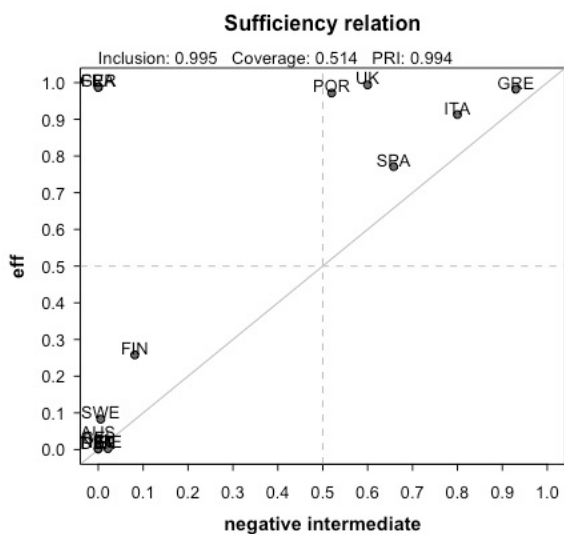
13 1 1 0 0

15 1 1 1 0

> SNI\$DCC

NULL

> XYplot(SNI\$.sol\$C1P1\$.solution[[1]], ~EFF, xlab = "negative intermediate", ylab = "eff", clabels = rownames(datafile_bazzan))



APPENDIX A6.2 – Test for contradictory simplifying assumptions

The analysis finds one path explaining the positive outcome: $\sim\text{SEP} * \text{CAPRM} \Rightarrow \text{EFF}$ with a consistency score of 0.882, a PRI equal to 0.860, and a coverage of 0.567 for the parsimonious solution. For this solution, the simplifying assumptions can be checked:

SEP INDRA ACCRA CAPRM

4 0 0 1 1

8 0 1 1 1

Out of the 9 logical remainders, only 2 have been used, and the rest did not contribute at all to the minimization. Then, I verified the existence of contradictory simplifying assumptions. To do so, the truth table for the negation of the outcome is presented (Table 6.13):

	SEP	INDRA	ACCRA	CAPRM	OUT	n	incl	PRI	cases
1	0	0	0	0	1	2	0.992	0.989	ITA, UK
5	0	1	0	0	1	2	0.991	0.989	GRE, SPA
3	0	0	1	0	1	1	0.987	0.982	POR
14	1	1	0	1	0	3	0.510	0.499	FRA, GER, NET
2	0	0	0	1	0	3	0.367	0.099	BEL, FIN, IRE
6	0	1	0	1	0	1	0.364	0.136	SWE
10	1	0	0	1	0	0	0.239	0.217	AUS, DEN
4	0	0	1	1	?	0	-	-	
7	0	1	1	0	?	0	-	-	
8	0	1	1	1	?	0	-	-	
9	1	0	0	0	?	0	-	-	
11	1	0	1	0	?	0	-	-	
12	1	0	1	1	?	0	-	-	
13	1	1	0	0	?	0	-	-	
15	1	1	1	0	?	0	-	-	
16	1	1	1	1	?	0	-	-	

The analysis of sufficiency identifies $\sim\text{CAPRM} \Rightarrow \sim\text{EFF}$ with a consistency score of 0.896, a PRI equal to 0.886 and a coverage of 0.711 for the parsimonious solution.

I checked for the simplifying assumptions:

SEP INDRA ACCRA CAPRM

7 0 1 1 0

9 1 0 0 0

11 1 0 1 0

13 1 1 0 0

15 1 1 1 0

Since none of the rows are present in both matrices (for the positive and the negative outcome), there are no contradictory assumptions.

APPENDIX A6.3 - Output of analyses performed with R software, QCA package, CCubes algorithm

In order to test robustness of my analyses, the analyses of sufficiency for both the positive and the negative outcome are run employing also the CCubes algorithm, to prove the same end results (Duşa, 2018).

```
### DATASET BAZZAN CCUBES ALGORITHM ###
```

```
> #solution positive CCubes algorithm
```

```
> #complex solution
```

```
> SCP <- minimize(TTP, include = "", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol = TRUE, details = TRUE, use.tilde = TRUE, method = "CCubes")
```

```
> SCP
```

```
n OUT = 1/0/C: 4/10/0
```

```
Total : 14
```

```
Number of multiple-covered cases: 0
```

```
M1: ~SEP*~ACCRA*CAPRM <=> EFF
```

```
inclS PRI covS covU cases
```

```
-----  
1 ~SEP*~ACCRA*CAPRM 0.930 0.914 0.502 - BEL,FIN,IRE; SWE  
-----
```

```
M1      0.930 0.914 0.502
```

```
> SPP <- minimize(TTP, include = "?", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol = TRUE, details = TRUE, use.tilde = TRUE, method = "CCubes")
```

```
> SPP
```

```
n OUT = 1/0/C: 4/10/0
```

```
Total : 14
```

```
Number of multiple-covered cases: 0
```

```
M1: ~SEP*CAPRM <=> EFF
```

```
inclS PRI covS covU cases
```

```
-----  
1 ~SEP*CAPRM 0.882 0.860 0.567 - BEL,FIN,IRE; SWE  
-----
```

```
M1      0.882 0.860 0.567
```

```
> #prime implicant parsimonious
> SPP$PIchart
```

```
      2 6
~SEP*CAPRM x x
```

```
> SPP$SA
$M1
SEP INDRA ACCRA CAPRM
4 0 0 1 1
8 0 1 1 1
```

```
> SPP$DCC
NULL
> XYplot(SPP$solution[[1]], EFF, xlab = "positive parsimonious", ylab = "EFF", clabels
=rownames(datafile_math))
```

```
> SPI <- minimize(TTP, include = "?", dir.exp = "1,1,1,1", sol.cons = 0, sol.cov = 0, row.dom = TRUE,
all.sol = TRUE, details = TRUE, use.tilde = TRUE, method = "CCubes")
> SPI
```

```
n OUT = 1/0/C: 4/10/0
Total : 14
```

```
From C1P1:
```

```
Number of multiple-covered cases: 0
```

```
M1: ~SEP*CAPRM <=> EFF
```

```
      inclS PRI covS covU cases
-----
1 ~SEP*CAPRM 0.882 0.860 0.567 - BEL,FIN,IRE; SWE
-----
M1      0.882 0.860 0.567
```

```
> #prime implicant intermediate
> SPI$PIchart
```

```
      2 6
~SEP*CAPRM x x
```

```
> SPI$SA
$M1
SEP INDRA ACCRA CAPRM
4 0 0 1 1
8 0 1 1 1
```



```
> SPI$DCC
NULL
```

```
> XYplot(SPI$i.sol$C1P1$solution[[1]], EFF, xlab = "positive intermediate", ylab = "EFF", clabels
=rownames(datafile_math))
```

```
> SNC <- minimize(TTN, include = "", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol =
TRUE, details = TRUE, use.tilde = TRUE, method = "CCubes")
> SNC
```

```
n OUT = 1/0/C: 5/9/0
Total : 14
```

Number of multiple-covered cases: 2

```
M1: ~SEP*~INDRA*~CAPRM + ~SEP*~ACCRA*~CAPRM <=> ~EFF
```

	inclS	PRI	covS	covU	cases	
1	~SEP*~INDRA*~CAPRM	0.993	0.991	0.367	0.046	ITA,UK; POR
2	~SEP*~ACCRA*~CAPRM	0.994	0.993	0.469	0.147	ITA,UK; GRE,SPA
M1		0.995	0.994	0.514		

```
> SNP <- minimize(TTN, include = "?", dir.exp = "", sol.cons = 0, sol.cov = 0, row.dom = TRUE, all.sol
= TRUE, details = TRUE, use.tilde = TRUE, method = "CCubes")
> SNP
```

```
n OUT = 1/0/C: 5/9/0
Total : 14
```

Number of multiple-covered cases: 0

```
M1: ~CAPRM <=> ~EFF
```

	inclS	PRI	covS	covU	cases	
1	~CAPRM	0.896	0.886	0.711	-	ITA,UK; POR; GRE,SPA
M1		0.896	0.886	0.711		

```
> #prime implicant parsimonious
> SNP$PIchart
```

```
1 3 5
~CAPRM x x x
```

```
> SNP$SA
```

\$M1

SEP INDRA ACCRA CAPRM

7 0 1 1 0
9 1 0 0 0
11 1 0 1 0
13 1 1 0 0
15 1 1 1 0

> SNP\$DCC

NULL

> XYplot(SNP\$solution[[1]], ~EFF, xlab = "negative parsimonious", ylab = "eff", clabels = rownames(datafile_math))

> #intermediate solution

> SNI <- minimize(TTN, include = "?", dir.exp = "0,0,0,0",
+ sol.cons = 0, sol.cov = 0,
+ row.dom = TRUE, all.sol = TRUE,
+ details = TRUE, use.tilde = TRUE, method = "CCubes")

> SNI

n OUT = 1/0/C: 5/9/0

Total : 14

From C1P1:

Number of multiple-covered cases: 2

M1: ~SEP*~INDRA*~CAPRM + ~SEP*~ACCRA*~CAPRM <=> ~EFF

inclS PRI covS covU cases

1 ~SEP*~INDRA*~CAPRM 0.993 0.991 0.367 0.046 ITA,UK; POR
2 ~SEP*~ACCRA*~CAPRM 0.994 0.993 0.469 0.147 ITA,UK; GRE,SPA

M1 0.995 0.994 0.514

> #prime implicant intermediate

> SNI\$PIchart

1 3 5

~CAPRM x x x

> SNI\$SA

\$M1

SEP INDRA ACCRA CAPRM

7 0 1 1 0
9 1 0 0 0

```
11 1 0 1 0
13 1 1 0 0
15 1 1 1 0
```

```
> SNI$DCC
NULL
```

```
> XYplot(SNI$i.sol$C1P1$solution[[1]], ~EFF, xlab = "negative intermediate", ylab = "eff", clabels
=rownames(datafile_math))
```


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