



Deliverable D1.3

Report on a regulatory regime perspective on trust and the analysis of the regulatory regimes' structure in the involved countries

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Abbreviations, Participant short names

Abbreviations

| | |
|-----|-------------------------|
| DPO | Data Protection Officer |
| EU | European Union |
| WP | Work Package |

Participant short names

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| UNIL | Université de Lausanne |
| UAntwerpen | Universiteit Antwerpen |
| IBEI | Institut Barcelona d'Estudis Internacionals, Fundacio Privada |
| HUJI | The Hebrew University of Jerusalem |
| Uni-Speyer | German University of Administrative Sciences |
| AU | Aarhus Universitet |
| UiO | Universitetet i Oslo |
| UU | Universiteit Utrecht |
| Kozminski | Akademia Leona Kozminkiego |
| SCIPROM | SCIPROM Sàrl |



Introduction to the deliverable

This deliverable D1.3 develops a common project-wide perspective on trust relations within regulatory regimes, and to map the structure of the selected regulatory regimes (finance, communications and data protection, food safety) in the nine polities involved. It builds on the first two deliverables to develop a project-wide approach to the study of trust and regulation. It offers a refinement of the theories of trust so that they will be used more fruitfully to understand daily and policy-oriented trust relations in regulatory settings. This report asks how can we best conceptualize the relations between trust and regulation? How can we conceptualize their relations to provide a better, e.g. deeper and wider, understanding of governance? The main assertion is that that we need to understand the role and interactions of trust and regulations as a politically contested issue. When we speak on (dis)trust, when we assess (de)regulation, when we consider their relations, we are in the terrain of conflicting worldviews, ideologies, institutions and interests. Trust and regulation are weaponized by all actors. Their relations are political issue and the analysis of their interactions is grounded in conflicting paradigms of the social sciences research. The first part of the report identifies four different approaches to the relations between trust and regulation and to the challenges of the decline of trust and the 'war' against regulation. The second part of the report extends a thin apolitical understanding of the trust-choice into a more political and policy oriented analysis of actors' preferences in governance settings. This is done by in the context of actor-centred choice architectures as well as via structural-institutional analysis. Trust choices are embedded in two types of regimes: monocentric and polycentric and with regards to the design of four mechanisms of regulation: certification, reporting, ranking & rating and auditing. The structural analysis is thereafter complemented by an analysis of regulatory strategies of trust and distrust. The deliverable concludes with some suggestions on how to reframe the politics of regulation taking trust into account and how to reorient the study of trust so as to take the politics of regulation seriously.

The annex of the deliverable offers a regulatory regime perspective on trust. It draws on a mapping of trust relations, issues and puzzles within the three sectors (finance, food safety, communications and data protection) and the ten polities that will be analysed in the TiGRE project. To that purpose, an analysis of the structure and legislation of each regulatory regime in each country taking part in the project, plus the regime at the EU level. The analysis of the structures and legislations is performed in order to identify and map stakeholders and trust issues to set a wide scope for the research's framework and in order to feed into the next WPs.

Abstract

How can we best conceptualize the relations between trust and regulation? How can we conceptualize their relations to provide a better, e.g. deeper and wider, understanding of governance? A useful starting point is to understand the role and interactions of trust and regulations as a politically contested issue. When we speak on (dis)trust, when we assess (de)regulation, when we consider their relations, we are in the terrain of conflicting worldviews, ideologies, institutions and interests. Trust and regulation are weaponized by all actors. Their relations are political issue and the analysis of their interactions is grounded in conflicting paradigms of the social sciences research. The first part of the report identifies four different approaches to the relations between trust and regulation and to the challenges of the decline of trust and the 'war' against regulation. The second part of the report extends a thin apolitical understanding of the trust-choice into a more political and policy oriented analysis of actors' preferences in governance settings. This is done by in the context of actor-centred choice architectures as well as via structural-institutional analysis. Trust choices are embedded in two types of regimes: monocentric and polycentric and with regards to the design of four mechanisms of regulation: certification, reporting, ranking & rating and auditing. The structural analysis is thereafter complemented by an analysis of regulatory strategies of trust and distrust. The report concludes with some suggestions on how to reframe the politics of regulation taking trust into account and how to reorient the study of trust so as to take the politics of regulation seriously.



A Regime Perspective on Trust and Regulation¹

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The way we imagine trust-choices has implications that matters. They matter because they guide our models and theories. They shape, guide and frame the challenges (e.g., the problem definition) involved in using both regulation and trust. Political and administrative analysis of governance call for political imagination of the relations between trust and regulation. Consider Gambetta and Hamill's trust study in the taxi industry. Their "*Streetwise; how Taxi Drivers Establish Their Customers' Trustworthiness*" [2005] had analysed trust-choices of taxi drivers and their potential clients. Theirs was a field study among drivers in Belfast and New York; two cities that differ in many respects except for one; both cities were at the time highly dangerous and risky for Taxi Drivers. Terrorists and robbers posed as innocent passengers in order to rob or even kill drivers. Do not underestimate the risks, data cited by the two authors suggest that taxi driving is one of the riskiest occupations in the US. Drivers confront, every day and night, a series of hard trust-decision problems, wrote the two authors. They are thus under severe pressure to decide quickly, on the basis of only a little information, whether or not to accept potential passengers. The price of mistake can be high, perhaps the highest of all, the driver's life. Trust decisions are very fast; they take few seconds or even less. At the same time these are strategic choices. Drivers learn to pick up passengers only at well-lit corners, not in dark alleys.

Now consider how the trust-choice in the political and policy processes differ from the trust-choices of taxi drivers. The price of a wrong choice in the political world might be high, perhaps not as high as picking the wrong passenger, but still high if one lives under an authoritarian or despotic political regime. The wrong trust-choices have consequences in both worlds, but what is significantly different for our purpose is the fact that actors in governance regimes do not make instantaneous choices to trust or not. They often have time and resources to take their trust decisions at their convenience and to do that conditionally. They can negotiate the terms of the trust decision in ways that taxi driver cannot and they can do research, and take advice from colleagues in ways that taxi drivers cannot. At least when they have to pick passengers in dark alleys. In many ways and cases, policy actors will follow the Russian proverb of "trust, but verify", including regulatory controls over the decision. Meaning that they will condition it on some terms that will minimize the potential of harm from a breach of trust. They have more options, more time and they might have a stable decision environment. Governance actors usually stay in the game for a long time, they are not one-time clients or drivers. Trust choices in governance differ than in hailed transport. We need political imagination of trust-choices and to do so we need to set our imagination free from the cage of survey-data. It is not that survey data on trust are not useful, they are. But, like the taxi ethnography above, they cannot provide us with everything, or even the most essential data, in order to conceptualize and better understand trust with/out regulation. What survey data are missing is often the environment of trust choice and the conditionality of trust. The regulatory environment, and the way regulation and trust interact, significantly change the trust choice. This is rarely taken into account by survey data and, of course, does not come into the anthropological analysis of the taxi-drivers' choice to pick or not to pick potential clients.

How should we best imagine, conceptualize and explain the relations between trust and regulation in governance regimes? One option is to imagine trust and regulation choices on the basis of the epic betrayal of Julius Caesar by Brutus (*Et tu, Brute?*). This will be one useful way. A second way to think about trust and regulation, and indeed more useful and forceful would be using trust-crisis from the world of food-safety crises, privacy scandals and financial panics. In all these cases, the political imagination suggests moments (or period) of heightened distrust in purpose, integrity, legitimacy and effectiveness of the regime and its

¹ I am grateful for useful comments from Libby Maman, Adi Yakoel, Ofir Agai, Uri Kotlarsky, Monika Galvina, Frederique Six, Dominika Latusek-Jurczak, Koen Verhoest and Jacint Jordana, Edoardo Guaschino, Martino Maggetti and Ioannis Papadopoulos. Responsibility is of course all mine.



core players. A third way would be to imagine a crisis of trust within the regime: adversarial interactions, repetitive conflicts among the core players in the regime, among different business actors; among different regulatory authorities; between politicians and bureaucrats, and between different types of regulators; and of course between them and business and civil actors in the regime.

One fruitful way that is developed here is to consider the environment of trust decisions. Imagining trust environments allows us to think about different settings of the trust-choice. We usually distinguish between low and high trust countries using survey data measures. But countries are one type of environment. Other relevant units of analysis are sectors fields, regions, organisations and regulatory regimes. Trust varies largely across these environments and we can expect trust to vary largely and to exhibit different dynamic or even conflicting trend even when the country is defined as high or low trust dynamics. Regulatory regimes differ in the ways they reflect trust and they do have some significant independence from the trust dynamic at the country level. One important characteristic of regime is the distribution of power and authority. Some regimes are monocentric in their authority structure, other tend to be more polycentric and this has implications for trust. Monocentric regimes are indifferent to trust. Trust is not an issue. Control is the only issue. But in polycentric regime trust and distrust are central issues. In other words, and perhaps more specifically, trust becomes a central issue with the multi-levelness of the regime. The demand for trust increases with the increase in the number of actors; with the growing in the scope of decentralization; and with the introduction of more procedures. More complexity, more trust.

The discussion is organised as follows. The first part discusses how these four types of relations between trust and regulation are understood as political world views and ideologies. The second part of the report provides a discussion of the relations between trust and regulation from an interpersonal, actor-centred, approach. It discusses options of how to conceptualize the actors, how to conceptualize the content of interactions as well as how many and which main actors in the trust-choice it is useful to consider. The third part moves from actor-centred analysis to institutional analysis presenting a regulatory regime approach to the relations between trust and regulation in different regime architectures. The fourth part moves to regulatory strategies of dis/trust. The fifth part concludes.



1 The Relations between Trust and Regulation

Let us clarify what we mean by trust and regulation. Trust, for our purpose, is expressed in a choice to engage actively with another actor, accepting uncertainty and risk and putting oneself in a vulnerable position while assessing the trustee as credible, capable honest and with benevolent intentions (Rousseau, Sitkin, Burt, and Camerer, 1998, p. 395; Möllering, 2006, p.111; Oomsels 2016). Mayer et al's (1995) ABI-model is possibly the most often cited in regards to the various components of trust, referring to the assessment of the Ability of the trustee (expectations that the other party has the competence to successfully complete its tasks), Benevolence (the expectation that the other party cares about the trustor's interests and needs) and Integrity (the expectation that the other party will act in a just and fair way) (cf. Koen, Six et al., our deliverable 1.1). Regulation is something different to a point. Regulation is governance by rule making. Indeed, it is the process of rule-making, rule monitoring and rule-enforcement. As a choice decision it is a choice on and how to promote rules, to monitor them and enforce them. Unlike trust, regulation uses different mechanism and different rationale for ordering society but regulation and trust also have some commonalties. Both trust and regulation reduce uncertainty; both allow cooperation and both nurture civil society and fairness in governance.

Regulation and trust are rarely discussed together in the social sciences literature. Still, a literature review that was done for deliverable 1.1. of the TiGRE project suggests that it is useful to distinguish between four analytical approaches to the relations between trust and regulation: **independent, competitive, substitutive and supportive**. Each implies different relations and indeed points to different research strategies, problematization and framing. What is important to our purpose is that these four approaches are understood differently from the point of view of public and private interest theories of regulation. Trust is the least contested of the two. Most of the politically relevant public and scientific discourse turn around the perceived decline of trust or the rise of distrust in government on the one hand and the benefits of trust for social, economic and political performances on the other hand. In comparison, regulation takes a much more politicized and contested view with clear camps of proponents and opponents of regulation. The war of regulation and on big government more generally is politicized in ways that trust is not. There are no proponents and opponents of trust in the way and scope in which we see around regulation. Still, it is useful to discuss them both and to understand how discourses of regulation and trust are perceived.

1.1 Trust and Regulation are Separate, Independent and Essentially Different

First, regulation and trust work separately and independently from each other. They operate in parallel universes and are not interdependent or necessarily related. They may serve the same goals (good or bad, redundant or essential) or conflicting goals, but in both cases they are independent forces. Trust is not intertwined with regulation, or vice versa. Most of the literature – but not this project - ignores one or the other. Therefore, it is important to note this possibility, although it does not exist in reality, because it reflects much of the research agenda so far (but see Six & Verhoest, 2017). For example, in the legal field we would say that administrative law and fiduciary law do not evolve together or overlap in any significant way. Of course, this approach is somewhat impractical and inconceivable. The governance literature equally tries to minimize arrangements that combine trust and regulation. It follows that one can distinguish between trust-based governance and regulatory governance as two distinct forms of governance. Powel, for example, suggests that 'trust-based forms of governance' are important mechanisms of cooperation, and in their ideal 'pure' form they do not involve regulations or private contracts (Powel, 1996). The major manifestations of these trust-based forms of governance are formal and informal networks—of business, civil society organisations and governmental actors. Most of the time, these distinctions are not explicit. The literature simply does not place the interaction between trust and regulation at the centre of the analysis. Thus, most of the regulatory governance literature, with the notable exception of Six and Verhoest (2017), tends to ignore issues of trust. This approach reflects to some extent the division of labour in social science analysis—society, economics, psychology and politics are all studied separately. Trust and regulation in such a division



of labour derive from different dynamics. While trust belongs to the sphere of individual, societal and psychological conditions, regulation belongs in the realm of politics, administration and economics.

Bringing politics into account the so-called decline in trust in governments and the “war on regulation” are also independent of each other. Big Government and “Distrust” belong to two different realms of social, political and economic life. The problem of big government is not an issue of trust and the challenge of distrust in government is not significantly connected to size and extent or mode of intervention of government.

1.2 Trust and Regulation Compete with Each Other

A second approach to the relations suggests that regulation and trust function in competing roles, one eroding the effectiveness and legitimacy of the other. In this approach, regulation (and contracts more generally) erodes trust, turning it into a marginal aspect of the relations between the actors. Another manner whereby regulation erodes trust is by giving rise to new sources of conflict and new and asymmetrical forms of power. Hult (2018), for example, suggests that the main problem of creating trust by means of legislation and regulation is that control tends to crowd out trust rather than creating it. Malhotra & Murnighan (2002) use laboratory experiments to show that contracts (a proxy for regulation) erode trust, especially in binding contracts. Schilke, Reimann and Cook (2015) demonstrate that power decreases trust in social exchange. Gordon, Garen, and Clark (2017) find that government growth erodes trust; they find strong evidence that two aspects of government size—transfer payments and regulatory activity—conform with the political economy model in which government growth erodes trust. Specifically, they find co-integration indicating the following: negative associations between trust and lobbying activity and between trust and each of these two measures of government, i.e., transfer payments and regulatory activity, and a positive association of trust and productivity (Gordon, Garen, Clark, 2017). The competitive approach is also evident in arguments and literature that suggest that too much trust in regulatory regimes and among all actors leads to a lesser degree of compliance, and might even entrap rule-makers. The preference here is for more formal, contractual and hierarchical relations among actors while limiting or crowding out trust altogether.

Bringing politics into account of the so-called decline in trust in governments and the “war on regulation” might be understood as highly connected. Big government can be understood as causally linked to the decline of trust by proponents of small government and ‘free markets’, or the other way around, meaning reverse causality by their opponents. Here in this later view failure of government and governance increase distrust. The response should be more regulation or at least smarter regulation. From the point of view of public interest theories of regulation, more regulation means more trust. For private interest theories, it is the other way around, less regulation, more trust and less trust mean more regulation.

1.3 Trust and Regulation Are Substitutive

A third approach to the trust-regulation relations suggests that regulation and trust function in substitutive roles. They do not compete so much as one replaces the other in the absence, weakness or scarcity of the other. This approach implies that regulation and trust are functionally equivalent. An experimental study by Gasparotto and colleagues (2018) found, for example, that it is possible to recover customer trust through improvements in organisational processes (i.e., regulation) and discounts (i.e., financial compensation). Remarkably, regulation and financial compensation led to similar trust levels, which means that these trust recovery tactics are equally successful. Lack or scarcity of trust might serve as the catalyst of regulation: where there is no trust, regulation emerges either as an institutional response or as a strategic response. After a crisis that weakens public trust, regulation sometimes expands in order to replace and ‘compensate’ for the loss of trust. At the same time, lack of regulation might lead to the evolution of trust. Perhaps a highly regulated or controlled environment does not enable the development of natural trust. In this case, trust and regulation are not only substitutive but also functionally equivalent. They minimize risks and increase the certainty of behaviour among actors. Aghion et al. (2010) suggest that government regulation is strongly and negatively correlated with trust. Their major source of data is the World Values Survey and the Life in



Transition Survey (the latter devoted to life in former communist economies). Both trust and regulation are examined via a wide range of indicators. Aghion et al. (2010) show both (mis)trust and regulation in a cross-section of countries in a sample of individuals from around the world that distrust increases where support for government regulation abounds. Even when people realize that their government is corrupt and ineffective, they prefer state control to unbridled activity by non-civic entrepreneurs. Similarly, Carlin, Dorobantu and Viswanathan (2009) argue that trust and regulation are substitutive in financial markets, and Van den Berg and Keymolen (2017) proceed along similar lines in the case of cybersecurity.

Substitutive relations between trust and regulation are also discussed by Anania & Nisticò (2004). In their analysis, the need to trust arises from the problem of information asymmetry between sellers and consumers in the food market. The problem arises especially in credence goods—goods where consumers cannot possibly know the characteristics of a product even after consumption. The solution for this problem - the author assumes while modelling for it - might be regulation. The substitutive relations are taken for granted and the analytical efforts are aimed at modelling the emergence of imperfect regulation as the best option for both low and high quality credence goods. On another level, substitutiveness might be a good norm of governance if we expect rule-makers—especially unelected officials of the state—to perform as expected in democratic settings. One expression of the substitutive approach is the assertion that trust fosters deregulation. This strand of the literature suggests that the more we trust firms, business associations and professions to regulate themselves in line with the public interest, the more we will be inclined to support deregulation. Six (2013) claims similarly that regulators’ trust in their regulatees can increase compliance, thereby increasing their trustworthiness, and perhaps leading to less regulation. No less important is a second strand of this literature that focuses on the role of distrust in fostering regulation. This approach is especially useful for low-trust societies. Bohnet et al. (2001) finds that in these situations, there is a demand for “more law” in order to enforce contracts and secure property rights. When the state cannot provide high enough enforcement so as to deter breaches, the demand for protection is satisfied privately by organisations and networks that operate outside the state (such as the Mafia in Sicily; see Gambetta 1993).

1.4 Trust and Regulation Are Mutually Supportive

A fourth approach to the relations between trust and regulation suggests that regulation and trust function in mutually supportive roles where one reinforces and complements another. The basic idea here is that trust and regulation have similar goals. Trust can be seen as the goal of regulation; regulation aims to increase trust among the regulatory actors via institutional designs that nurture and reinforce trust. Regulation, that is, the modification of actors’ behaviour, can also be seen as the goal of trust; in this role, trust function as the lubricant of cooperative behaviour via informal or backstage non-regulatory means. Trust and regulation are mutually supportive because they aim to do the same thing—reduce uncertainty, simplify complexity and minimize transaction costs, therefore producing a more stable and predictable environment for purposeful co-action. The “trust fosters regulation” approach suggests that trust in government allows the expansion of its role as a mechanism of welfare maximization. The historical process is often portrayed as developmental. More responsible, more capable and more democratic government is more trustworthy, and therefore a dynamic of regulatory expansion follows the emergence of more systemic trust. To the extent that regulation is about democratic delegation, then the more we trust the agent (i.e., the government) the more we allow it to regulate.

Six (2013) suggested that regulation and trust could complement one another if regulation controlled and enhanced self-determination. If regulators trust regulatees, this enhances compliance, which in turn leads to higher trust. The relationships are probabilistic. Trust in government—that is, in its capabilities and good intentions—does not necessarily foster regulation. One can trust the government, but prefer, for private or public reasons, other mechanisms of governance—whether communal or market-based. Larsson and Engdahl (2012) showed how Sweden opted to reinforce trust through self-regulation in the context of decentering economic regulation in Sweden.



Perhaps the best way to think about the mutually supportive role of trust and regulation is by evoking the Russian proverb “trust but verify.” This proverb became internationally known when Ronald Reagan, then President of the United States, adopted it publicly as his motto in the context of the nuclear control and disarmament negotiations with the Soviet Union. The international nuclear disarmament regime that emerged from these discussions aimed to strengthen the regulation of nuclear weapons—to increase trust within the regime, and more importantly, beyond it. (How did it increase trust?) The norm that emerged has embraced the principle of “trust and verification.” This proverb captures an important aspect of our theoretical approach. Good governance suggests that trust and regulation are highly interconnected in a way that is mutually supportive. We cannot regulate unless we trust, and we cannot trust unless we regulate. On balance, the question is how to combine trust and regulation in a way that maximizes legitimacy and effectiveness, minimizes transaction costs and will allow the interacting sides to update their strategies and adapt them to changes in the behaviour of the actors, the circumstances, and the tasks at hand.



2 Trust and Reregulation: Actor-centered Analysis

From an actor-centred analysis (Scharpf, 1997) trust and distrust are characteristics of the relations between actors. But how does the literature conceptualize the actors and the trust decision? What are the alternatives to current approaches? Who are the actors and what are they exchanging? What would be a fruitful conceptualization? The discussion that follows provides a thick, political theory of the trust-regulation choice-decision from an actor-centred perspective.

2.1 How to Conceptualize the Actors: Beyond Regulator-Regulatee

Actor-centred analysis tends to conceptualize trust relations in a regulatory context as the relations between regulator and regulatee (interpersonal trust) and the relations between members of the public (e.g., citizens) to different regulatees. By extension, the main trust-dilemma from this perspective is the act of balancing trust within the regime and trust in the regime. All other things being equal, the more trust exists within the regime, the more suspicious and distrustful might be the regime outsiders that are not part of the trust circle. A more fruitful discussion would recognize the multiplicity of roles in the regime, their different functions and the extent to which they are always both regulators and regulatees. Thus, instead of narrowly asking **does the regulator trust the regulatee on what, why and when?** We might want to ask **does A Trust B on what, why and when?** In other words, we need to start with actors' interactions rather than assume their relations and explicitly and implicitly their power relations of functions as regulators or regulatee. A can be any actor outside the regime and so is B. They can be regulators or citizens, regime insiders or outsiders; clients, intermediaries and journalist and readers. The point so far is that the interacting actors are not only regulators and regulatees. Sometimes, they are not even the main subjects of trust relations. Not only that such a conceptualization extends the number and type of trust relations but also it reflects one of the major theoretical shifts in the study of regulation: polycentrism (Black, 2001; 2008); regulatory pluralism (Gunningham & Sinclair, 1999); the shift from government to governance; and big governance (Levi-Faur, 2012).

2.2 How to Conceptualize the Content of the Interactions?

Actors exchange not only trust and distrust but also regulation, deregulation or reregulation. Much of the modelling and imaginary so far in the literature on trust in politics had captured the interaction between the sides in the same way that choice was conceptualized in Gambetta and Hamill's study of taxi drivers (see above). This is an apolitical way. As long as the interaction is not only momentary or spontaneous and there is a room for negotiation around the conditions of trust. Indeed, we better think about choice as a package that includes regulation. We can again conceptualize it narrowly or more openly and widely. We can ask **does the regulator trust or promote more regulation over the regulatee?** Or even more widely, we can ask **does A trust or regulate B?** Even more sensible might be to increase the options of our actor and so as to include different combinations of trust and regulation. In this formulation, the question becomes **how does A combine trust and regulation of B on what, why and when?** The interactions between our actors are both regulatory and trust related. Multidimensional rather than unidimensional. An important new challenge that follows from this conceptualization is to understand what it means to combine trust and regulation.

To combine trust and regulation is to conceptualize the trust choice decision as a conditional trust, that is, trust conditioned on negotiation on how to decide on rules, how to promote rules, how to monitor their effects and how to enforce them. Options are there in governance, even if not all options are available to all actors equally. The choice decisions in political arenas are often thicker than the taxi-driver model suggests.



2.3 Dyads or Triads?

Actor-centred analysis is often dyadic, taking forms such as, principal and agent; leader and follower; mentor and protégé; inspector and inspected; co-worker and co-worker; bureaucrats and elected officials; legislator and ministers; regulator and regulatee; and trustor and trustee. These dyadic relations are often perceived as the key component of social and policy networks. Dyadic analysis allows simple modelling and analysis. These are their great advantages but for certain purposes, it is useful to move to triadic relations and to understand the relations between actors as they are grounded and institutionalized in an intermediary role of a third party that mediates between the two. Intermediaries serve as formal and informal rule-brokers between regulators (rule-makers) and regulated (rule-takers). They certify products; report compliance; rank and rate consumers; label products; monitor performance; gate-keep access; screen behaviour; rate organisations, whistle blow misbehaviour; and audit organisations (Abbott, Levi-Faur & Snidal, 2017). When intermediaries succeed, they may facilitate efficiency by increasing the capacity to solve problems and the willingness to accept and comply with authority. When they fail, they may undermine and subvert rule-making and rule-enforcement processes and create a legitimacy deficit. It follows that for certain purposes we should bring a third actor, say actor “I”, into the analysis. The question then becomes **how does actor A use intermediary, say actor “I”, in order to trust and regulate B?** On top of the problematization of the A and B and the ways trust and regulation can be combined, there is now also the need to problematize the intermediaries.

2.4 Triads or Tetrad?

Enter the beneficiaries of the regime – they can be the public or a segment of it; business or citizens; representatives of ecological groups or not in my back yard groups. They can have an active role or representation at the core actors of the regime, among the more peripheral actors of the regime or they can be outside the regime altogether. When one takes into consideration the beneficiaries we move to four actors’ analysis, a tetrad or quadrat. The question then becomes **how does A use I in order to trust and regulate B in order to benefit C?** A new dimension of problematization – concept, theory, empirics – comes to the analysis – who are the real beneficiaries of the regime?



3 Trust and Distrust in Polycentric and Monocentric Regimes

As suggested already, trust-choices are taken in different institutional environments. Trust varies largely across these environments and we can expect trust to vary largely and to exhibit different dynamics or even conflicting trends even when the country is defined as high or low trust dynamics. This holds for a country as well as regimes. The concept of regime encompasses the “principles, norms, rules, and decision-making procedures around which actors’ expectations converge...” (Krasner 1982: 185). Governance Regimes are the institutionalization of principles, norms, rules, and decision-making procedures around also domains, sectors, nations and regions. A regime can be institutionalized at the global level or any other level. In many cases, they are multilevel, de-facto or formally. A regime can be formal or not; regulatory or fiscal; with risk-orientation or not. We use the concept of a governance regime in order to capture the variety of procedures, designs, norms and actors’ constellation in different domains of governance (Atkinson & Coleman, 1989; Waarden, 1992). There are many ways to do so and each has its own theoretical purpose in mind. Regulatory regimes can be étatist, liberal, intergovernmental and supranational (Levi-Faur, 1999). They can involve different combinations of business-led, civil-led and state regulation (Levi-Faur, 2011).

For our purposes, it is useful to start from the suggestion that regulatory regimes differ in the ways they reflect trust. Sectoral regimes have some significant independence from the trust dynamic at the country level. Imagine, the trust in the food safety regime in Belgium for example, as reflecting trust in the food safety regime in France not less or even sometimes more than it reflects the environment of trust in Belgium. Learning and emulation tend to be within sectors and across countries Sectors matter and diffusion of trust across similar sectors matters as well. But it is not only that sectors matter for trust, they also reflect trust. Consider the self-regulatory powers that are delegated to professional associations such as lawyers and physicians in some countries. The explanatory forces beyond these self-regulatory powers might be found in power, institutional path-dependency or any other possible causes. What matters is that they are widely trusted with public functions. Their existence as self-regulatory arrangement attests to trust in the design of the legal or health regimes. In other words, our political imaginary around trust decisions may include the many instances of self-regulation (and its challenges). This paper suggests that self-regulation designs (and their brothers and neighbours) represent high trust-environment and attest to its existence no less, or at least similar, to the evidences taken from national surveys on trust. While self-regulatory regimes, de-facto or by design, reflect strategies of trust, while state-led, Command & Control regimes reflect strategies of distrust. In developing these theoretical assertions, I expect to provide a more comprehensive and more penetrative discussion of the relations between different types of regulation and trust and how to understand their interactions.

I advance two ideal types of environments of trust. One is structurally polycentric and is characterized by a responsive mode of interaction in the regime. The second is structurally monocentric and is characterized by responsabilization as the preferred strategy of interaction. One might think about the difference between transnational or EU policy processes and that of national decision-making processes in China, for instance. While the first is polycentric, the latter is much less so – but still sometimes more pluralistic than we might imagine (Van Rooij et al., 2016). In **polycentric regimes** relational and institutional power is dispersed among many, partly interdependent centres of authority. Polycentric governance reflects a situation where self-governance and delegation are prevalent. Interactions are responsive, in the spirit of responsive regulation, they are sensitive and flexible in response to the behaviour of the two sides. Both sides are regulated and the relations are not necessarily always hierarchical. Trust is paid by trust, distrust by distrust and in between there is a process of signalling that allow the sides for interaction to assess each other trustworthiness and response to different approaches. **Monocentric regimes**, by contrast to polycentric ones, reflects the opposite situation, in which power is concentrated in one independent centre. It is a characteristic of authoritative regimes that find it difficult to accept decentralisation of authority. Monocentric governance suggests centralization, hierarchy, and sanctions, as well as a monopolistic position on regulation and its



legitimation. A major strategy in such regime is that of responsabilization, that is, the assignment of an increasing number of demands and duties to a wider set of regulatory actors via punitive and sanction-driven policy processes (cf. Shamir, 2008; Gray, 2009; Gray & van Rooij, 2020; Garland, 2001). State-led modes of governance are most frequently associated with responsabilization. It is a strategy of deterrence rather than persuasion, of control more than empowerment.

Monocentric and polycentric regimes use similar mechanisms of regulation, but they use them differently. Mechanisms of regulation are the techniques which interconnect policy instruments and action into stable and internally consistent procedures and processes of governance (cf. Williamson, 1996). This definition of mechanisms, and indeed the research agenda on the subject, draws on, and extends, the policy instrument approach (Salmon, 2002, Hood, 1983; Hood and Margret, 2007; Lascoume & Le Galès, 2007; Howlett, 2011). Mechanisms of governance are not the same as policy tool or instruments, even if they have instrumental use. The distinction can be made via the well-known quip about a boy with a hammer: a boy who has only a hammer tends to perceive everything (and everyone) around him as a nail. The hammer is a “tool” or “instrument,” the nail a “device.” The combination of hammers, nails, and the procedure of introducing the nail to the hammer is the mechanism which governs the action and the process of building, say, a desk. Moving to governance, mechanisms can be used to govern the relations between principals and agents, but also between them and an intermediary; hence: “mechanisms of intermediation.” We study mechanisms because their success and failure impact governance but also the way they are structured reflects the trust environment in the regulatory regime. A study of mechanisms of regulation allows us to understand how they are used, and can be used, to shape effective and legitimate regulatory governance. In what follows I discuss four mechanisms of regulation and show how their designs vary in monocentric vs. polycentric regimes.

3.1 Certification and Accreditation

Certification and accreditation are verification and assurance procedures by which the one actor (the certifier) formally and authoritatively assesses the targets on their conformity to standards, attainment of certain qualifications, or adoption of certain processes and norms of other actors (Freiberg, 2017; Bartley, 2011; Loconto, 2017; Gustaffon & Hallstrom, 2018). Accreditation refers to the certification of the professional qualities, capacities, and behaviour of the certifier. As a mechanism of regulation certification and accreditation vary on significant attributes, on their strengths, and weaknesses; and with regards to their emergence, institutionalization, spread, and transplantation. There are many ways in which certification and accreditation can be integrated as mechanisms of verification and assurance into regulatory regimes. Certifications and accreditation can be voluntary in the sense of certification and standards that are not legally sanctioned. They can also be legally required or preconditioned for market entry or entitlements. Both certification and accreditation represent authoritative attestation of facts or statements. As regulatory processes, they are often directed towards some form of formal written documentation or label that attests that the certified successfully meets or conforms to the standards of the (accredited) certifier. Certification is used for products (e.g., fair trade coffee), sustainability standards (e.g., forest certification), services (aircraft services), persons (e.g., accountants), systems (cyber protection), facilities (e.g., hospitals), sources and traceability of products, religious standards (e.g., kosher, halal), and professional competence (e.g., nurses, physicians). The alternative for certification is often a state license and in many cases it is more likely that we will find it in polycentric regimes. Nonetheless certification can be also very hierarchical and monocentric. Just consider the option where the certifier and accreditor are directly controlled and owned by the rule-makers.

Certification and accreditation can be used both in monocentric and polycentric regimes. Certification in a monocentric regime would be compulsory. It would be carried by the same organisation that is responsible of the rule-making. Ownership and control will be the same and centralized. Control by the state would make accreditation less relevant and less frequent. Certification in a polycentric regime would be voluntary, carried by an independent intermediary (rather than an agent of the rule maker), it will often be for-profit or civil



rather than statist. Because it is voluntary it would often be accompanied by multi-stakeholders' accreditation organisation and it will be often transnational. In other words, certification will be more centralized and étatist in monocentric regimes and decentralized and pluralist in polycentric regimes.

3.2 Reporting

Reporting is a regulatory mechanism that requires agents to report – usually on their actions, on the environment around them, or on certain actors – to other actors via formal channels and sometimes according to carefully prescribed standards. It focuses on reporting, and in particular the duty to report, with the aim of providing a comprehensive and systematic study of reporting as a mechanism of regulation and how it is linked to effective and legitimate governance. It follows different reporting requirements, looking at how they vary in their saliency and accessibility to other actors; in their scope and demands from the reporting agent; and their centrality in the regime. Reporting can be mandated or voluntary. It can be promoted by duty (legal, hierarchical), incentivized (rewards), socialized by norms, or supported by call centres and warning systems (e.g., *how is my driving?*). It can apply to specific activities such as child abuse, domestic violence or financial performance. Reports serve to assess performance (e.g., ecological footprint). They can also serve to alert to phenomena such as adverse reactions to drugs (e.g., hospital reporting programs), or, as in the case of communicable diseases and public health emergencies, to communicate with a national or international centre for disease monitoring. While some of the reported issues may be mandatory (e.g., corporate financial reporting), others, such as sustainability performance, are often voluntary. Still others are contractual. Reporting can be periodic or event-triggered.

Reporting, in all of its forms serves as the infrastructure for more complex political, administrative, and social governance. Still and like the mechanism of certification it can be used in both types of regime. In a monocentric regime reporting is compulsory, to the rule-maker, legally mandated and unidirectional towards the centre of the regime. In polycentric regimes reporting is incentivized and sometime voluntary and it encompasses all actors who have to report on their action, performances and plans. Reporting in polycentric regimes is reciprocal and normative rather than unidirectional and legally mandated.

3.3 Ranking & Rating

Ranking and rating are forms of performance evaluation and regulation by numbers. To rank and rate is to apply a hierarchical order to a group of regulatees. Ranking, like rating, creates a hierarchical order on a scale of achievement or status. Ranking subjects assesses them against one another. Rating subjects involves assessment against pre-determined standards rather than against each other (Mehrpooya & Samiolo, 2019; Espeland & Sauder, 2007). The outputs of ranking and rating activities include league tables, indexes, or labels. Mechanisms of ranking and rating are often studied as 'regulation by information,' regulation by numbers, and performance regulation. All reflect the growing ability of actors to collect, assess, and use data; the importance of performance indicators; and also, of course, the potential of these indicators for abuse, manipulation, goal displacement, and gaming (Bevan, & Hood, 2006). Ranking & rating differs as well in the ways they are working in monocentric and polycentric regimes. One important difference is in who is doing the ranking and rating. In a monocentric regime the principal, that is the governor or the rule-maker, is in control over the process of ranking and rating. Controls vary but some of the relevant criteria is ownership of rate ranker and rater organisation, decisions about criteria and scope as well as on assessment and evaluation. In a polycentric regime however, ranking and rating are being carried by independent organisation(s); criteria for ranking might be shaped by various and multiple stakeholders and the results of the exercise often does not carry sanctions.



3.4 Auditing

Auditing is probably the most comprehensive regulatory mechanism. It is commonly understood as the authoritative process of obtaining and evaluating evidence regarding assertions about actions and performance to ascertain the degree of correspondence between those assertions and established standards and criteria (Cooper & Robson, 2006; Suddaby et al., 2007; Power, 1999; Carruthers, & Espeland, 2007). Auditing is mostly a for-profit activity, but the chosen case is interesting because accounting had been developed as a professional group with academic ties. The study of auditors, and governance by auditors, affords a fresh look at how professionals in society are related to intermediation. In its earliest form, auditing was the providing of an opinion on financial accounting statements, while the origins of accounting, in turn, lie within the field of bookkeeping (Chelmsky, 1985, 484). Historically, then, auditing developed as a procedure for detailed checking. Its concerns were essentially that of verification. In time, it became more formal, more procedural, more professional, and more prevalent (Power, 1997). Auditing can be internal (e.g., within a governmental or other organisation) or external (by an independent party). If auditing was once exclusively a financial activity, it is nowadays expanding to “social auditing”, defined as “a dynamic process that an organisation follows to account for and improve its performance, consisting of planning, accounting, auditing and reporting, embedding and stakeholder engagement” (Gao and Zhang, 2006). Social audits that originated in the second part of the 20th century were followed later on by various types of sustainability audits. Today, everything is being audited, with new issues and actors targeted, and with more formal demands placed on the auditors and the auditing process.

Auditing, as a mechanism of regulation, may sustain both monocentric and polycentric regime. Of course it can also be a hybrid of the two ideal types. Auditing can sustain self-governance of firms or organisations; it can supply some indication for the performance of the audited entity. It is hard to give up on auditing even if not mandated by the corporate’ rules, government or security of exchange. It is an essential management tool that can be reflexive rather than punitive or judgmental. At the same time auditing practices can be mandatory, centralized and punitive reflecting a culture and norms of Command & Control.

It all comes to a conclusion. While it is hard to measure and we do not have measures of centric regimes we can identify the environment of trust and decide to which extent it reflects more or less trust.



4 Strategies of Trust and Strategies of Distrust

Trust is not only evident from the structure of the regime but also from its regulatory strategies. Of course, it makes sense to expect for some computability between the structure and strategy. In the words of Alfred Chandler (1962: 16) “...structure follows strategy and that the most complex type of structure is the result of the concatenation of several basic strategies” (cited by Majone, 1997, 139). But how can we identify strategies of trust and how do they differ from distrust. Perhaps the most influential strategy of trust is reflected in the theory of “responsive regulation” where the interactions between regulator and regulatee are understood as a set of options, as reflected in the widely used pyramid of enforcement (Ayres & Braithwaite, 1992; Parker, 2013). At the centre of the theory of responsive regulation is the effort to build trust relations between the regulator/inspector to the regulatee/inspectee. The idea is to develop strategies that fit the many ways regulatees respond to regulation. To encourage compliance via education and persuasion rather than by sanctions and punitive measures. The approach is trustful at its core but recognizes that some are less trustworthy than others. Enforcement strategies are tailored accordingly. In the words of Lange and Gouldson:

“...[R]esponsive regulation is a specific regulatory style informed by trust relationships which can be deployed in order to implement traditional command and control regulation more smartly. The application of responsive approaches embodied many of the wider arguments about the pros and cons of trust relationships in that where trust between regulators and regulated appears to improve some of the measures of regulatory performances...” (Lange and Gouldson, 2010, 5239).

But responsive regulation is not the only trust-driven strategy of regulation. Take for example the work of Coglianese and Lazer (2003) on management-based regulation. The two defined and conceptualized a little-studied regulatory approach that they have called ‘management-based regulation’. It directs regulated organisations to engage in a planning process that aims toward the achievement of public goals, offering firms flexibility in how they achieve public goals. This regulatory approach is opposed to the more traditional technology-based or performance-based regulation. Coglianese and Lazer (2003) have shown how management-based regulation can be an effective strategy when regulated entities are heterogeneous and regulatory outputs are relatively difficult to monitor. In conclusion, they have argued that management-based regulation requires a far more complex intertwining of the public and private sectors than is typical of other forms of regulation. The paper and the analysis do not mention trust but management based regulation is a trust-based strategy as it requires co-regulation and a degree of delegation of authority and responsibility to the regulatee. Perhaps management-based regulation is simply more useful and is not motivated by trust-approach or consideration but it reflects high-trust environments not less than, say, the Scandinavian polities. Interesting enough, one can probably find it in sectors, such as food safety, not only in Scandinavia but also in food safety sectors in low trust polities.

If “responsive regulation’ and ‘management-based regulation’ are strategies of trust, responsabilization and adversarial legalism are strategies of distrust. Responsibilization is the assignment of punitive and increasing number of demands and duties to a wider set of regulatory actors (cf. Shamir, 2008; Gray, 2009; Gray & van Rooij, 2020). It reflects a punitive culture of control (Garland, 2001) and is associated with punitive and sanction-driven policy processes. State-led modes of governance are most frequently associated with responsabilization. While responsabilization punishes and deters and in this sense distrusts; empowerment strategies that are associated with responsible regulation trust the capacity of the others to act in trustworthy ways (Ayres & Braithwaite, 1992). Some regulatory mechanisms, e.g., duty to report, are more likely to reflect and result in responsabilization than others. The choice of strategy is expected to have significant implications for the structure and to serve as yet another indication for an environment of trust. Similarly, to responsabilization strategies the theory of adversarial legalism suggests that some countries and sectors (say regimes) are more adversarial than others. Adversarial legalism is a theory of conflictual and highly legalist regulatory style (Kagan, 2001 [2019]). It is characterized by its emphasis on detailed rules, emphasis on transparency, narrow discretion in applying regulation for both regulator and regulatee, strong



accountability procedures; recourse for judicial intervention and preference to adversarial procedures of dispute regulation (Waarden, 1995).

It is useful to note that all these theories do not explicitly theorize trust. They often do not even mention trust. Still, hidden assumptions on trust are easy to identify when one considers their logic of control and compliance.



5 Conclusions

This report enhances a project-wide perspective on trust in regulatory regimes. In doing so it first emphasizes the different ways in which trust is political. Trust is political because political strategies of trust and distrust are used in order to advance the actors' interest, ideas and preferences. They are not objective characteristic of the political arena but involve calculated and strategic considerations around the best way to accumulate and operate power and influence. That trust is subjective rather than objective feature of a regulatory regime does not mean that trust (or distrust) has limited impact on the way the regime operates, its legitimacy or effectiveness. On the contrary, subjective perceptions of trust may have significant and critical affects. So, the first thing that this report advances is a political perspective on the trust and regulation. At the same time, and secondly, this report emphasizes the important ways in which trust in regulatory, administrative and political settings differ significantly from the situations described both in the Gambetta and Hamill's taxi driving and surveys. Trust in regulatory, administrative and political settings is negotiated, conditioned and reversible. The choice-decision is considerably different. Thirdly, the report promotes the idea that trust in politics is reflected in different preferences, institutions and interests around the structure of the regulatory regime (e.g., self-regulation and delegation) and about the strategies of control and compliance (e.g. responsive regulation vs. adversarial legalism). Starting with structure, this report approach to trust and regulation suggests that the relations between trust and regulation take different forms and are expressed not only in actors' choice decisions but also in the structure and strategies of the regime itself. Trust is political in the sense that trust choices in politics, policy and governance involve not only the choice to trust or not to trust but to condition the trust on certain rules, monitoring and verification techniques and enforcement strategies. Political actors do not simply trust or not but condition their trust. But trust in regulation is not only about choice decisions. Trust is embedded into the design and strategies of the regulatory regime. It is not only a choice opportunity but organisational design and strategies that are normative. Trust and regulation are also the environments that structure the choice and not only the choice itself.

Trust choices, in political and policy processes, are often negotiated and prolonged where timing is a strategic tool to optimize the interests and preferences of actors. In this way, trust-choices, in policy and political contexts, are choices to trust or regulate as well as how to combine trust and regulation. Choices vary in different regimes and different institutional environments; they vary with the choice-architectures. The four approaches to trust that were identified here are political in the sense that each is reflected in a different world view. They are not necessarily a mirror of objective reality but represent an effort to shape society, politics and economics in different and conflicting ways. Each of the four has its own merits and weaknesses. The most interesting is, however, the mutually supportive relation approach as it deals with the use of regulation to enhance trust and the use trust to enhance regulation. It is interesting not because one should always trust regulation and not because regulation should enhance trust. Distrust and deregulation have their own merits in democratic governance in general and in regulatory regimes in particular. When actors are not trustworthy; when the norms of the regime are misguided; when regulation is outdated or captured, it makes sense to distrust and reregulate. What makes mutually supportive relations especially interesting is that they involve, often in creative ways, two central and important mechanism of governance, without presuming the primacy of one over the other. The analysis moves beyond the interpersonal perspective of a single unidimensional trust-choice. In politics and policy, trust is not only an interpersonal, dichotomous decision to trust (or not to trust). It often comes as part of a package of governance choices where trust is accompanied and conditioned by the many forms of regulation. Actors get to choose how to trust rather than only or mainly whether to trust. It is a choice of one package of arrangements, often from multiple ones.

The framework developed here should allow a more penetrative and comprehensive analysis of trust and regulation than was available before. At the actor level and from an interpersonal analysis, it allows a more realistic design of trust choices. Actors and interactions are not only between regulator and regulatee. The environment is much more pluralistic and all actors are both subjects and objects of trust and regulation. Instead of dyadic analysis, the interaction was extended in order to distinguish between intermediaries and



intermediation roles as well as the regulatory beneficiaries. The relations between actors are conceptualized as both relations of both of trust (or distrust) and of regulation (or de/re regulation). Actors' choice is the choice of a certain package of trust and regulation rather than one or the other. All actors face the trust and/or regulate dilemma, in other words, when, to what extent and how to manage their regulatory and trust relations.



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Appendix: Mapping the Regulatory Regimes in Data Protection, Finance and Food Safety

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² In this part we distinguish between two types of mapping. “The content part” refers to the structure and legislations of the regulatory regimes in each country. The “mapping exercise” refers to the list of actors which have served both, the content part, and the survey.



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1 Introduction and Rationale of the Mapping Exercise

This document includes the description of each of the sectors under investigation and offers detailed guidelines for the mapping exercise including a classification of the categories of actors we focus on. The classification covers the following policy arenas:

- Data Protection** – (Electronic communication of personal data and Health data)
- Food Safety**- (Animal welfare and sustainable agriculture)
- Finance**³ - (Banking and Securities)

In this document, you will find the guidelines on how to record and code actors in the three sectors. Please record the information in an Excel sheet and follow the format of the template closely. Please note that there are three different tabs in the excel spreadsheet template that we have used. **For Federal Countries, please select the regions that you consider most relevant to the regulatory regimes in all three sectors. Please note that these regional actors, although very relevant, cannot be part of the “core actors” in the survey.** In addition to mapping actors, we also identified the main mechanisms of control in each of the three sectors. We specify the main features of the sectors and the main trust issues. In addition, we offer an overview of the relevant laws, the main debates and big crisis over the last few years.

The mapping exercise is composed of 2 main parts: (1) the mapping of actors and (2) the main mechanisms of control. These elements need to be integrated in the mapping in each country. Thus, we propose two different deadlines:

1.1 A. Sector description and general instructions: Data Protection

Data processing apply to all sectors and all actors. By looking at the main issues the regulators deal with, we observe a variety of areas that are concerned by data protection. For example, airports’ use of facial recognition can be very problematic. Similarly, cameras on train pass, pool safety cameras, online payments, mobile data, supermarkets’ fidelity cards, private insurance’s data storage and ‘wearables’ (smartwatches data collection during fitness activities) can also be of great importance for protection of personal data. Overall, the proliferation of digital technology raises many concerns regarding data processing.

The main issues regarding data protection essentially converge towards the **processing of personal data**. ‘Personal data’ is defined as “all data about an identified or identifiable natural person.”⁴ ‘Processing’ is defined as any operation or set of operations which is performed on personal data or on sets of personal data. This includes collecting, storing, disclosing, erasing,...⁵

As the challenges of data protection regulation cut across all sectors, it is necessary to define boundaries. We thus select two areas in which personal data to focus on: (1) electronic communication of personal data and (2) health data. In particular we focus on personal data transmitted over the internet and personal medical data. Personal data is data that refers to the identity of a natural person, medical data is data that refers to the health of a natural person. In GDPR, medical data is considered ‘sensitive’, which means organisation who process this data have to comply with extra regulations.

To sum up, by looking at these two types of data, we are able to cover a very broad area of data protection.

- We start generally with **electronic data**. We focus here on personal data that are collected and stored when surfing on the internet. We thus refer to data generated by internet users. In this regard, we apply the definition of personal data provided within the GDPR: <https://gdpr-info.eu/issues/personal-data/>

³ A note on each actor should contain information on whether the actor deals with micro-prudential/conduct of business.

⁴ GDPR, art. 4

⁵ GDPR, art. 4



- Regarding Health Services we focus on **medical data** or **health data**, which can be considered as a category of personal data. We focus here on health data that are related to the health status of a person, according to the definition provided within the GDPR: <https://gdpr-info.eu/recitals/no-35/>

Note that the selection of regulatees in this sector can be problematic. All public bodies, private firms, professionals, or private persons are subject to data protection regulations. Therefore, we propose the following selection of the regulatees, which is distinguished between publics and privates.

As to Health data we mainly refer to public Hospitals. As to interest organisations, we refer to: Hospitals' associations/interest groups, association/interest groups of health insurances, consumer associations and interests' groups/associations of physicians and dentists.

Regarding electronic communication of personal data, we mainly refer to registered internet providers. As to interest organisations, we refer to: association of internet providers, information and communication technology (ICT) associations and ICT umbrella organisations (representing IT companies).

1.2 Sector description: Finance

The financial sector has been divided historically into three large sub-sectors: banking services (credit institutions), securities (typically including stock exchanges), and insurance products (typically including pensions), including in all cases a certain extent of self-regulatory activity. A further distinction is made between the nature of financial risks involved, namely macro, micro, and conduct-of-business supervision. The formal responsibilities of financial regulation across subsectors and types of risks may be distributed among public authorities in different ways, as it is reflected in multiple configurations of regulatory authorities that can be observed across countries and over time.⁶ An additional dimension to take into account when comparing these configurations is the institutional dilemma of involving or not central banks into banking or even the whole financial regulatory activities.⁷

Turning to the regulatees, the picture in the financial area is also complicated because many firms are active in more than one sub-sectors, while others remain circumscribed to one specific subsector, or even a particular niche. This creates situations of financial companies being subjected to multiple frameworks and supervisions, potentially by different regulatory authorities. For instance, banks may sell insurances to individual customers and hence fall under multiple types of regulatory frames; but also some activities of insurance-only companies may be considered investment products. We thus focus on **licensed banks** and **electronic payment companies**.

Given these constrains, certainly we have to be quite selective to identify a limited number of regulatory issues and configurations in which we would be able to develop our empirical analysis. TiGRE will **focus on the following combination of sub-sectors and risk-level cases**:

- subsectors: **banking and securities**. The regulation of banking concentrates on the market for credits and the operation of financial services. Usually there are two main components, licencing (to own and to operate a bank) and supervision (of banks' activities). The regulation of securities refers to the supervision of tradable financial assets, which create markets related to two types of financial products, equities and debts, as well as their hybrids and derivatives.
- risk-levels: **micro-prudential** (controlling the safety and soundness of individual financial business firms) and **conduct-of-business** regulation, which focuses on supervising the relationship between a financial firm and its customers, to protect the latter from the risk of asymmetric information misuse.

⁶ Bach, T., Boon, J., Boye, S., Salomonsen, H. H., Verhoest, K., & Wegrich, K. (2019). In the Line of Fire: European Financial Regulators before, during, and after the Crisis. *der moderne staat*, 12(1), 5-29.

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⁷ Jordana, J., & Rosas, G. (2019). Central banks and banking regulation: historical legacies and institutional challenges. In T. Bach & K. Wegrich (Eds.), *The blind spots of public bureaucracy and the politics of non-coordination* (pp. 195-216). Basingstoke: Palgrave Macmillan.



- in addition, we specifically will focus more in detail on micro-prudential and conduct-of-business regulation of **financial technology companies** in banking services, as opposed to traditional financial institutions. The literature distinguishes between two different types of companies, depending on the initial business of the company. FinTech⁸ companies focus on creating technology-based solutions for financial services (e.g. electronic payment such as PayPal), whereas TechFin companies are those that have a technology-based business and use the information they have about customers to develop financial services (e.g. Amazon).⁹ For the time being, we do not distinguish between these two types, as both are eventually subject to similar types of financial regulation and supervision.

1.3 Sector description of food safety regulation

The food industry can be split up in several ways, and one way is to look at the nature of the product: dairy, meat, fish, vegetables, etc. For this mapping, we looked at several possibilities to divide the industry in a relevant way. Regulation and legislation of the food industry is most often divided up according to the food chain “**from farm to fork**”. This takes into account agriculture, fisheries and other actors in the primary sector (1), the food handling and processing sector (2), food storage (3), the distribution, hotel and catering industries (4) and lastly, consumers (5).

Food safety regulatory bodies generally look at this entire production chain as a whole, and call on experts of the different links in the production chain of food products. Furthermore, European legislation on food safety is made up of four main European laws. First, after the BSE-crisis (mad cow disease), the European Union adopted the General Food Law¹⁰, which pins down general principles for food safety across the European free market. Then, after other crises at the beginning of the 2010s, like the fipronil crisis and the horse meat scandal, three other important laws were adopted to ensure a better exchange of information and a more uniform risk management across member states: the animal health law¹¹, the plant health law¹² and the official controls regulation¹³. The latter arranges control activities on the application of food safety laws across the European Union.

The food industry is very fragmented and varied. Many different product categories use very diverse production methods. Furthermore, regulatory actors look at a diverse range of food safety issues. To study the trust relationships between regulatory actors and the regulatory regime on food safety, we make a selection of this large and diverse sector.

Together with the IBEI team, we have reviewed the “farm to fork” strategy, published in 20.05.2020¹⁴, which is part of the EU Green Deal. In this document, the EU Commission emphasizes that the general objective is to provide sustainable food aftermath of the COVID-19 pandemic / to construct a robust and resilient food system. Against this backdrop, one important aspect is to take into account environmental implications/to provide sustainable food.

We identified two aspects that can be subject to trust relationships (we could examine such aspects as subsectors):

⁸ Fintech is hence not a subsector, but a specific type of product or regulatees that is promising in terms of posing challenges to regulation.

⁹ Zetsche, D., Buckley, R., & Arner, D. (2019). THE RISE OF TECHFINS: REGULATORY CHALLENGES. In J. Madir (Ed.), FINTECH: Law and Regulation (pp. 280-301). Cheltenham: Edward Elgar.

Marous, J. (2018). The Future Of Banking: Fintech Or Techfin? (<https://www.forbes.com/sites/jimmarous/2018/08/27/future-of-banking-fintech-or-techfin-technology/#58b72c605f2d>, accessed 09.03.2020)

¹⁰ More info: https://ec.europa.eu/food/safety/general_food_law_en

¹¹ More info: https://ec.europa.eu/food/animals/health/regulation_en

¹² More info: https://ec.europa.eu/food/plant/plant_health_biosecurity/legislation_en

¹³ More info: https://ec.europa.eu/food/safety/official_controls/legislation_en

¹⁴ Link https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf



1. Animal welfare (focused on **poultry and poultry-meat based products, eggs and eggs products**), which can include the following aspects that are subject to debate/regulation
 - the usage of veterinary medicinal products/antimicrobials/feed additives in animals
 - animal transport and the slaughter of animals
 - organic farming
2. Sustainable agriculture (focused on **fruit and vegetables**):
 - the usage of chemical pesticides/ antimicrobials/fertilization
 - agro-ecology/organic farming

All these aspects can be examined through the stages of the food chain: **Primary sector, processing, distribution** (retailing, packaging, and transportation).

This mapping exercise will therefore focus on the product categories **(a) poultry meat, eggs and products based on poultry and eggs and (b) fruits and vegetables**. For the product categories, we use the delineation from the Rapid Alert System for Food and Feed (RASFF)¹⁵. By selecting fruits and vegetables, we select the largest market of European food product categories. We further focus on poultry meat because this is a protein-based product, which entails a very different production process. Lastly, food safety of egg and egg products recently came under scrutiny as a result of the European fipronil crisis. Furthermore, poultry meat and egg products are always relevant because of the ever present risk of salmonella contamination. These product categories are also of considerable magnitude in terms of production in each of the countries involved. Within these product categories, we focus two kinds of regulatory issues, being (a) **biological¹⁶ and chemical hazards¹⁷** and (b) **organic foods**. Biological and chemical hazards make up the lion's share of food safety issues. They are often controlled by public or private laboratories that perform tests on samples, taken by controllers at food companies. Organic food is a new upcoming category that involves many private regulatory mechanisms like certifications and labels.

Legislation on food safety is dominated by European law. The competence to regulate and control compliance with this legislation lies with member states. The food safety regulatory bodies in member states generally look at the entire production chain of a food product as a whole and call on experts of the different links in the production chain of food products to execute controls of regulatees.

Food safety legislation puts the responsibility to ensure food safety with the operators of food products (e.g. primary sector, transport, distribution companies...). Through a series of efforts and measures, food operators have to ensure (1) compliance with food safety regulation and prescriptions, (2) meet quality standards and regulations and (3) ensure traceability of all the products. Certification companies have arisen to control and certify these measures of food operators. Often, a food operating company can only start its activities after this system of food safety measures has been certified by an authorized certification organisation. This makes for a large network of many private and public actors that perform regulatory functions. When it comes to organic farming/food, much of the specific regulation for that sector/issue is done by private regulators, in the form of certification by private certification bodies.

¹⁵ https://ec.europa.eu/food/safety/rasff_en

¹⁶ Biological hazards are amongst others bacteria, viruses and protozoa (see <https://www.dropbox.com/s/272mxj5uchtexwk/HACCP-Mentor-Biological-hazards.png?dl=0>)

¹⁷ Chemical hazards for food safe may be naturally occurring (like...), added (like feed additives, antibiotics and other medicines, pesticides), contaminates (pest control products), and <https://www.dropbox.com/s/uueaiz8o2vnhhgk/HACCP-Mentor-Chemical-Hazards.png?dl=0>



Lastly, the food industry is an important industry in the European economic system. Many companies are represented in various national and international interest organisations and sector groups. The chosen product categories are of considerable size in all countries involved in TiGRE, which would not be the case when we would focus on other product categories e.g. fisheries.

In short, we focus on **two subsectors**:

- From the viewpoint of animal welfare, we focus as product category on **poultry, eggs and products based on poultry meat and eggs**
- from the viewpoint of sustainable agriculture, we cover as product category **fruit and vegetables**

The **regulatory issues** to be studied--through different stages of the food chain-- would be in both product categories:

(a) biological hazards and chemical hazards (including medicinal and anti-microbials/feed additives -- chemical pesticides and fertilization)

(b) organic farming/agro-ecology

In the product category of poultry, eggs and related products, an extra regulatory issue would be: animal transport and animal slaughter

1.4 The selection of the organisations

Description of categories for Food Safety and Finance

| Numerical actor code | Description |
|---|--|
| Sector Specific Legislative bodies Code: 1 | By legislative bodies we refer to bodies where legislation and regulation is developed. Please list: (1) (the) relevant permanent parliamentary committee(s) (unless a crisis in one of our delineated subsectors led to the creation of a temporary committee) (2) The members in these commissions and their political parties. If applicable, please consider the inclusion of legislative committees in both the Upper house and Lower chamber - specifically, for federal and quasi-federal countries. |
| Sector Specific Judiciary branch/appellate courts Code: 2 | The judicial actors are (1) part of the judicial branch and (2) have formal power to sanction non-compliance and regulation breaches. In particular we want you to identify the courts where hearings of food safety and financial regulation breaches are organized. Please note that the courts are usually the same for all the sectors (unless some specialized courts). Additionally, identify other actors (if any) who decide on penalties and sanctions and bodies where appeal can be filed against a decision by the regulating authority. This can be an internal, autonomous division of the regulating authority. Please include courts in the mapping, but do not collect email addresses. |
| Regulatory agencies Code: 3 | We refer here to the actors that control, support and enforce compliance with food safety and financial regulation. There might be several regulators (e.g. for banking, for securities, for micro-prudential/conduct-of-business regulation) or just one regulator. |
| Regulatory Intermediaries | Intermediaries are actors that operate in between the regulatees and the regulators. They perform tasks like licensing, accreditation and certification. Please list organisations that perform provide certifications or accreditation (or labelling). This kind of intermediary is |



| | |
|---|--|
| Code: 4 | usually private but they can also be connected with ministerial offices. For the financial sector please consider also the rating agencies. |
| Executive bodies | Please list ministries, departments, directorate-generals, or governmental actors that are involved in policy development and support. These actors are in charge of general policy issues as well as oversight functions. If applicable, please also list advisory or scientific bodies that are included in policy development. |
| Code: 5 | |
| Regulatees | For this category it is important to investigate whether e.g. regulatory agencies have publicly available lists of regulated firms. |
| Code: 6 | Regarding the financial sector, please include companies licensed as banks and electronic payment companies . The ministry sometimes possesses list of these licensed companies For food safety, regulatees include food producers (like farmers), companies involved in food processing (including slaughter houses and food processors), and distribution (including packaging, and transportation and retailing – including trading and distribution centers like ‘veiling’ in Dutch). Note: For the selection of regulatees in the Food Safety sector, we will make use of the NACE-nomenclature of Eurostat. We will elaborate on this further on in the document. |
| Interest organisations representing regulatees | This category includes: 1) market-oriented interest organisations of regulatees (in food safety for all stages of the food chain ¹⁸) and professional organisations (like farmers association, or an association for bank managers) 2) trade unions 3) consumer associations. ¹⁹ |
| Codes: 71,72,73 | Please note: Market-oriented interest organisations (representing the regulatees): give the code 71 Trade unions: give the code 72 Consumer associations: give the code 73 |

¹⁸ In the food safety sector one should look for interest groups representing those actors (regulatees) involved in one or all stages of the food chain

- Interest groups representing producers. For example, farmers are mostly represented both in general farmer associations, covering all product categories, and specialized farmer associations linked to a product category, like all poultry producers
- interest groups representing the firms processing food
- interest groups representing the companies and actors involved in food distribution (including packaging, and transportation and retailing)

So the mapping could look for interest groups representing the regulatees in all these stages, which are involved in food in general and in the specific product categories.

¹⁹ One way to identify many of these interest groups is to check whether regulatory bodies have advisory groups/structures which often entail the most important interest groups.



Sector specific ombudsman or arbitration commission/body

Code: 8

Please include bodies which play an important role dealing with citizen complaints. They must take independent decisions. Therefore, this category includes sector specific ombudsman and private arbitration bodies.

Description of categories for Data Protection

| Categories (code) | Description |
|---|---|
| <p>Sector Specific Legislative bodies</p> <p>Code: 1</p> | <p>By legislative bodies we refer to bodies where legislation and regulation is developed. Please list: (1) (the) relevant permanent parliamentary committee(s) on data protection (if any) (unless a crisis in one of our delineated subsectors led to the creation of a temporary committee). Please also list the permanent parliamentary committees on public health and on telecommunications (2) The members in these commissions and their political parties.</p> <p>How ?</p> <ol style="list-style-type: none"> 1. When the parliament or the committee has an institutionalized body helping it with advice and reports. 2. When the data protection legislation or regulations establish such a body. They can submit to the Constitution, Law and Justice Committee and the Minister of Justice reports and recommendations. <p>If applicable, please consider the Upper house and Lower chamber - specifically, for federal and quasi-federal.</p> |
| <p>Sector Specific Judiciary branch/ appellate courts</p> <p>Code: 2</p> | <p>The judicial actors are (1) part of the judicial branch and (2) have formal power to sanction non-compliance and regulation breaches. In particular we refer here to the actors who organize hearings to data protection, actors who decide on penalties and sanctions and bodies where appeal can be filed against a decision by the regulating authority. Please note that the courts are usually the same for all the sectors (unless some specialized courts). The relevant courts on data protection can be found in the decisions, in particular check what are the courts that deal with data protection issues both at national and regional levels. Please include courts in the mapping, but do not collect email addresses.</p> |
| <p>Regulatory agencies</p> <p>Code: 3</p> | <p>We refer here to the actors which control, support and enforce compliance with data protection. There might be several regulators for data protection, or just one regulator.</p> |
| <p>Regulatory Intermediaries</p> <p>Code: 4</p> | <p>Intermediaries are actors that operate in between the regulatees and the regulators. They perform tasks like licensing, accreditation and certification. Please list organisations that perform provide certifications or accreditation (or labelling). This kind of intermediary, are usually private but also select certifications are sometimes provided within the ministerial offices.</p> |



For example, please list the accreditation bodies in the data protection sector (if any). Based on the accreditation, please list the certification bodies who have been accredited. Another way is, once you identify the regulatees, to check whether the regulatees have been certified or comply with some label/certifications.

Executive bodies

Code: 5

Please list ministries, departments, directorate-generals, or governmental actors that are involved in policy development and support. These actors are in charge of general policy issues as well as oversight functions for data protection. Thus, please select ministries, departments and/or directorate and regulatory agencies in the telecom and health sectors.

If applicable, please also list advisory or scientific bodies that are included in policy development and supporting executive bodies in policy implementation.

Regulatees

Code: 6

Regarding public regulatees for health data we refer to: registered or licensed general hospitals (check the list of accredited or licensed companies provided by the ministries of health).

Regarding electronic communication of personal data, we refer to: registered internet providers and, if relevant, holders of general-purposed licenses (as they can also provide internet services) (check the lists of accredited companies usually provided by the ministry of telecommunication).

Interest organisations representing regulatees

Code: 7

Hospitals' associations/interest groups, association/interest groups of insurance companies or interest groups of physicians and dentists. Please check the most relevant ones in the most recent policy debates (for instance in response to policy proposals in front of legislative or executive bodies).

For electronic communication of personal data, we refer to: association of internet providers (and/or hosting companies), information and communication technology (ICT) associations and ICT umbrella organisations (representing IT companies). Please check the most relevant ones in the most recent debates.

Sector specific ombudsman or arbitration commission/body

Code: 8

Please include bodies which play an important role dealing with citizen complaints. They must take independent decisions. Therefore, this category includes sector specific ombudsman and private arbitration bodies.



2 Mapping the Swiss Regulatory Regimes

2.1 The Swiss Data Protection Regime

The structure for data protection in Switzerland is relatively old, as the initial attempts to introduce a legislation for data protection were made in the 1970s' and a Federal Act on Data Protection (FADP) came into force in 1993²⁰. According to the federal data protection commissioner, the main purposes of the FADP are “to protect the privacy, interests and fundamental rights of data subjects”, the maintenance of good data file practice and to provide a comparable level of data protection to facilitate international data exchange²¹. It must also be noted that FADP regulates the activities of the federal administration and the private sector while the activities of cantonal administrations are regulated by the federal law, “unless there are cantonal data protection regulations that ensure an adequate level of protection” (FADP art.37). Although the FADP has gone through a first revision in the 2006²², a further revision of this law has been one of the major debates over the last ten years. In fact, in view of the GDPR but also other EU regulations²³, the federal act on data protection has been subjected to a complete revision. The revised law will come into force from 2022. The goal of this revision is to incorporate the major elements of the GDPR and to catch up with the proliferation of digital technology to set a level of data protection which is comparable to the EU countries.

In the revised version of the Data Protection Act, some major changes emerge. For example, the commissioner does not have sanctioning powers, which remain under the responsibility of courts (both federal and cantonal). However, some of the commissioner's powers have been strengthened (e.g. opening new investigations against federal offices)²⁴. Another major change is that the revised law on data protection foresees a new actor called “data protection officer” within each organisation, both private and public. However, it is still on a voluntary basis.

In conclusion, a further key law is the Swiss Federal Act on the Principle of Freedom of Information in Public Administration²⁵. This act aims at seeking to enhance transparency of the administration.

The regime of data protection in Switzerland is not centralized like the financial sector. The regime is multilevel – regulation is divided between the Cantons, the Federal level and the Organisational level via self-regulatory duties. Horizontal fragmentation is also considerable but not as much as in the food safety sector. In general, the main challenges of this sector in Switzerland are to deal with a very large number of regulatees (a challenge that is not necessarily specific to Switzerland) and to coordinate between three levels of governance: national, cantonal and local.

Legislative bodies for Data Protection

In Switzerland we can identify two relevant legislative bodies of the bicameral legislature (with equal power) discussing data protection legislations at the national level: the National Council and the Council of States, the latter representing the cantons. At the national level there are also two specialized committees dealing

²⁰ <https://www.edoeb.admin.ch/edoeb/en/home/the-fdpic/legal-framework/background.html>

²¹ <https://www.edoeb.admin.ch/edoeb/en/home/the-fdpic/legal-framework/ii--a-few-facts-about-the-federal-act-on-data-protection.html>

²² Ibidem

²³ <https://www.bj.admin.ch/bj/fr/home/staat/gesetzgebung/datenschutzstaerkung.html>

²⁴ <https://smetille.ch/2020/09/25/revision-totale-de-la-loi-federale-sur-la-protection-des-donnees-enfin/>

²⁵ <https://www.admin.ch/opc/en/classified-compilation/20022540/index.html>



with data protection: [the political institutions committees](#) at the national council and at the council of states. Cantonal parliaments are also in charge of discussing cantonal legislations on data protection.

Courts and Data Protection

There are no specific or specialized courts for data protection in Switzerland. However, we can identify two main judicial authorities: the [federal supreme court](#) and the [federal administrative court](#). In particular, the federal administrative court “acts as an appeal body in relation to decisions of Federal authorities with regard to data protection as well as in relation to cantonal judgments based on Federal public law on data protection”²⁶. The [division I of the Federal Administrative Court](#) is the division in charge of handling cases relating to data protection and is composed by twelve judges. The [first division on public law of the Federal Supreme Court](#) deals with appeals on cases on data protection. It must also be reminded that data protection is also regulated at the cantonal level. Therefore, cantonal courts can also deal with law disputes on data protection at the cantonal level.

Regulatory agencies

There are mainly two regulatory levels on data protection, the federal and the cantonal level. At the national level, it is the [Federal Data Protection and Information Commissioner \(FDPIC\)](#). The FDPIC, which has been appointed in 1993, has the role to supervise and to enforce data protection regulations in two main areas: the federal administration and the private sector.

The second important actors are the [cantonal commissioners](#), which are in charge of supervising cantonal public bodies and to enforce cantonal regulations.

Cantonal and federal regulators’ cooperation takes place within a network called [Privatim](#). This network has the goal to gather together all these actors to strengthen exchanges of information and to enhance coordination. Finally, [local commissioners](#) are sometimes established in some large municipalities like Bern and Zurich. Although we haven’t included them in our mapping, these local commissioners are usually in charge of supervising local public administrations (here the full list: <https://www.privatim.ch/de/privatim/>).

Regulatory intermediaries (certification bodies)

There are very few certification bodies on data protection in Switzerland. One possible reason is that data protection is a relatively emerging field. However, data protection certification is regulated by the Ordinance on Data Protection Certification²⁷, in force since 2008. The FDPIC is in charge of providing the authorization to operate as a certification body. It is plausible to expect that in the upcoming years, new private certification bodies will enter the market to provide certifications complying with the revised law that will be in force from 2022. However, we could already identify two bodies. The [Swiss Association for Quality and Management System \(SQS\)](#) is the main private body in charge of certification of data protection management systems. In addition, the [Swiss DRG](#) is a certification body providing standards on transparency for all health services providers.

Executive bodies

It is difficult to identify an executive body in charge of setting guidelines and taking part in policy development. However, it must be mentioned that the Federal Council has appointed in 2011 the Federal

²⁶ <https://www.edoeb.admin.ch/edoeb/en/home/the-fdpic/legal-framework/ii--a-few-facts-about-the-federal-act-on-data-protection.html>

²⁷ <https://www.admin.ch/opc/en/classified-compilation/20071826/index.html>



Department of Justice and Police (FDJP) to explore the possibility to strengthen the data protection act. In addition, the Federal Office of Justice (OFJ) established an expert group and drafted a first report about the potential additional measures to improve the current legislation on data protection. Afterwards, based on this report, the FDJP prepared the draft of the revision.²⁸

As to the subsectors, none of the two main federal offices, the [Federal Office of Public Health](#) and [Federal Office for telecommunication](#) are directly in charge to promote data protection.

Regulatees

One peculiarity of this “sector” is that, besides the national and the cantonal regulators, all public and private organisations can be considered as “regulatees” However, the regulatees we have selected (same for all countries) have been limited to hospitals and internet providers. In Switzerland there are around 100 general hospitals²⁹ and around 150 registered internet providers³⁰ (note that internet providers do not have the obligation to register at the federal office of communication).

Interest organisations

Although interest organisations are numerous in Switzerland, interest organisations which are specific on data protection are very few. The organisations that are directly involved in consumers’ data protections are the three main consumers associations in Switzerland ([FRC](#), [Kf](#) and [ACSI](#)). All other interest organisations that we identified are professional or business organisations in both the health and telecommunication sectors. As to the health sector, the large majority of interest organisations are professional organisations, like associations of physicians, insurers’ associations and also patient associations. As to the telecommunication sector, organisations are more “business oriented”. For example, one of the main interest groups on new technology is ICT Switzerland, which is an umbrella organisation defending the interests of new technology companies.

Private arbitration bodies

For data protection and only for the private sector, the FDPIC acts as an ombudsman³¹. According to the art. 29 of the FADP, “If a recommendation made by the Commissioner is not complied with or is rejected, he may refer the matter to the Federal Administrative Court for a decision. He has the right to appeal against this decision”.

No other arbitration bodies could be identified for this sector at the national level. However, some ombudsman or mediation offices are established at the cantonal level. In addition, we could identify ombudsman institutions in charge of subsectors. For example, the [ombudsman for Telecom](#) and the [ombudsman of health insurances](#).

²⁸ <https://www.bj.admin.ch/bj/fr/home/staat/gesetzgebung/datenschutzstaerkung.html>

²⁹ <https://www.bfs.admin.ch/bfs/fr/home/statistiques/sante/systeme-sante/hopitaux.html>

³⁰ <https://www.bakom.admin.ch/bakom/en/homepage/telecommunication/telecommunication-services-providers/list-of-registered-telecommunication-services-providers.html>

³¹ <https://www.edoeb.admin.ch/edoeb/en/home/the-fdpic/legal-framework/ii--a-few-facts-about-the-federal-act-on-data-protection.html>



Examples of crisis, scandals

February 2018: The data of 800,000 customers, including their name, date of birth and cell phone number, was stolen from one of the operator's partners.³²

February 2020: a report on SRF's Rundschau program made public the fact that Omnicore AG, a major Swiss manufacturer of encryption systems, was also controlled or compromised by the American and German secret services. Crypto AG's cryptography products contained hidden vulnerabilities that were used by U.S. and German intelligence services to spy on other countries between the 1970s and 1990s.³³

March 2018: A database, named "collection 1-5" on the Internet provides access to hacked passwords to more than three million Swiss electronic accounts. The RTS found federal councilors, state councillors and thousands of federal employees. At the national level, the extent of the loophole is illustrated by the presence of more than 2,500 emails from the federal administration. Cantonal administration were also affected, as well as the police and other state actors.³⁴

2.2 The Swiss Financial Regime

Switzerland is well known to be one of the main financial hubs in the world and a country where there are around 250 licensed banks and financial assets companies. The financial sector in Switzerland is regulated at the national level through two key actors, the Swiss Financial Market Supervisory Authority (FINMA) and the Swiss National Bank (SNB). Overall, mechanisms of control are very much centralized.

Compared to the other sectors, the number of relevant actors (which are not regulatees) involved in the regime is relatively low. The main reason is probably the high centralization of this sector. However, as for the subsectors our study covers, in Switzerland there is a very high heterogeneity of banks where 24 are cantonal banks, 60 are regional, 72 foreign-controlled banks, 24 are Swiss branches of foreign banks and 2 are global systemically relevant banks. This heterogeneity is one of the main challenges the regulators have to deal with³⁵.

The financial sector in Switzerland is regulated by numerous laws. In particular, two key laws have recently been adopted. Financial service providers and financial institutions in Switzerland are regulated by the Federal Act on Financial Services³⁶ and the Federal Act on Financial Institutions³⁷. These two laws, which are in force since January 2020, have brought several changes. For example, independent portfolio managers become also subject to supervision by FINMA and affiliation to an Ombudsman's office has become compulsory³⁸. Two others laws are key: the Federal Act on Financial Market Infrastructures³⁹ which sets the legal basis for market infrastructures⁴⁰ and the Anti-Money Laundering Act⁴¹. As for the subsectors that our

³² <https://www.letemps.ch/economie/vol-donnees-800000-clients-swisscom-nest-anodin>

³³ <https://www.letemps.ch/economie/scandale-crypto-ag-une-tache-limage-suisse>

³⁴ https://www.swissinfo.ch/fre/cyber-s%C3%A9curit%C3%A9_toute-la-suisse-politique-touch%C3%A9e-par-un-vol-de-donn%C3%A9es/44805320

³⁵ <https://www.lexology.com/library/detail.aspx?g=400e075a-f8af-42d1-9549-50c9db6e6866>

³⁶ <https://www.admin.ch/opc/en/classified-compilation/20152661/index.html>

³⁷ <https://www.admin.ch/opc/en/classified-compilation/20152662/index.html>

³⁸ <https://www.finma.ch/en/authorisation/fidleg-und-finig/>

³⁹ <https://www.admin.ch/opc/en/classified-compilation/20141779/index.html>

⁴⁰ <https://www.finma.ch/en/authorisation/financial-market-infrastructures-and-foreign-market-participants/swiss-financial-market-infrastructures/>

⁴¹ <https://www.admin.ch/opc/en/classified-compilation/19970427/index.html>



project covers, banks and securities firms are regulated by the Banking Act and savings banks⁴² which is in force since 1934. Regarding Fintech companies, to operate they need to be licensed by the national regulator (FINMA). Cantonal laws also regulate the operation of cantonal banks.

Legislative bodies

In Switzerland we can identify two relevant legislative bodies of the bicameral legislature (with equal power) discussing financial legislations at the national level: the National Council and the Council of States, the latter representing the cantons. At the national level there are also two special committees on financial regulation: [the economic affairs and taxation committees](#) at the National Council and the Council of States. With respect to the subsectors, cantonal parliaments adopt legislations about cantonal banks.

Judiciary branch (courts)

In Switzerland there are no specialized courts on financial regulation. The Federal Administrative Court and the Federal Supreme Court deal with cases in this sector. In addition, these courts, for example, have the final say on appeals against FINMA rulings⁴³⁴⁴.

However, there is a division within the federal administrative court which is specialized in financial matters, the [division 2, section 6](#). This section handles cases on venture capital companies, national bank, supervision of financial institutions, money laundering, supervision of private insurances, administrative assistance and audit oversight. The [second division on public law of the Federal Supreme Court](#) deal with appeals on bank supervision, insurances and stock exchanges. Cantonal courts could also deal with cases pertaining to the financial sector.

Regulatory agencies

In Switzerland there are two main regulators in the financial sector. The first is the [Swiss Financial Supervisory Authority \(FINMA\)](#) and the second is the [Swiss National Bank \(SNB\)](#). FINMA is a relatively recent independent body which has been established in 2009 as a public law institution in its own right⁴⁵ employing more than 500 staff members⁴⁶ following a reform of the Swiss Federal Banking Commission. The Federal Act on the Swiss Financial Market Supervisory Authority⁴⁷ sets the main powers and instruments that FINMA has at its disposal. One of the main tasks of FINMA is to supervise principally activities of banks, fund management companies and other institutions such as collective investment schemes and insurance companies. In addition, FINMA also issues numerous licenses to engage in the financial market, and ensure compliance with the law through enforcement proceedings.

The second regulator is the Swiss National Bank (SNB)⁴⁸. The SNB is an independent body conducting the Swiss monetary policy and ensuring price stability. The statutory basis for the SNB is set out in the National Bank Act (NBA), determining its tasks, competences and its formal independence⁴⁹.

⁴² <https://www.admin.ch/opc/fr/classified-compilation/19340083/index.html>

⁴³ <https://www.finma.ch/en/finma/activities/enforcement/>

⁴⁴ <https://www.finma.ch/en/enforcement/case-reports-and-court-decisions/gerichtssentscheide/>

⁴⁵ <https://www.finma.ch/en/finma/finma-an-overview/>

⁴⁶ <https://www.finma.ch/en/finma/organisation/>

⁴⁷ <https://www.admin.ch/opc/en/classified-compilation/20052624/index.html>

⁴⁸ <https://www.snb.ch/en/i/about/snb>

⁴⁹ <https://www.admin.ch/opc/en/classified-compilation/20021117/index.html>



Regulatory intermediaries (certification bodies)

Regulatory intermediaries are not numerous in the financial sector. Beside the authorized rating agencies, we were able to identify two certification bodies, which certify both companies and private individuals operating in this sector: [Swiss Association for Quality](#) and [FEDAFIN](#). It must also be mentioned that FINMA, the national regulator, also provides numerous certifications, operating also as a certification body. Self-regulation has also a long tradition in the Swiss financial sector⁵⁰. FINMA and Banks elaborate together binding codes of conduct defining good industry practices⁵¹.

Executive bodies

Powers and competences are very much centralized at the FINMA. However, we are able to identify only one executive body for this sector, which is the [State Secretariat for International Finance \(SIF\)](#). The SIF is responsible for representing the Swiss interests in financial in the international institutions in this field and to implement the financial market policy of the federal council⁵².

Regulatees

Traditionally, in Switzerland banks are numerous. According to the FINMA's list, there are more than 300 licensed banks in Switzerland, a list which also includes securities companies⁵³ and more than 300 fund management companies⁵⁴. Surprisingly, only one company holds a FinTech license⁵⁵.

Interest organisations

The number of interest organisations is not as high as in the food safety sector. The large majority of interest organisations are professional organisations, defending the interests of bankers and staff members, as the [Swiss Bankers Associations](#), or market oriented organisations such as the [Swiss Union of Cantonal Banks](#)

Private arbitration bodies

We could identify only a few private arbitration bodies for the financial sector. The Swiss branch of the International Chamber of Commerce ([ICC Switzerland](#)) and the [Swiss Chambers' arbitration institution](#), [which](#) plays an important role as it provides dispute resolution services⁵⁶.

Example of scandals and crisis

1960: *Chiasso's scandale*: In the 60's Ernst Kuhrmeier, Deputy Director of the Ticino branch of Credit Suisse, will use customer money through "a bank within a bank". In April 1961, he founded Texon in Liechtenstein to conduct its off-balance sheet business. With the help of other Chiasso employees, he attracted a predominantly Italian clientele. The first setbacks occurred in the mid-1970s when a loan could not be repaid.⁵⁷

⁵⁰ <https://www.swissbanking.org/en/topics/regulation/self-regulation>

⁵¹ Ibidem

⁵² <https://www.sif.admin.ch/sif/en/home/das-sif/auftrag.html>

⁵³ <https://www.finma.ch/en/finma-public/bewilligte-institute-personen-und-produkte/>

⁵⁴ <https://www.finma.ch/en/finma-public/bewilligte-institute-personen-und-produkte/>

⁵⁵ Ibidem

⁵⁶ <https://www.swissarbitration.org/Arbitration/Introduction>

⁵⁷ <https://www.letemps.ch/economie/grandes-affaires-economiques-suisse-26-scandale-chiasso-lhistoire-dune-banque-banque>



1967-1985: *Plumey case*: Between 1976 and 1985, APFSA, headed by André Plumey, attracted investors for a total amount of about 200 million francs. More than 1,200 savers entrusted their money to the company, which promised returns of between 20 and 30% through investments in oil, real estate and gold mines in the United States. The investments were much less profitable, and André Plumey uses the money from new investors to pay the interest of the older ones. Some 58 million francs will be lost.⁵⁸

1990: *Behring case*: During the nineties Dieter Behring, promised huge gains on investments. He developed a brokerage system that turned out to be a scam. He made more than 800 million francs disappear, eating up 2000 investors. According to the investigators, the case involves several hundred million francs and goes beyond the borders of Switzerland.⁵⁹

2000-2007: *HSBC Swissleaks*: In the beginning of the millennium, the Swiss branch of HSBC helped its clients to practice tax evasion on a large scale. Today, HSBC's Swiss operations have been drastically reduced: there are almost 70% fewer bank accounts, down to around 10,000.⁶⁰

2010: *The money of the African dictators*: While the monetary secret is still standing for non-OECD countries. In 2010, Switzerland passed a law (LRAI) "federal law on the restitution of assets of illicit origin of politically exposed persons" which makes it possible for the Swiss government to hand over blocked illicit funds to the spoliated populations, even if mutual legal assistance with the State concerned cannot succeed, which has not been possible until now. Nearly 1,7 Billion \$ have been restituted during the first decade of the millennium.⁶¹

2020: *Crédit Suisse Spying on ex-associate*: Since September, Credit Suisse has been shaken by revelations concerning the supervision of its former head of international asset management, Iqbal Khan, after his unexpected departure to join rival bank UBS. The objective was to protect the bank's interests by ensuring that Mr. Khan did not try to convince members of his team to join him at a competitor's bank. This scandal eventually led to the departure of Mr. Thiam, the former head of Credit Suisse.⁶²

2.3 The Swiss Food Safety Regime

The food safety sector in Switzerland is very fragmented and thus very complex. Regulatory competences are spread over the cantonal and national levels. The cantonal level is mainly responsible for enforcing both cantonal and national regulations whereas the national sector is mainly responsible for setting the legal framework and developing policy tools. In some cases, the national level is also in charge of coordinating controls (which take place at the cantonal level) and supervision.

However, compared to the other two sectors, the food safety regime in Switzerland comprises a very large number of sector-specific actors. In particular we identified around 10 key certification bodies (intermediaries), 15 key interest organisations and 3 regulatory bodies.

⁵⁸ <https://www.letemps.ch/economie/grandes-affaires-economiques-suisse-36-andre-plumey-622-clients-leses-58-millions-dollars>

⁵⁹ <https://www.letemps.ch/economie/dieter-behring-grand-fabulateur-balois>

⁶⁰ <https://www.letemps.ch/economie/hsbc-honte-scandale-swissleaks>

⁶¹ <https://www.rts.ch/info/suisse/2906645-la-suisse-et-largent-des-dictatures.html>

⁶² <https://www.voaafrique.com/a/le-patron-de-credit-suisse-empourt%C3%A9-par-un-scandale-d-espionnage/5278322.html>



A new national plan has been released on January 2020 by the Federal Office for Agriculture (FOAG) and the Federal Food Safety and Veterinary Office (FSVO) (), which determines the competences and responsibilities of each actor, both at national and cantonal levels. According to this plan⁶³ the objectives are the following:

To be sure that food products comply with national and cantonal the legislations

To strengthen collaboration and coordination between different actors

To create the best conditions to ensure a competitive market

To prevent food crisis and to be able to face them

The plan of national control describes the main structure, objectives and the division of competences of the food safety regime in Switzerland⁶⁴. In addition, the food safety control system in Switzerland aims to align with the European principles 'from farm to fork' by covering each step of food's chain of production. This premise is part of bilateral agreements with the EU which have been necessary to ensure fair import and exports within the European countries⁶⁵.

The food safety regime in Switzerland is clearly separated between Food Safety on one hand and Agriculture on the other hand. The food safety sector is principally regulated by the Federal Act on Foodstuffs and Utility Articles⁶⁶ and the agriculture sector is regulated by The Federal Act on Agriculture⁶⁷. These two sectors, which could clearly overlap, require great cooperation between the [Federal Food Safety and Veterinary Office \(FSVO\)](#) and the [Federal Office for Agriculture \(FOAG\) and coordination across cantons](#). Other competences are also assumed across the 26 cantons. Federal offices usually ensure harmonization and coordinate the implementation of federal laws by cantons along the feed and food chain. In fact, cantonal offices agricultural, veterinary and food control units are in charge of the laws' implementation and enforcement at cantonal level.

Legislative bodies

Both the cantonal and the national parliaments discuss the legislations regarding food safety. The federal parliamentary commission in charge of discussing food safety legislations is the Science, education and culture committee in each Chamber of the national parliament. Legislations can also be handled at cantonal level within each cantonal parliament and within cantonal parliamentary commissions (if any).

Judiciary branch (courts)

Like the other two sectors, there are no specialized courts on food safety regulation. However, a specialized division of the Federal Administrative Court deals with cases pertaining food safety cases: the [second division of the federal administrative court, section 4. The second division on public law of the Federal Supreme Court](#) deal with appeals pertaining food safety cases (including agriculture).

Cantonal courts may deal with food safety lawsuits.

⁶³ <https://www.blv.admin.ch/blv/fr/home/das-blv/organisation/blk/nationaler-kontrollplan.html>

⁶⁴ <https://www.blv.admin.ch/blv/fr/home/das-blv/organisation/blk/nationaler-kontrollplan.html>

⁶⁵ Ibidem

⁶⁶ <https://www.admin.ch/opc/en/classified-compilation/20101912/index.html>

⁶⁷ <https://www.admin.ch/opc/en/classified-compilation/19983407/index.html>



Regulatory agencies

Regulatory competences are spread over the national and the cantonal levels. According to our subsectors we identified three key actors holding regulatory tasks: one regulator at national level and two regulators at the cantonal level.

The first one is the [Federal Food Chain Unit \(FFCU\)](#), which operates under the supervision of FOAG and FSVO. The FFCU is in charge of supervising the implementation of legislations at cantonal level. Another duty is to supervise the inspections on animal feeds, animal imports and animal production at federal level.

The second regulators are the cantonal veterinary services, usually one per each canton. The cantonal veterinary services are in charge of enforcing national food safety legislations.

The third regulator which can be identified are local enforcement authorities for food and utility articles which operate under the control of the cantonal chemists.

Similarly to the agriculture sector, in some cases the cantonal agriculture offices hold also regulatory tasks such as enforcement of the relevant laws (see annex C “Swiss Veterinary Service” at this link <https://www.blv.admin.ch/blv/fr/home/das-blv/organisation/blk/nationaler-kontrollplan.html>)

Regulatory intermediaries (certification bodies)

Certification bodies are numerous in Switzerland and operate at national level and cantonal levels, around 70⁶⁸. The certification bodies in this sector mainly certify BIO products or provide different types of labels, for example promoting sustainable development products. It is also interesting to note that very few of them, around 7, are themselves certified by the [Swiss Accreditation Service \(SAS\)](#), a public body operating on behalf of the federal administration.

Executive bodies

In Switzerland, at the national level, there are four key actors that we consider “executive bodies” in the food safety sector. These actors have as major roles policy developments and guidelines settings related to food safety.

The first is the Federal Office for Agriculture (FOAG), which is the centre for competence on agriculture. The FOAG has under its responsibility the [Agroscope](#), a key research institute in Switzerland. The main tasks of FOAG are: the implementation of regulations on plants, the authorization of phytosanitary products, the registration of new varieties of plants and the supervision of hygiene controls of primary production.

The second executive body is the Federal Food Safety and Veterinary Office (FSVO). The FSVO is principally responsible to identify health risks related to food stuffs and to detect new risks. It also develops strategies to improve healthy diets and elaborates scientific standards within its laboratories.

The third executive body, although less relevant to this project, is the Military Veterinary Service. This office, which operates under the responsibility of the FOAG and FSVO, implement and enforces the food safety regulations within the army.

At the cantonal level, both the veterinary cantonal offices and the cantonal agriculture offices are in charge of policy development and developing cantonal strategies.

⁶⁸ <https://www.labelinfo.ch/fr/labels?&group=36>



Regulatees

Regulatees in the food safety sector are all those who act in the chain 'from farm to fork', such as any kind of business manufacturing foodstuffs⁶⁹, poultry establishments, centers for trade animals, animals transporters, etc., Food producers are very numerous in Switzerland. There are currently 3'975 authorized businesses manufacturing foodstuffs⁷⁰. Cantonal authorities issue licenses to operate in accordance with the Swiss law⁷¹.

Interest organisations

In the food safety sector, we selected 16 relevant organisations, which most of them represent the interest of farmer and food producers (e.g. meat, milk, fruit and vegetables, eggs..) However, the number of organisations is certainly higher, especially if we look also at the interest organisations at the cantonal levels. The main interest organisations in Switzerland are operating at the national level, but usually have regional offices as well. This is the case of the Swiss Farmer's union⁷², the main farmers' association in Switzerland.

Private arbitration bodies

In Switzerland, there are no private arbitration bodies on food safety regulation. Lawsuits takes place in the regular venues, namely in the cantonal and federal courts

Examples of scandals and crisis

1980: *Nestlé tötet babies*. The groupe Public Eye, ancently named declaration de Berne led an action toward Nestlé: abusive advertising and the massive presence of powdered milks in hospitals were denounced as dangerous attacks on breastfeeding and children's health. While the perpetrators were sued and sentenced to a symbolic fine of 300 Frs, the scandal triggered an international boycott of Nestlé products. The ground was then favorable for the adoption by the WHO, in 1981, of a code on the marketing of infant food.⁷³

2013: *Horse gate*. Switzerland was also affected by the horse meat in lasagna scandal. Indeed some brand of Nestlé were caught declaring horse meat as beef: Buitoni's raviolis contained traces of horse meat as well as in French and Spanish lasagna. In Switzerland Hilcona product have been found containing horsemeat and have been withdrawn by the big distributors. In 2014 The Federal Office of Food Safety and Veterinary Affairs (FOSV) publishes the results of a national campaign of analyses carried out by the cantonal chemists. Of the 50 samples analyzed and labeled as containing beef, no traces of horse meat were detected.⁷⁴

2014: Carna Grischa, the fifth bigger Swiss meat producer, declared horse meat as beef, Hungarian chicken as Swiss chicken and frozen meat as fresh meat.⁷⁵

⁶⁹ <https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/listen-bewilligter-betriebe.html>

⁷⁰ <https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/listen-bewilligter-betriebe.html>

⁷¹ https://www.blv.admin.ch/blv/en/home/import-und-export/rechts-und-vollzugsgrundlagen/listen_bewilligter_betriebe.html

⁷² <https://www.sbv-usp.ch/en/>

⁷³ <https://www.publiceye.ch/fr/news/detail/le-lait-en-poudre-enfreint-le-code>

⁷⁴ <https://www.frc.ch/horsegate-une-chronologie/>

⁷⁵ <https://www.rts.ch/info/suisse/6335869-carna-grischa-sexcuse-pour-les-fausses-declarations-de-viande-et-reagit.html>



2016: Meat-and-bone meal could make a measured comeback in cattle feed. This announcement has made a big splash in the Swiss media landscape. Since the discovery of the first cases of mad cow disease, bovine spongiform encephalopathy (BSE), federal authorities have taken a long series of preventive measures. Tissues deemed to carry the prion - the BSE agent - such as the brain or spinal cord, were banned in 1990. In 2001, the Federal Council banned meat-and-bone meal for all animals and established a "BSE Unit" to monitor measures taken to control the disease, which is suspected of transmitting the new variant of Creutzfeldt-Jakob disease to humans. To date, Switzerland has reported 452 cases of BSE in its cattle. ⁷⁶

2020: Ethylene Oxide was found in Sesame Seeds from India, which led to the withdrawal of most of the sesame containing products in Switzerland ⁷⁷

⁷⁶ <https://www.letemps.ch/suisse/berne-envisage-dassouplir-linterdiction-farines-animales-lalimentation-betail>

⁷⁷ <https://www.blv.admin.ch/blv/fr/home/lebensmittel-und-ernaehrung/rueckrufe-und-oeffentliche-warnungen.html>



3 Mapping the Dutch Regulatory Regimes

3.1 The Dutch Data Protection Regime

Data protection in the Netherlands is ruled by the *Algemene Verordening Gegevensbescherming* (i.e. the GDPR).⁷⁸ However, some aspects of data protection are left to the discretion of the member states of the European Union. The additional provisions of the Netherlands are laid down in the *Uitvoeringswet Algemene Verordening Gegevensbescherming* (UAVG). The Dutch Data Protection Authority (AP) is the main actor in the accountability regime of the Netherlands who supervises the implementation of the (U)AVG. All processing of personal data is supervised by the AP, except for the processing of personal data by judicial bodies. Much of the actual work is done by Data Protection Officers (DPOs) who internally supervise all public bodies, government agencies and organisations that are mainly tasked with processing ‘special categories’ of personal data and/or process personal data on a large scale. They are often just employees who have an extra task of being a ‘thorn in the side’ with regard to data protection issues.

Health data is one of the ‘special categories’ in the UAVG and it is therefore in principle forbidden to process this kind of data.⁷⁹ There are five exceptions to this rule which, broadly speaking, allow organisations to process health data if it is really necessary. For example, schools are allowed if it is necessary for the special assistance of students. Furthermore, all organisations that are mainly tasked with processing health data are required to have a DPO.

Legislative bodies

The Permanent Committee for Justice and Security (House of Representatives) deals with all subjects that are under the responsibility of the minister of the Ministry of Justice and Security.

The Permanent Committee Health, Welfare and Sport (House of Representatives) deals with all subjects that are under the responsibility of the minister of the Ministry of Justice and Security.

The Temporary Committee Digital Future (House of Representatives) was initiated by the Lower House to gain insight in the developments in digitalization.

The Permanent Committee for Justice and Security (Senate) deals with all bills concerning justice and security.

The Permanent Committee for Health, Welfare and Sport (Senate) deals with all bills concerning health, welfare and sport.

Judiciary branch/Appellate courts

Complaints against decision from the Dutch Data Protection Authority can be filed with the Dutch courts in the sector administrative law.

Regulatory agencies

The Dutch Data Protection Agency (AP) is the main regulatory body in the Netherlands for data protection matters. The AP also accredits certification bodies, investigates violations, fining violators, and advising governmental legislation.

⁷⁸ <https://autoriteitpersoonsgegevens.nl/nl/over-privacy/wetten/algemene-verordening-gegevensbescherming-avg>

⁷⁹ <https://autoriteitpersoonsgegevens.nl/nl/onderwerpen/gezondheid>



Regulatory intermediaries

The RvA (*Raad voor Accreditatie*) is tasked with accrediting certification bodies that can deliver GDPR-certificates for products and services. However, there are no certification bodies yet in the Netherlands.

Executive bodies

The site of the Dutch government mentions three ministries as being responsible for ‘privacy and personal data’: The Ministry of Interior and Kingdom Relations, The Ministry of Justice and Security and the Ministry of Health, Welfare and Sport.

The current cabinet also has a Minister for Legal Protection (Sander Dekker) who is responsible for, among other things, data protection.

The Governmental Agency for Personal Data is the executive body in the area of personal data and travel documents. The RvIG is part of the Ministry of the Interior and Kingdom Relations.

The CIBG is tasked with, among others, registering of data. The CIBG is part of the Ministry of Health, Welfare and Sport.

The Radiocommunications agency allocates frequency space and monitors its use.

Interest organisations

The Dutch Association of Hospitals is the branch association for general and specialist hospitals in the Netherlands.

Zorgverzekeraars Nederlands (ZN) is the umbrella organisation of ten health insurers in The Netherlands.

They are: a.s.r., CZ, Eno, DSW, IptiQ, ONVZ, Menzis, VGZ, Zilveren Kruis, en Zorg en Zekerheid.

COIN is the association of Dutch providers of electronic communications networks and services.

Sector specific ombudsman or arbitration commission/body

Complaints against the AP can be filed with the National Ombudsman.

Debates, crises, reforms and trust issues

Privacy and data protection have become hot topics in recent years. Once every few weeks a privacy-related issue pops up in the news that is often short-lived. One of the latest debates concerned the ‘covid-19’-app.⁸⁰ The app tracks people and can help the public services workers who conduct contact research for those who are tested positive. The people who have been in close contact with the person who tested positive also receive a warning on their phone. Initially, there were many privacy concerns. The first designs were all criticized by experts for being prone to privacy issues.⁸¹ Even the app that was eventually adopted by the Dutch government (*CoronaMelder*) insufficiently safeguards the privacy of its users, according to the Dutch Data Protection Agency.⁸² Nonetheless, as of October 29 – only three weeks after the app was launched – it was downloaded 3.7 million times on a population of 17 million.⁸³ So, citizens do not seem to be concerned about privacy issues even though privacy and data protection are recurring themes in popular news media. Another recent concern is the AP’s clout.⁸⁴ In November 2020, the director of the AP sounded the alarm bell about the insufficient financial means and understaffing that the regulator has to deal with. According to the

⁸⁰ <https://coronamelder.nl/en/>

⁸¹ <https://www.rtlnieuws.nl/nieuws/nederland/artikel/5094711/corona-app-privacy-shortlist>

⁸² <https://autoriteitpersoonsgegevens.nl/nl/nieuws/ap-privacy-gebruikers-corona-app-nog-onvoldoende-gewaarborgd>

⁸³ <https://nos.nl/1/2354879>

⁸⁴ <https://www.nrc.nl/nieuws/2020/11/19/privacytoezichthouder-wil-verdubbeling-budget-om-taak-te-kunnen-uitvoeren-a4020694>



director, the AP will not be able to perform its statutory tasks if the budget is not doubled in the coming years. These tasks are already under pressure as there are ‘laughable backlogs’ in the regulation of algorithms processing personal data.

3.2 The Dutch Financial Regime

Figure 1.1 provides an overview (in Dutch) of the regulatory framework of the financial sector. It shows that the Netherlands Court of Audit (*Algemene Rekenkamer*) is tasked with monitoring the Ministry of Finance and the two regulatory bodies: the Nederlandsche Bank (DNB) and the Authority for the Financial Markets (AFM). The Netherlands Court of Audit also reports to the Dutch House of Representatives (*Tweede Kamer*). The Ministry of Finance has a duty to report to the House of Representatives and also supervises the two regulatory bodies. The Minister of Finance in particular is “responsible for the functioning of the financial system as a whole and for the laws and regulations for the financial markets”.⁸⁵ The supervision of the DNB by the Ministry of Finance is described as “supervision at a distance”⁸⁶ to ensure that the DNB can execute its regulatory tasks independently and confidentially.

The international, European and national regulatory framework are depicted in Figure 2.1. The main one, positioned in the left bottom corner, is the Dutch Financial Supervision Act (*Wet op het financieel toezicht, Wft*) that came into force on September 28 2006. The Wft outlines the way in which the regulation of the financial sector is organized in the Netherlands and incorporates many of the regulations of the European Union.⁸⁷

Legislative bodies

The Permanent Committee for Finance (House of Representatives) deals with all matters concerning the Ministry of Finance.

The Permanent Committee for Finance (Senate) deals with all bills relating to finance.

Judiciary branch/appellate courts

Financial business firms can appeal against AFM’s or DNB’s decision regarding previous objections with a Dutch court.

To appeal decision from Dutch courts, the businesses can go the Trade and Industry Appeals Tribunal.

Regulatory agencies

The DNB is tasked with prudential regulation which focusses on “the financial solidity of financial companies and contributes to the stability of the financial sector”.⁸⁸

The AFM is tasked with the conduct-of-business regulation which aims at “orderly and transparent market processes, integrity of relations between market parties and the proper handling of clients of financial companies”.⁸⁹

⁸⁵ <https://www.rekenkamer.nl/binaries/rekenkamer/documenten/rapporten/2017/09/27/toezicht-op-banken-in-nederland/Rapport+Toezicht+op+banken+in+Nederland+WR.pdf>, p. 9

⁸⁶ *idem*, p. 10

⁸⁷ *idem*, p. 25

⁸⁸ *idem*, p. 14

⁸⁹ *idem*, p. 15



Regulatory intermediaries

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Executive bodies

The Ministry of Finance is responsible for all matters concerning banking and securities.

Within the Ministry, there is the Directorate Financial Markets that shapes the structure of the regulation of the financial sector. This Directorate is also part of the General Treasury.

Interest organisations

The Dutch Payments Association is the branch organisation for providers of payment services in the Netherlands

The Dutch Banking Association represents the interest of the banking sector. This association is also a member of the AFM's advisory panel.

Consumentenbond is a consumer association. It is also a member of the AFM's advisory panel.

Sector specific ombudsman or arbitration commission/body

Complaints about a financial product or service can be filed with the 'Klachteninstituut Financiële Dienstverlening' (Kifid). The Kifid mediates between costumers and financial business firms which often results in a legally binding ruling from their arbitration committee.

Debates, crises, reforms and trust issues

The 2008 banking crisis obviously had a major impact on the Dutch financial sector as a whole and the regulation of the sector in particular. The crisis cost the Dutch government approximately 90€ billion in financial support and 80€ billion in guarantees.⁹⁰ One important change has been the establishment of the European Central Bank (ECB) that took over the direct supervision of the major banks. As a result, the Nederlandsche Bank (DNB) is only tasked with supervising the medium-sized and small banks in the Netherlands (ca. 30 banks). The laws and regulations on a national level also underwent considerable revisions to intensify the regulation of the financial sector.

The decade after the banking crisis saw many attempts to organize strict regulation and to increase the resilience of and trust in financial companies.⁹¹ In the last three years, the DNB and AFM were most concerned about the effects of geopolitical insecurity and Brexit in particular, digitalization, cybercrime, the BigTech entering the sector, the prolonged low interest rate and financial-economic crime such as financing terrorism or facilitating money laundering.^{92,93,94,95,96} According to a DNB employee, cryptocurrency in particular is now a main issue. The DNB recently put it under more strict supervision as cryptocurrency is often used for money laundering and the financing of terrorism. The jury is still out with regard to the regulation of FinTech. The current debate revolves around finding a proper regulation framework for this new type of service without hampering its development.

⁹⁰ idem, p. 6

⁹¹ https://www.dnb.nl/binaries/DNB%20Toezicht%20voorblik%202016_tcm46-333676.pdf

⁹² https://www.dnb.nl/binaries/Toezicht%20Vooruitblik%202018%20Web_tcm46-365944.pdf

⁹³ https://www.dnb.nl/binaries/Toezicht%20Vooruitblik%202019_tcm46-380420.pdf

⁹⁴ https://www.dnb.nl/binaries/Brochure_Toezicht_Vooruitblik_tcm46-387008.pdf

⁹⁵ <https://www.afm.nl/~/profmedia/files/afm/trendzicht/rapport-2019-nl.pdf>

⁹⁶ <https://www.afm.nl/~/profmedia/files/afm/trendzicht-2020/rapport-nl.pdf>



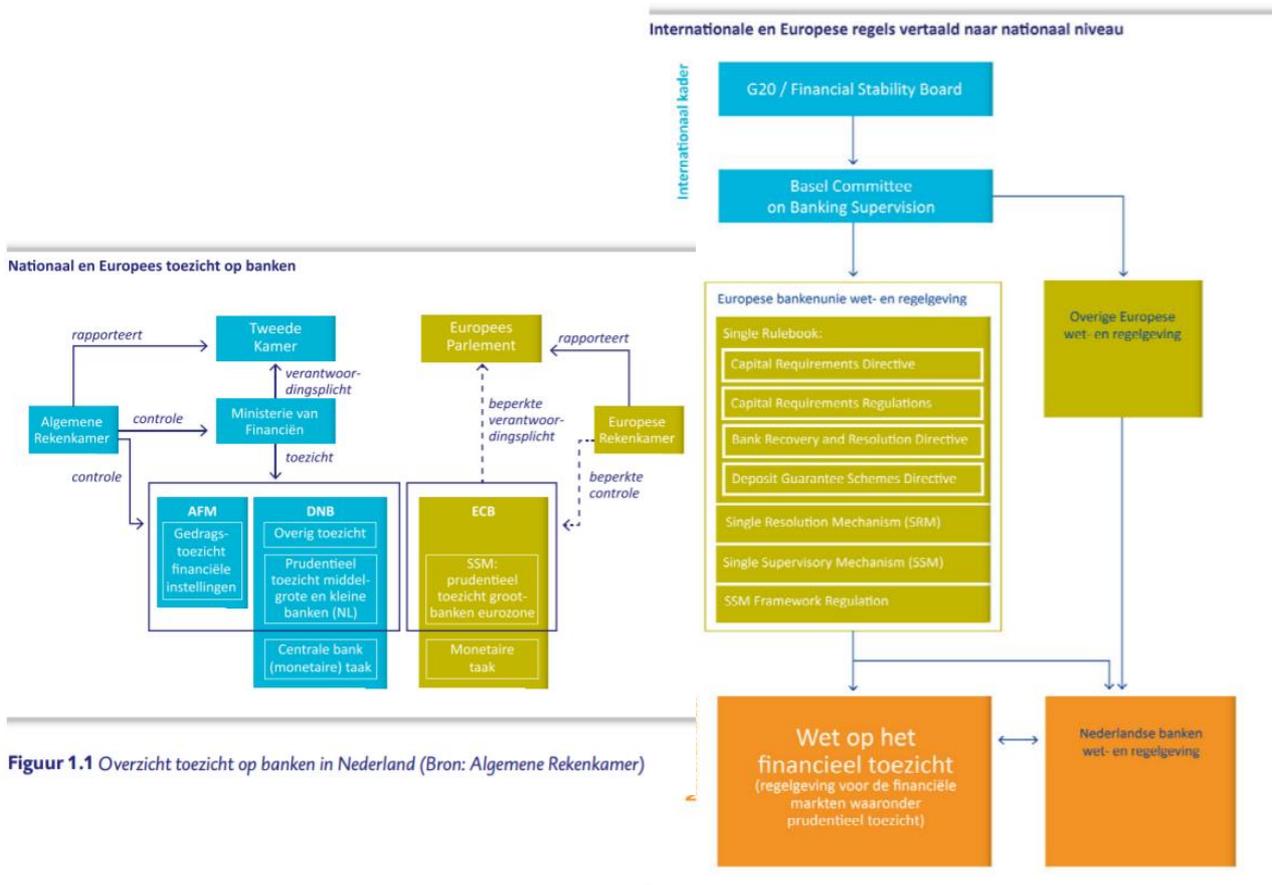


Figure 2.1 Regelgevend kader prudentieel toezicht op banken (Bron: Algemene Rekenkamer)

3.3 The Dutch Food Safety Regime

In her dissertation, Gussow⁹⁷ states that “In the Netherlands, the EU food and feed regulation is implemented through various national laws, such as the “Wet Dieren” [Animals Act, 2011] and the “Warenwet” [Commodities Act, 1935], as well as the “Landbouwkwaliteitswet” [Agricultural Products Quality Act, 1971]”. The main regulator is the Netherlands Food and Consumer Product Safety Authority (NVWA).⁹⁸ The NVWA supervises companies and checks whether they meet the legal requirements for food safety. It does so in a unique way. Unlike its European counterparts, the NVWA can enforce the laws through both an administrative law approach as well as a criminal law approach or a combination thereof.²⁰

⁹⁷ Gussow, K. E. (2020). *Finding food fraud: Explaining the detection of food fraud in the Netherlands*. Amsterdam: VU Amsterdam. (p. 59)

⁹⁸ <https://www.rijksoverheid.nl/onderwerpen/voeding/toezicht-op-voedselsector>



Regulative framework

Legislative bodies

The Permanent Committee Agriculture, Nature and Food Quality (House of Representatives) deals with all subjects that are under the responsibility of the minister of the ministry of Agriculture, Nature and Food Quality.

The Committee for Economic Affairs and Climate / Agriculture, Nature and Food Quality (Senate) deals with, among others, issues regarding food quality, animal welfare, nature and biodiversity.

The Permanent Committee Health Welfare and Sport with the policies of the Ministry of Health, Welfare and Sport.

Judiciary branch/Appellate courts

Appeals against decisions of the NVWA regarding the *Wet gewasbeschermingsmiddelen en biocide*, *Gezondheid- en Welzijnswet dieren* and *Wet Dieren* can be filed with the Rotterdam District Court and the Trade and Industry Appeals Tribunal.

Regulatory agencies

The Netherlands Food and Consumer Product Safety Authority (NVWA) registers, regulates and fines businesses in the area of food, consumer products, animal welfare and nature. Also, they can retract permits. The COKZ registers and regulates (a relatively small number of) businesses in the poultry industry.

Regulatory intermediaries

The *Raad voor Accreditatie* is tasked with accrediting and renewing the accreditations of conformity-assessment bodies: laboratories, inspection bodies, certification bodies and verification bodies. For example labelling organisations in the food sector.

Executive bodies

The Ministry of Agriculture, Nature and Food Quality is responsible for, among other things, hygiene and inspection of slaughterhouses, storage of meat, quality and safety of feed industry, production of vegetables and fruit, use of pesticides.

Within the Ministry of Agriculture, Nature and Food Quality, the Directorate General Agro is deals with, among other things, all matters concerning animal welfare and food quality.

The Ministry of Health, Welfare and Sport is responsible for, among other things, healthy food and food safety.

Within the Ministry of Health, Welfare and Sport, the National Institute for Public Health and the Environment performs a number of tasks in the field of food safety. They develop models to determine food safety, and they maintain databases of relevant information. They also work on the further development of methods for risk assessment.

Wageningen Food Safety Research provides solicited and unsolicited advice to government authorities. The largest client of Wageningen Food Safety Research is the government.

Interest organisations

The Consumentenbond is an association that voices the interests of consumers.

The Netherlands Agricultural and Horticultural Association represents over 35,000 agricultural entrepreneurs and employers.



The *Centraal Bureau Levensmiddelenhandel* is the branch organisation representing the interests of supermarkets and foodservice businesses.

The *Federatie Nederlandse Levensmiddelenindustrie* is the umbrella organisation and advocate for processing and importing businesses and branches in the Dutch food industry.

The *Algemene Nederlandse Vereniging van Eierhandelaren en Eiproductfabricanten* is the branch organisation for the wholesale of eggs and egg products in the Netherlands.

The *Nederlandse Vakbond Pluimveehouders* is the interest organisation for poultry farmers.

The *Nederlandse Pluimveeverwerkende Industrie* is the interest organisation for the poultry processing industry.

The *Nederlandse Fruittelers Organisatie* is the interest organisation for fruit growers.

The *Vereniging van de Nederlandse Groenten- en Fruitverwerkende Industrie* is the interest organisation for the fruit and vegetable processing industry.

Groentenfruihuis is the interest organisation for the wholesale of vegetables and fruit.

Sector specific ombudsman or arbitration commission/body

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Debates, crises, reforms and trust issues

The Netherlands has had several cases of food fraud in recent years.⁹⁹ Horse meat was sold as beef, honey was mixed with or replaced by sugar water and cases in which the country of origin of fruits and vegetables was tampered with. The fipronil crisis – revolving around eggs and egg products in which harmful insecticide fipronil was found – was a significant breach of trust in 2017. The NVWA underwent severe criticism because of the late and inadequate response to this crisis.¹⁰⁰ More recently, the NVWA was criticized for responding indifferent and negligent to warnings about unsafe situations in slaughterhouses.¹⁰¹ In July 2020 an investigation into the malpractices in the slaughterhouses stopped because it took the NVWA too long to come up with documentary evidence.¹⁰² This may be due to a major problem that the NVWA is struggling with: understaffing.¹⁰³ A recent study showed that the understaffing is causing the NVWA to fall short in two-thirds of their tasks. Furthermore, a previous study showed that employees who supervise slaughterhouses do not only experience a high workload but are also pressured and even intimidated by the slaughterers.

⁹⁹ <https://www.rijksoverheid.nl/onderwerpen/voeding/voedselveiligheid-in-nederland>

¹⁰⁰ <https://nl.wikipedia.org/wiki/Fipronilcrisis>

¹⁰¹ <https://nos.nl/nieuwsuur/video/2339666-nvwa-negeerde-signalen-over-slachthuizen.html>

¹⁰² <https://nos.nl/artikel/2341835-om-staakt-onderzoek-naar-slachthuizen-door-traagheid-nvwa.html>

¹⁰³ <https://www.volkskrant.nl/nieuws-achtergrond/de-nvwa-kan-het-werk-niet-meer-aan~bbbaa208/>



4 Mapping the Danish Regulatory Regimes

The purpose of this discussion report is to identify and describe the main mechanisms of control in the sectors of 1) Data Protection, 2) Food Safety, and 3) Finance. The starting point of the descriptions is the core actor(s) supervising compliance in the given sector. The main features of each sector will be described by providing an overview of the regulative framework which relate to the regulation of that sector. Furthermore, the main debates, and big crises over the past few years (since 2010) will be highlighted.

4.1 The Danish Data Protection Regime

The mechanisms of control of Data Protection in Denmark are centred around the Danish Data Protection Agency. Like in other EU-member states, all public bodies, private firms, professionals, or private persons are responsible for their own processing of personal data but are subjects to the Danish Data Protection Agency's control. This is the independent authority below the Ministry of Justice that supervises compliance with the rules on protection of personal data. It does so through ongoing supervision, handling of complaints, and sometimes it takes up its own cases. However, it does not have the authority to hand out administrative fines by itself. Instead, the employees elucidate and assess cases and in case of rule infringement they report the regulatee's data responsible to the police. The police then investigate whether there is basis for a charge, etc., and finally a possible fine will be decided by the courts. The decisions of the Data Protection Agency cannot be appealed to another administrative authority. These decisions can however be brought before the courts at any time. In addition, one can complain about the Danish Data Protection Agency's handling of a case to the Ombudsman. The control mechanisms in this sector is not affected by intermediaries. There is an ongoing debate about establishing a Fair Finance Guide like in other European countries, but this has still to come. Another interesting fact about this sector is, that the Danish Data Protection Agency is the only supervisory agency across the sectors which claim to be independent. Its' board (The Data Council) is however selected by different Ministers. Finally, it is worth mentioning that the health data sector has an agency dedicated to administer health data from across the country – the Danish Health Data Authority. This agency is not a formally a part of the control mechanisms but is subject to the control of the Danish Data Protection Agency.

Regulative framework

The two main acts when it comes to data protection in Denmark are:

The General Data Protection Regulation (GDPR)

Regulation (EU) 2016/679 of the European Parliament and of the Council

The Data Protection Act

This Act supplements and implements GDPR

In a wide range of areas, the Data Protection Regulation allows for provisions to be laid down in national law to adapt the application of the Regulation.

Other laws in the sector:

Directive (EU) 2016/680

Implemented in Danish context through the Law Enforcement Act (Retshåndhævelsesloven)

The Television Surveillance Act (Tv-overvågningsloven)

Rules about in which cases and how private companies and private citizens may monitor television.



Crises over the past few years:

Personal sensitive information stolen from the National Police: In 2012, the National Police was exposed to “the worst hacker attack in Danish history”. Hackers gained access to read and modify millions of persons’ sensitive information through, among other things, the Schengen register, the driving license register and the CPR register.

”Se og hør-skandalen”: In 2014-2017: An IT consultant at Nets’ (Danish Payment Company) subcontractor IBM sold confidential credit card information about celebrities and royalty to the weekly magazine ”Se og Hør” (MUCH DEBATE ABOUT THIS ONE)

Leakage of Politicians’ passwords: In April 2017, it emerged that every fourth member of the Folketing has had their e-mail addresses and passwords leaked. Employees in the Danish Defense Intelligence Service were also affected.

The Danish Customs and Tax Administration (SKAT) leaks citizens' tax information: In March 2017 an error in SKAT's system leaked 140 Danes' tax information.

Leakage in the Danish travel card company: In August 2016, the company behind the Danish travel card by accident made the name and address of the customers freely available on the Internet. (Also customers with a secret address)

Health data send to China: In July 2016, a letter from Statens Serum Institut to Statistics Denmark with unencrypted health data of over five million Danes ended up at the Chinese company Chinese Visa Application Center.

Open access to confidential patient records: In March 2016, it emerged that 20,000 users in the Capital Region of Denmark was given access to patient records with confidential information.

Ministry publishes 900,000 CPR numbers: The Ministry of Economic Affairs and the Interior send out a so-called Robinson list to companies of Danes who have chosen marketing protection. By mistake, the ministry included CPR numbers of approximately 900,000 Danes.

Cancer patients' CPR numbers posted on the Internet: In 2014, 69 cancer patients from Lillebaelt had their CPR numbers published on the internet in a research project.

4.2 The Danish Financial Regime

First, it is important to emphasize that the control mechanisms in the finance sector are not centered around the Ministry of Finance because this ministry primary deals with issues concerning the national budget. Instead, the domain belongs to the Ministry of Industry, Business and Financial Affairs. The relevant agency below this Ministry is the Danish Financial Supervisory Authority (FSA). The primary task of the Danish FSA is supervision of financial undertakings – banks, mortgage-credit institutions, pension and insurance companies, the stock market, consumer protection etc. In practice, the Danish FSA hands out directions to make actors change behavior. In case of law infringements, it hands out a public reprimand if the infringement is already corrected. If not, it reports the actor to the police which can investigate whether there is basis for a charge, etc., and finally a possible fine will be decided by the courts. It can also use a risk notice to inform the actor about a certain risk concerning a case without a specific infringement. The Danish FSA cooperates with the Ministry of Industry, Business and Financial Affairs and the Danish central bank (Danmarks Nationalbank) to make sure that there is no over- or underlap in the attempt of ensuring a healthy financial market. In addition to the supervisory activities, the Danish Financial Supervisory Authority contributes to the formulation of financial legislation and notices on financial regulation. Another important part of the Danish FSA is the Governing Board. The board members is appointed by the Minister of Industry, Business and Financial Affairs and they approve the supervisory business and determine the strategic



objectives of the organisation. It also makes supervisory decisions in matters of principle or which have significant consequences.

Regulative Framework

There are several rules in the financial sector. It does not make sense to describe them all, but they are available here: <https://www.dfsa.dk/Rules-and-Practice>. It is notable that the rules do not seem to be based on EU-directives in the same degree as in the other sectors.

Crises over the past few years:

The Financial Crisis: From 2007-2009 Denmark was affected by the financial crisis as every other country was.

Scandal about money laundering: In the years 2007 to 2015, 15,000 foreign customers sent a more than 200€ billion through Danske Bank's branch in Estonia. The bank did not intervene despite several obvious predictors of money laundering.

Flexinvest Fri case: From 2017 to 2018, Danske Bank sold the product Flexinvest Fri to a large group of customers knowing that the customers were about to lose money on the product. (1,2 million € fine)

Dept collection of vulnerable citizens: In 2020, Danske Bank is once again involved in a scandal. The bank has for many years recovered debt, which the bank was not entitled to. The bank has charged too much, charged debt, which was outdated, and in some instances charged the same debt from more than one person or from the wrong persons.

Selling electronic payment companies: In 2017, a CEO earned approx. 85€ million on the sale of 'Nets' (payment company) to an American fund. In 2019 the same man received an additional approx. 250€ million as a result of the sale of 'Betalingsservice' (payment company) to Mastercard. In total, the Executive Board earned approx. 1€ billion from being allowed to be responsible for selling Danish infrastructure.

4.3 The Danish Food Safety Regime

In the Food Safety sector, the control mechanisms are a bit more complicated. The control authority is split up between two agencies below the Ministry of Food, Agriculture, and Fisheries. The first and most important agency is the Danish Veterinary and Food Administration. It controls compliance with food safety regulation in every part of the "from farm to fork"-chain except of the agriculture. It helps to ensure compliance with the rules primarily through its unannounced visits at food companies. It does so through a sample strategy, and to make this strategy flexible and effective it differentiates between three control strategies; 1) Basis control (fixed control frequencies), 2) Prioritized control (Based on risk assessments), and 3) control campaigns (focus on selected issues). The latter makes it possible to make in-depth changes in extra-challenging branches. After an unannounced visit the agency evaluates the company in a control report, and if the company is a shop or restaurant the agency gives a certain smiley (public certification). In case of rule infringement, the sanction could be an injunction, a prohibition, a directive, a fixed-penalty notice (An offer for the company to get the case settled quickly without the involvement of the police and the courts). Furthermore, the agency can also report the company to the police which can investigate whether there is basis for a charge, etc., and finally a possible fine will be decided by the courts. In addition to these sanctions, the companies are also obliged to pay a fee for an unannounced visit, and the fee rises if a company's lack of compliance forces the Danish Veterinary and Food Administration to give the company extraordinary visits.

The second relevant agency is the Danish Agriculture Agency which among other things supervises compliance in agriculture. It makes sure that the citizens can trust that ecological production is in fact ecological. In case



of rule infringement, it has the same possibilities of sanctions as the Danish Veterinary and Food Administration.

Besides these agencies' standard control, the control mechanisms in the Danish food sector is much more dependent on intermediaries than in the other sectors. There are several providers of labels and certification, but the Danish Veterinary and Food Administration manage some of the most important ones like the Ø-label (ecological), and the Keyhole-label (healthy food).

Regulative framework:

The control of the two agencies is based on EU regulation, Danish regulation, and a joint control strategy for the Ministry of the Environment and Food. The food sector is heavily regulated, especially through EU directives, and according to the control agencies it is a major task to maintain the overview of the legislation. Below you will find some of the regulation:

The Food Act (Bekendtgørelse af lov om fødevarer)

Most important regulative framework; The purpose of the law is to ensure consumers' high quality food and to protect consumers from deception.

The law contains provisions that implement parts of the EU-Directives
EU-directives

Here you will find a fact sheet with some of the European regulation about Food Safety:
<https://www.europarl.europa.eu/factsheets/en/sheet/51/food-safety>

Other regulation (only in Danish):

<https://www.foedevarestyrelsen.dk/Selvbetjening/lovstof/Sider/Lovstof.aspx#k=>

Crises over the past few years:

Illegal animal transport: Over a period (2015-2017), more than a thousand animal transports have been conducted illegally. The transport companies have systematically exceeded basic rules of transportation time and number of animals on a truck.

Cheating with date marking: In 2009, a random check of 20 supermarkets revealed a lot of cheating with best-before-date marking.

Horse meat in minced beef: I 2013 horse meat was found in minced beef in several cases. This was a scandal in Denmark as well as in other European countries. This was not the first scandal of its kind. In 2009, there was found pork in the lamb meat.

Listeria bacterium in cold cuts: In August 2014, 13 sick and debilitated Danes are believed to have died of the life-threatening disease listeriosis, which they obtained after eating rolled lamb or other cold cuts from a Danish company.

Christmas ducks smelled bad: At Christmas 2015, A danish company had to withdraw around 1400 rotten duck on the 23rd of December.

Toxic eggs: Like in other European countries in 2017, eggs had to be withdrawn because the eggs were contaminated with the insecticide fipronil, which is harmful to humans

MRSA bacteria in Danish pork: Even though a minister in 2015 made a strategy of phasing out tetracycline which courses the antibiotic-resistant MRSA bacteria in pork products, the new minister in 2016 despite warnings slows down/stops the plan. This lead to much criticism of the minister.



5 Mapping the Belgian Regulatory Regimes

5.1 The Belgian Data Protection Regime

With the introduction of the General Data Protection Regulation (GDPR), the European Union (EU) has put personal data in a “complex and protective regulatory regime” (Hoofnagle et al., 2019, p. 66). This has important consequences for the study of this regulatory regime. First, data protection regulation and its enforcement will probably be quite similar in EU member states as the enforcement of the regulation is largely prescribed in the GDPR. Second, regulation and enforcement across sectors will also be, quite similar as the GDPR regulates the processing of personal data regardless of sectors. This is contrary to, for example, the United States where there is a sectoral privacy regulation system (Hoofnagle et al., 2019, p. 76).

The GDPR puts significant enforcement authority on the national level, through their Data Protection Authorities, and even with the data processing organisations themselves, through their Data Protection Officers. Companies and organisation which process data on a large scale, or which process sensitive data (e.g. medical data) are obliged to appoint a Data Protection Officer (DPO) which “greases the wheel of enforcement” (Hoofnagle et al., 2019, p. 68). Through the accounting of data processing these DPOs are charged with, they provide proof of their own non-compliance (Hoofnagle et al., 2019, p. 68).

In this document, we will map the most important regulatory actors in the regulatory regime of data protection regulation in Belgium. As data protection is a regulatory issue that cuts across all economic sectors, a further delineation of subsectors is necessary. The focus in this mapping is on the processing of medical data on the one hand and the processing of personal data in the telecommunications sectors on the other hand.

5.1.1 Legislation and parliamentary control

The Belgian law is adapted to the GDPR with the Law of the 3rd of December 2017 concerning the founding of the Data Protection Authority (“*Wet van 3 december 2017 tot oprichting van de Gegevensbeschermingsautoriteit*”), which is the legal foundation of the Belgian data protection authority, and the Law of the 30th of July 2018 about the protection of natural persons concerning the processing of their personal data (“*Wet van 30 juli 2018 betreffende de bescherming van natuurlijke personen met betrekking tot de verwerking van persoonsgegevens*”), which brings the Belgian legislation in line with all the remaining articles of the GDPR.

As the legislation regarding the protection of personal data is a federal matter, the **Chamber of Representatives** (“*Kamer van Volksvertegenwoordigers*”, the Belgian federal parliament) issues legislation and also provides parliamentary control through parliamentary questions and debates. Data protection policy and legislation is most often discussed in the Parliamentary Commission of Justice and the Parliamentary Commission of Economy, Consumer Protection and Digital Agenda. Questions about the functioning of the Belgian Data Protection Authority are handled in the Commission of Mobility, Governmental organisations and Federal institutions. Questions about medical data and health insurance companies can also be handled in the Commission of Social Affairs, Work and Pensions.



5.1.2 Executive bodies

5.1.2.1 Federal level

The **Federal Ministry of Justice** (*"Federale Overheidsdienst Justitie"*) supports and implements most policy regarding data protection legislation and regulation. The ministry is currently led by the Minister of Justice Vincent Van Quickenborne. The Department of Privacy and Equal Rights of the Directorate-General of Fundamental Rights and Freedoms is the concerned department.

The **Federal Ministry of Economy** (*"Federale Overheidsdienst Economie"*) is an important executive policy actor as well. They implement policy regarding telecommunications, digital agenda, e-government and related to these issues, also data protection. Within the ministry, the Department of Telecommunications and Information Society is the most relevant department. The ministry is currently led by the Federal Minister of Work and Economy Pierre-Yves Dermagne and the Federal State Secretary of Digital Agenda and Telecommunications Mathieu Michel.

The **Federal Knowledge centre for Public Health Care** (*"Federaal Kenniscentrum voor de Gezondheidszorg"*) is an independent scientific institute which issues scientific advice on matters that concern the public health. They are also one of the managing partners in the eHealth Platform, on which we will elaborate below.

5.1.2.2 Regional level

While data protection is not a competence of the regional policy levels of Belgium, there are several executive and advisory bodies at the regional level that are relevant.

Information Flanders (*"Informatie Vlaanderen"*) is a departmental agency within the Flemish administration and it is tasked with the digital transformation of the Flemish government. They aim to bring together all government data, a transition to smart data, to provide digital channels to customers and citizens. They are the contact point for e-government efforts and ambitions in Flanders. A similar body in the Walloon regional government is **Digital Wallonia**.

In the Brussels-capital region and in the Walloon region, there are two bodies that have an important role in supporting eHealth-projects: **eHealth.Brussels** and **eHealth Wallonia** respectively.

5.1.3 Regulatory intermediaries

5.1.3.1 Federal level

Intermediary functions in the fields of the processing of personal data in telecommunications and the processing of medical data are mainly performed by, mostly federal, bodies.

The **E-health Platform** is a federal institution that was created to facilitate data exchange and electronic service delivery in the Belgian health sector. The eHealth platform is an important intermediary for medical data in Belgium. They pose strict standards and conditions for organisation about authentication of data and data protection before they can connect to the eHealth platform (using a so-called data vault). Further, organisations who want to connect to the eHealth platform need to go through an intensive procedure. Not every data vault can be connected to the eHealth platform and the decision on this lies with the eHealth platform.



The **Information Safety Committee** (*“Informatieveiligheidscomité”*) is a federal committee that consists of two chambers: social security and health sector (1) and Federal government (2). The task of the chamber for social security and health sector is to issue good practices and support DPO’s of health and health insurance organisations. They also provide pre-advice to involved organisations for specific data exchanges involving personal data whether such exchanges are in line with relevant regulations. The social security and health chamber consists of doctors, lawyers and IT-professionals. This chamber of the Information Safety Committee has an important competence regarding the formulation of the rules with which data on the eHealth Platform and in the Crossroads Bank of Social Security have to comply.

The **Crossroads bank of Social Security** (*“Kruispuntbank Sociale Zekerheid”*) contains a lot of health data of Belgian citizens. It is a central databank that is managed by the Federal Ministry of Social Security. They are intermediaries because they have a working group who decides the minimal data safety norms for all social security organisations.

The **RIZIV** is the public health insurance fund. Is represented in the management committee of the eHealth platform. It also has a department of ‘datamanagement’ and ‘information safety’. The RIZIV is an *authentic data source* for the eHealth platform, which means their data standards are used as a reference for other similar data vaults that want to connect to the eHealth platform.

The **Belgian Institute for Postal services and Telecommunications (BIPT)** (*“Belgisch Instituut voor Post en Telecommunicatie”*) is the Belgian regulator for Postal services and telecommunications. They have a department on security and information safety and play a role in the procedure for data breaches in telecommunications through their department ‘Network Security’ (NetSec). If telecomoperators or data providers have security breaches, they have to report this to the Network Security department and, in the case of a danger for the protection of personal data, they pass this on to the Data Protection Authority.

5.1.3.2 Regional level

In Flanders, the **Flemish Supervision committee** (*“Vlaamse Toezichtscommissie (VTC)”*) serves as the Data Protection Authority for Flemish governmental organisations. Its members are appointed by the Flemish Government. The commission consists of a president and two effective members and two depute members. They are academics and data protection experts. The commission is supported by a secretariat of two employees of the Flemish government. The legal basis of the Supervision Committee is Article 10 of the Flemish e-Govdecree. They issue advice and can initiate investigations as described in the GDPR. They cannot sanction non-compliance, but they can transfer their investigation to the judicial authorities. People can also file complaints with the Flemish Supervision Committee. The Walloon and Brussels region do not have a similar organisation.

In Flanders, **V-ICT-OR vzw** is an actor that supports local governments in their digital transition. They have an important influence in the implementation of data protection legislation to local governments, which includes the processing of personal and sometimes even medical data.

5.1.4 Regulatory agency

5.1.4.1 Federal level

The **Belgian Data Protection Authority** (*“Gegevensbeschermingsauthoriteit (GBA)”*) is the regulatory agency. They handle requests for information and mediate in conflicts on different issues of data protection. They



also conduct investigations as a consequence of complaints filed by the government, companies or citizens, or on their own initiative. These investigations are conducted by their investigative department consisting of lawyers, experts and auditors. The **GBA** also plays an important part in the enforcement of the GDPR as their **litigation chamber** has some enforcement instruments at its disposal that can be used as a consequence of an investigation. These instruments range from correcting measures, like reprimands or warnings, to administrative fines. The data protection authority can also order the suspension of data processing activities or order the erasure of data. The litigation chamber of the GBA is composed of a president of the GBA and six external members.

5.1.5 Judiciary branch and appeal

As mentioned, complaints can be filed with the GBA by citizens about breaches of data protection regulation. The GBA has a **litigation chamber** (*“Geschillenkamer”*) with academics and lawyers, who decide on certain penalties. This litigation chamber is hence a non-judicial arbitration and appeal body).

Lawsuits can be filed against a data processing company or government in the member states, and more specifically in the Belgian case at the **Courts of First Instance** (*“Rechtbanken van Eerste Aanleg”*). Appeal against a decision of the GBA can also be filed at the Courts of First Instance.

5.1.6 Regulatees

As mentioned, a company or government or organisation that processes data on a large scale is ordered to appoint a **data protection officer** by the GDPR. These take on an *“ombudsman-like role”* within the involved organisation and are crucial in the enforcement of compliance with GDPR (Hoofnagle et al., 2019, p. 86).

In Belgium, there are three licensed telecomoperators which provide internet: Proximus, of which the Belgian government is the primary share holder, Telenet Group (including mobile brand Base) and Orange. In 2021, a fourth will enter the Belgian market. VOO and EDPnet are additional internet providers.

Public hospitals make up a second category of regulatees. The public hospitals often share the services of one data protection officer.

5.1.7 Interest groups

The following interest groups are relevant for dataprotection in the concerned sectors. We distinguish three categories: interest groups representing regulatees, labour unions and consumer organisations.

5.1.8 Interest groups representing telecommunications companies

The **Association of Belgian Enterprises** (VBO, *“Verbond Belgische ondernemingen”*) is the largest professional organisation for Belgian companies. They are active in most sectors and hence also represent internet providers.

AGORIA is a professional organisation representing technology companies. They are represented in the advisory council for telecommunications.

BELTUG is the largest Belgian association of digital technology leaders. They are represented in the advisory council for telecommunications.



The **Belgian Internet Providers Association (ISPA)** is the professional Association representing Belgian internet service providers. They are represented in the advisory council for telecommunications. Similarly, **FeWeb** is the Federation of Web Companies.

BeCommerce is an interest group representing Belgian e-commerce companies.

Interest groups representing processors of medical data

The **Order of Doctors** are an organisation of public law that registers all people who execute a medical profession in Belgium. Their representatives are included with as advisory members of the management committee of the eHealth platform. The Order have issued guidelines for general practitioners to follow GDPR regulation. Similarly, **Domus Medica** represents general practitioners in Flanders and the **Scientific Society of General Practitioners** (“Société Scientifique des Médecine Générale”, SSMG) and the **General Pharmaceutical Bond** (“*Algemene Pharmaceutische Bond*”) represents pharmacists.

Carenet Icuro (“Zorgnet Icuro”) is a Flemish network of care organisations. Among others, they represent public hospitals and care homes. Similarly, the **Federation of Medical Institutions** (“*Fédération des Institutions Hospitaliers*”) and **Santhea** represent care organisations in the Walloon region.

5.1.9 Labour unions

The labour unions in Belgium are the **General Belgian Labour Union**, the **General Christian Union** and the **General Central for Liberal Unions**. They are often organized per sector: for example, the telecommunications or service sector.

5.1.10 Consumer organisations

Test-Purchase (“*Test-Aankoop*”) is the most important consumer organisation in Belgium. They are active in all economic sectors. Their sector experts are contact points for consumers for legal and other advice.

The **League of Human Rights** (“*Liga voor de Mensenrechten*”) is an interest group for human rights who are very active in the field of data protection and privacy.

The **Ministry of Privacy** is another interest group active on privacy.

The **Flemish Patient Platform** (“*Vlaams Patientenplatform*”) is an interest group representing Flemish patients. They are also involved in the eHealth Platform.

The **mutualities** are organisations that offer health insurance. They are often involved in policy development and have a role as an interest group representing patients. Further, they possess a lot of medical data, which also makes them a regulatee.

5.1.11 Non-judicial arbitration body or ombudsman

The **Ombudsman for Telecommunications** (“*Vlaamse Ombudsman voor Telecommunicatie*”) is a civil servant who can operate as a mediator between the end-users and providers of telecommunications and electronic communications services.



5.2 Financial Sector (Belgium)

In the aftermath of the global financial crisis, the Belgian regulation of the financial sector was reformed in 2011. Financial regulation in Belgium is now organized along the lines of the 'Twin Peaks'-model with macro- and micro-prudential competences placed in the hands of the central bank, the National Bank of Belgium (NBB), and conduct-of-business-regulation placed with a new agency, the Financial Securities and Markets Authority (FSMA) (Bach et al., 2019). The competences regarding financial regulation are at the Federal policy level, and there are no competences for the regional governments in this respect.

5.2.1 Legislation and parliamentary control

The **chamber of representatives**, the Belgian Federal Parliament, is the relevant legislative actor. The Commission of Finance is the most important commission for legislative activities and parliamentary control in this field. The legislative framework of the Belgian Financial legislation was originally laid down in the "Law of the 2nd of August 2002 concerning the oversight of the financial sector and the financial services" (*"Wet van 2 augustus 2002 betreffende het toezicht op de financiële sector en de financiële diensten"*). The aforementioned reform of the Belgian financial regulation was legally anchored in the "Law of the 2nd of July 2010 concerning the adaptation of the Law of the 2nd of August 2002" (*"Wet van 2 juli 2010 betreffende de wijziging van de wet van 2 augustus 2002"*).

5.2.2 Executive bodies

The **Federal Ministry of Finance** (*"Federale overheidsdienst Financiën"*) has a directorate-general of the treasury. Here, important micro-prudential regulatory competences are placed, like the administrative support of the **Guarantee Fund** (*"Garantiefonds"*) and the **Protection Fund** (*"Bescherminsfonds"*). These funds protect customers (and the economy) in case financial institutions fail to meet their responsibilities. The Federal Minister of Finance is Vincent Van Peteghem.

The **Federal ministry of Economy** (*"Federale Overheidsdienst Economie"*), through its directorate-general of economic inspection, develops and executes regulation on financial institutions and products, through inspections for example. The Federal Minister of Economy is Pierre-Yves Dermagne.

5.2.3 Regulatory intermediaries like certification and accreditation bodies

The **central labeling agency (CLA)** is a non-profit organisation created by **Forum Ethibel** (a non-profit created by several academic institutions) that strives for sustainable saving and investing practices. It awards the 'Towards Sustainability' label through its eligibility committee of academics and experts of the financial sector and representatives of civil society organisations.

Fairfin is another non-profit organisation that promotes a more sustainable financial market. They award the Fairfin label, one of the two most prominent labels in Belgian finance (the other one is the aforementioned 'Towards Sustainability'-label). Applications are judged by the label committee, which consists of members from the social economy.

The **Institute of External Auditors** was founded by law in 1953 and focuses on the education, support and formation of Belgian external company auditors, which check the reporting of the companies' accounts and assets. Company auditors perform an important intermediary function on the securities market.



5.2.4 Regulatory agencies

As mentioned in the introduction, the **National Bank of Belgium** (*“Nationale Bank van België”*) is a core actor in the Belgian regime of financial regulation. The regulatory functions regarding macro- and microprudential supervision are executed by this central bank. They also have a **sanction commission** in which the council of state and the court of cassation is represented, along with two judges and two other members. The sanction commission can issue administrative fines in case of non-compliance (and are therefore a non-judicial arbitration body).

The **Financial safety and markets authority (FSMA)** is the second core actor for supervision of Belgian financial regulation. This financial regulator is financed by the regulatees, within a legislative framework that is decided by Royal Decree. FSMA is responsible for the regulation, assessment and management of conduct-of-business risks. Also here, a **sanction commission** is installed within the FSMA. This non-judicial arbitration and appeal body is an independent body within the FSMA which decides on administrative sanctions for breaches of the financial regulation. The commission consists of six magistrates and six non-magistrates. Members of the commission cannot be members of the staff or management of FSMA.

5.2.5 Judiciary branch and appeal

Private persons can sue banks (like other companies) for **the Court of First Instance** (*“Rechtbank van Eerste Aanleg”*). Appeal against administrative sanctions of the FSMA can be filed with **the Court of Appeal in Brussels** (*“Hof van Beroep Brussel”*).

5.2.6 Regulatees

The financial sector concerned in Belgium is very diverse with many banks, investment companies, securities firms etc. of differing sizes. The four biggest Belgian banks are ING Bank, BNP Paribas Fortis, KBC and Belfius, of which the latter is 100% state-owned. Aside from banks, we selected electronic payment companies, securities firms and funding companies.

5.2.7 Interest groups

5.2.7.1 Interest groups representing the financial sector

Various subsectors of the financial sector are represented by separate interest groups, but all these separate interest groups have organized themselves under one large *umbrella* interest group of the Belgian financial sector called the Belgian federation of the financial sector **FEBELFIN**. This umbrella organisation holds the membership of in turn, among others, the following interest groups representing regulatees that are relevant for our study:

- Belgian association of banks and listed companies;
- Belgian association of financial planning;
- Belgian risk management association (BELRIM);
- Belgian venture capital & private equity association (BVA);
- Federation for Insurance and Financial intermediaries;
- Professional association of credit;
- Private Bankers Association;
- Professional association of independent bank- and insurance intermediaries;
- Belgian Asset Managers Association (BEAMA);



Belgian association of financial analysts;
 Belgian risk management association;
 Belgian Chartered Financial Analyst Society
 Professional Association of Credit.

Fintech Belgium defends the interests of Belgian fintech companies.

5.2.7.2 Labour union

The labour unions in Belgium are the **General Belgian Labour Union**, the **General Christian Union** and the **General Central for Liberal Unions**. They are often organized per sector: for example, the banking sector.

5.2.7.3 Consumer organisations

The **Association of Belgian Enterprises** (VBO, "*Verbond Belgische ondernemingen*") is the largest professional organisation for Belgian companies. They are active in most sectors. In the case of the financial sector, they represent companies in their role of consumers as companies are consumers of the financial products and services. Similarly, the **Union of Entrepreneurs (UNIZO)** represents mostly small and medium sized entrepreneurs in Flanders, as consumers of financial products and services.

Test-Purchase ("*Test-Aankoop*") is the most important consumer organisation in Belgium. They are active in all economic sectors. Their sector experts are contact points for consumers for legal and other advice.

5.3 Food safety (Belgium)

The food safety regulatory regime in the European Union originally put the risk assessment at the European level and the risk management at the national level of the member states (Groenleer, 2009). In addition, risk assessment bodies exist at national or regional administrative levels as well, as one of the European Food Safety Agency's (EFSA) main competences is to advise national regulatory agencies and provide them with independent scientific knowledge. Risk management, audit and control competencies are located at the national level.

The food industry can be split up in several ways. One way is to look at the nature of the product: dairy, meat, fish, vegetables, etc. For this mapping, we looked at several possibilities to divide the industry in a relevant way. Regulation and legislation of the food industry is most often divided up according to the food chain "**from farm to fork**". This takes into account agriculture, fishery and other actors in the primary sector (1), the food handling and processing sector (2), food storage (3), the distribution, hotel and catering industries (4) and lastly, consumers (5).

Legislation on food safety is dominated by European law. The competence to regulate and control compliance with this legislation lies with member states. The food safety regulatory bodies in member states generally look at the entire production chain of a food product as a whole and call on experts of the different links in the production chain of food products to execute controls on the regulatees.

Food safety legislation puts the responsibility to ensure food safety with the operators of food products (e.g. primary sector, transport, distribution companies,). Through a series of efforts and measures, food operators have to ensure (1) compliance with food safety regulation and prescriptions, (2) meet quality standards and regulations and (3) ensure traceability of all the products. Certification companies have arisen to control and



certify these measures of food operators. Often, a food operating company can only start its activities after this system of food safety measures has been certified by an authorized certification organisation. This makes for a large network of many private and public actors that perform regulatory functions.

Lastly, the food industry is an important industry in the European economic system. Many companies are represented in various national and international interest organisations and sector groups.

5.3.1 Legislative bodies and parliamentary control

Belgium has a federal structure with three regions and three communities, which all have their proper competencies, as well as a parliament, cabinet and administration. Competences regarding food safety are mainly located at the federal level under the field of public health. Competences regarding agriculture and fishery are located at the regional level. This complicated structure leads to several important actors with a role in safeguarding food safety to be located at both the federal and the regional level. Risk management is primarily located at the federal level. Further, as mentioned, the control systems of regulatees are certified by private companies. This results in many private regulatory intermediaries in the form of certification bodies.

5.3.1.1 Federal level

Legislation regarding federal competences is adopted in the **Chamber of Representatives** (*"Kamer van Volksvertegenwoordigers"*). Food safety belongs to the policy domain of public health. The relevant legislation and most parliamentary interpellations are therefore handled in the **Commission of Public Health**.

5.3.1.2 Regional level

Some aspects of food safety regulation might be, although very rarely, issued or discussed at the regional level. Hence, the **Flemish Parliament** and its commissions are involved through parliamentary questions and interpellations regarding food safety issues in relation to the policies of the Flemish minister of agriculture and fishery and the Flemish minister of animal welfare. Similarly, the **Walloon parliament** has a commission of economy, spatial planning and agriculture.

5.3.2 Executive bodies

5.3.2.1 Federal level

Food Safety is a competence of the Federal Ministry of Public Health, Food Safety and environment. One of four pillars of the **Ministry of Public Health** (*"Federale Overheidsdienst Volksgezondheid"*) is the protection of the health of animals and plants, which encompasses food safety. This is done by issuing and implementing rules and guidelines regarding food and feed safety. The Ministry of Public Health also issues some consumer labels regarding food safety or sustainability. The most widely known example is the *Nutriscore*. This is an indication of healthiness on the packages of food products. In this regard, the Ministry of Public Health also performs an intermediary function.

The **Directorate-General of Animals, Plants and Food (DGAPF)** (*"Directoraat-Generaal Dier, Plant, Voeding"*) is responsible for these tasks. Coordination of policies of different ministries and agencies on the national level is also done by this Directorate-General. They issue rules and guidelines regarding five main domains: animal health, plant health, norms and certificates for the production and import of food products, animal feeds and protective goods for plants and fertilizers, and lastly the rules and guidelines regarding genetically manipulated organisms (GMO's).



Another important federal actor is **Sciensano**. This is a federal scientific institution, with a legal identity separate from the state, that conducts scientific research to support policy development in the domain of public health. Sciensano is also tasked with the coordination of public health policies across the many administrative levels in Belgium. The institute focusses primarily on animal health and is hence also involved in food safety.

To include relevant actors in policymaking, the Federal Government created the **Advisory council regarding food policy and the use of other consumer goods** (“Adviesraad inzake voedingsbeleid en het gebruik van andere consumptieproducten”). The instalment of this kind of advisory council is also prescribed in the General Food Law (2002) of the European Union. The members of this advisory council are decided by Royal Decree and include representatives of relevant sectors ‘from farm to fork’, but also from other policy domains. The 24 members include (representatives of) the following sectors or organisations:

- The ministry of Public Health
- The regulatory agency for food safety
- The Federal Ministry of Economy
- Producers of animal feeds
- The agricultural industry
- The food industry
- The industry of food supplements
- The chemical industry
- The trade and distribution sector
- The sector of hotels, cafés and restaurants
- The users or consumers

5.3.2.2 Regional level

As mentioned, the competence of agriculture (and fisheries) is located at the regional level. The **Flemish Department of Agriculture and fisheries** (“*Vlaams Departement voor Landbouw en Visserij*”) and the **Walloon Public Service of Agriculture, natural resources and environment** (“*Service Public Wallone de l’agriculture, des ressources naturelles et de l’environnement*”) are the two executive bodies within the regional government.

Both regions also have an agency for agricultural research: the **Flemish Institute for Agriculture and Fisheries Research** (“*Instituut voor landbouw- en visserijonderzoek*”, ILVO) and the **Walloon centre for agronomic research** (“*Centre Wallone pour la Recherche Agronomique*”). The Flemish is not an independent legal entity, but is a part of the Department of Agriculture and Fisheries.

In Flanders, the **Strategic Advisory Council for Agriculture and Fisheries** (“*Strategische Adviesraad voor Landbouw en Visserij*”, SALV) is an important participation body where civil society and the food sector are granted participation in policy development. The **Economic, Social and Environmental Counsel of Wallonia** (“*Conseil économique, social et environnemental de Wallonie*”, CESE Wallonie) is the counterpart in the Walloon region.



5.3.3 Regulatory intermediaries with a focus on certification and accreditation bodies

5.3.3.1 Federal level

As mentioned, private certification companies have an important regulatory function, as they certify the auto-control systems that are mandatory for regulatees in order to be allowed to produce food. These private companies are accredited by the federal government. Often they are large, international certification companies active in various sectors (think is ISO certifications, etc.) We list them below:

Foodcheck NV
 Inscert Partner SA
 Promag sprl
 Certisys
 Quality Control c.v.
 SGS Belgium NV
 Tüv Nord Integra BVBA

In the field of sustainable and organic foods, some labelling organisations that allocate labels in relation to specific quality standards to food operators or food products, are active on the Belgian food market. The most important label is **Bioguarantee**, for biological (also called 'organic') agriculture. The Bioguarantee label is issued by an organisation called **Bioforum**. Often, retail companies have their own labels as well, but there are no controls of these labels. We did not include them in this list.

The Federal food safety agency work together with, besides their own laboratories, a **network of certified laboratories** in order to test samples of food safety controls by the food safety agency.

5.3.3.2 Regional level

Regarding biological agriculture, both the Flemish and Walloon regions have intermediary bodies that promote and support biological agriculture. In Flanders, the department of agriculture certifies a variety of organisations (**Certified advisors in biological agriculture**, "*Erkende adviseurs Biologische landbouw*") which farmers and agricultural companies can ask for advice and counselling on how to farm in a biological way. In the Walloon region, **BioWallonie** is an organisation that was established as part of a strategic plan of the Walloon government to promote biological agriculture by 2020. They offer advice and financial support and promote biological production.

Lastly, the Walloon and Flemish region both have an agency that promotes local products (among others through the allocation of labels): the **Flemish agency for agriculture and fisheries marketing** ("*Vlaams Agentschap voor Landbouw en Visserij Marketing*", VLAM) and the **Walloon agency for the promotion of quality agriculture** ("*Agence Wallone pour la promotion d'un agriculture de qualité*").

5.3.4 Regulatory agency

The **Federal Agency for the Safety of the Food Chain** ("*Federaal Agentschap voor de Veiligheid van de Voedselketen*" (FAVV), "*Agence Fédérale pour la Sécurité de la Chain Alimentaire*" (AFSCA)) is the Belgian regulatory agency that is responsible for the risk management of the food chain. They execute all controls and audits of professionals and companies throughout the entire food chain 'from farm to fork'.



Furthermore, their responsibility includes the prevention regarding food safety risks and the communication of best practices and norms and guidelines to professionals.

To do this, the agency can count on 1300 employees, but they also employ professional engineers, veterinarians and researchers to perform controls and audits. The agency is divided in four departments, delineating the activities of the agency. First the department of control implements and executes the control and audit processes across Belgium through the local control units. The department is structured according to the food production chain 'from farm to fork'. Controls are organized through nine local control units. Thematic control teams can also be assembled to tackle specific safety risks, for example after notifications via the European RASFF-system or following complaints and warnings by citizens or the minister in charge. Such thematic control teams are then composed of external experts and controlling officials.

Second, the department of control policy is responsible for the general policy regarding controls and a multiyear control plan that takes into account the assessment of general risks. Thirdly, the agency makes use of several laboratories where samples can be analysed to support the risk assessment. 5 federal laboratories are managed by the agency itself and about 60 external laboratories are certified by the agency to perform tests and experiments on samples. The fourth department consists of general supporting services.

The FAVV is also the Belgian contact point for the RASFF system. Further, the director of the department of Animal health (part of the Department of Controlling policy) is also Belgium's Chief Veterinary Officer (CVO).

The regulatory agency is the only body that can determine food safety violations. However, it often coordinates targeted actions with the federal or local police or the Belgian customs department. For example, in order to control transports, a roadblock has to be installed by the local police, or at the border by the customs department.

The agency has two important structures in place for the participation of important stakeholders. First, a scientific committee independently advise the agency with respect to the risk assessment of specific food safety risks. Second, an advisory council is composed with relevant actors of the food sector. This advisory council includes forty representatives of the following groups of both the Flemish, Brussels-Capital and Walloon region:

Organisations representing consumers (consumers organisations, labour unions, federation of food banks,...)

Farmers

Packaging of animal feeds

Representatives of the food industry (consumer foods, dairy,...)

Chemical sector

Distribution and retail (supermarkets, butchers, self-employed people,...)

Hotels, restaurants, cafés

Transport sector

Ministry of Public Health

Ministry of Economy

Representatives of the diverse regions and communities



Animal processing companies (e.g. slaughterhouses) are obliged to register their animals and activities electronically in the **SANITEL system**. Several applications are used to access this central database, including Sanitrace, Beltrace, Cerise, Veeportaal.

Aside from the risk assessment and the controls and audits, the Belgian regulatory agency also has the competence to enforce compliance. They can issue warnings, revoke certifications and permission, issue fines and tickets. In certain cases, the police can be involved to prosecute offenders.

5.3.5 Judiciary branch and non-judicial appeal and arbitration bodies

The court of first instance is where lawsuits are filed. Prosecutions and cases of infringements against hygiene and food safety regulations are often tried together in special ‘thematic’ hearings. A prosecution for the court is very rare however, 80% of the infringements are sanctioned with an administrative fine.

5.3.6 Interest groups

5.3.6.1 Interest groups representing regulatees

As became clear throughout the discussion of important actors in the regulatory regime regarding food safety, interest groups are often participating in the development of food safety policies through their inclusion in the advisory council on food policy at the federal level, and/or in the advisory council of the regulatory agency. In Flanders interest groups are involved in decision making through their membership of the strategic advisory council of agriculture and fisheries. These interest groups often represent regulatees of one subsector. We list the most important ones below:

General Farmers Syndicat (Farmers)
 Fédération Wallone De L’agriculture (Farmers)
 Boerenbond (Farmers)
 Comeos (Retail)
 Groene Kring Vzw (Sustainable Agriculture)
 FEVIA (Food Industry)
 Landsbond Pluimvee (Companies Involved In Poultry)
 VBT (Horticulture)
 Professional Association Of Independent Food Stores
 Bond Of Belgian Horticulture Organisations
 National Bond Of Egg Traders
 Union of entrepreneurs (UNIZO)

5.3.6.2 Labour union

The labour unions in Belgium are the **General Belgian Labour Union**, the **General Christian Union** and the **General Central for Liberal Unions**. They are often organized per sector: for example, the food sector.

5.3.6.3 Consumer organisations

Test-Purchase (“*Test-Aankoop*”) is the most important consumer organisation in Belgium. They are active in all economic sectors. Their sector experts are contact points for consumers for legal and other advice.



Belgian association for research and expertise for consumer organisations (also represented in advisory council of FAVV)

National federation of the middle-class (*“Fédération Nationales des Unions des Classes-Moyennes”*) (also represented in advisory council of FAVV)

A couple of other consumer organisations are particularly active in the field of biological (or organic) and sustainable agriculture: **Groene Kring vzw, Velt, Voedselteams.**



6 Mapping the Polish Regulatory Regimes

6.1 The Polish Data Protection Regime

In Poland, between 1997 and 2018, on the basis of the Personal Data Protection Act of 29 August 1997, the Inspector General for Personal Data Protection operated. On April 27, 2016, The General Data Protection Regulation (GDPR) was adopted and then, after a two-year transition period in May 2018, it became applicable in all EU member states directly, without the need to issue national acts. Together with the Data Protection Directive in the area of police and justice, it is part of the EU data protection reform package¹⁰⁴. The Personal Data Protection Act was passed on May 10, 2018 by the Polish Parliament. The new act is to ensure the application of the General Data Protection Regulation (GDPA) and extend some of the provisions referred to therein, so that they are adequate to the national legislation. It describes in detail the issues involved:

the appointment of the Data Protection Officer,
 certification of entities in the field of personal data protection,
 industry codes of conduct,
 the role of the Personal Data Protection Office and its President as the supervisory authority,
 infringement proceedings,
 carrying out official controls.

On the basis of this new act a new supervisory body was appointed - the President of Personal Data Protection Office, in place of the former Inspector General for Personal Data Protection.

The above-mentioned act regulates also health data. This includes all data revealing information about past, present or future physical or mental health, information collected when registering for health care services (e.g. disease, disability, disease risk, medical history, clinical treatment, or physiological or biomedical condition)¹⁰⁵.

Additional Polish law concerning health data is The Act of 6 November 2008 on Patients' Rights and the Patient Ombudsman. It defines:

patient rights;
 the rules of sharing medical records;
 obligations of entities providing medical services related to patient rights;
 the procedure for the appointment, dismissal and powers of the Patient Ombudsman; handling practices that violate collective patients' rights.

Legislative bodies

Polish Parliament Committees with legislative functions:

Health Committee - the scope of the Committee's activities includes health protection issues.

Commission for Digitization, Innovation and Modern Technologies (CNT) – deals with issues of radio and telephone communication, computer networks, telecommunications, innovation, computerization and the development of the information society.

Administration and Home Affairs Committee - deals with matters of state administration and security.

¹⁰⁴ <https://lexdigital.pl/ochrona-danych>

¹⁰⁵ <https://lexdigital.pl/ochrona-danych-osobowych-w-sluzbie-zdrowia>



Justice and Human Rights Commission - its tasks includes matters of compliance with the law and the rule of law, courts, prosecutor's office, notary's office, the bar and legal services, the functioning of lawyers' and legal counsels, and matters of respecting human rights.

Health Committee Senate of the Republic of Poland - deals with health promotion, prophylaxis, health protection organisation system, health security and cooperation with foreign countries in the field of health. Commission, Human Rights, Rule of Law and Petitions Senate of the Republic of Poland - the subject of its activities are: civil rights and freedoms and their institutional guarantees, matters related to the functioning of the judiciary and public security, compliance with the law, respect for human rights, civil society institutions and non-governmental organisations, consideration of petitions addressed to the Senate and its bodies.

Regulatory Agencies

In Poland, there are two main regulatory agencies:

President of Personal Data Protection Office (President of UODO) - the main state authority dealing with personal data protection. Within the framework of the tasks assigned by art. 57 of the GDPR, this body, among others, monitors and enforces the application of the GDPR; disseminates knowledge about risks, regulations, safeguards and rights related to processing and understanding of these phenomena to the society; advises the national parliament, government and other institutions and bodies on data protection issues, handles complaints lodged by the data subject or by an entity, organisation or association; conducts proceedings on the application of the GDPR.

Office of Electronic Communications - is a regulatory authority responsible for telecommunications and postal activities and frequency resources management. It's also a supervisory authority responsible for controlling compliance of products emitting or vulnerable to emission of electromagnetic field, including radio equipment placed on the market in Poland.

Executive bodies

Ministry of Economic Development, Labour and Technology - working on a coherent social and economic development of Poland. It is responsible for following administrative sectors: the economy, construction and housing, as well as tourism¹⁰⁶.

Ministry of Health - heads all public health departments of the government administration.

Ministry of Justice - its tasks include matters relating to the judiciary, prisons, notaries, advocacy and legal advisers.

Ministry of Digital Affairs – heads the computerisation department of the government administration.

The Ministry of Internal Affairs and Administration - serving the minister responsible for three departments of government administration: public administration, internal affairs, religious, national and ethnic minorities¹⁰⁷.

¹⁰⁶ <https://www.gov.pl/web/development-labour-technology/the-initiatives-taken-by-the-ministry>

¹⁰⁷ <https://www.gov.pl/web/digitalization/about-us1>



Interest organisations

In Poland there are several interest organisations and associations representing regulates in the data protection sector. Among them we can find:

Polish Association of Hospital Directors,
 Polish Federation of Hospitals,
 Polish Federation of Private Hospitals,
 The Polish Chamber of Physicians and Dentists,
 Polish Chamber of Information Technology and Telecommunications,
 The Chamber of Electronic Economy.

Debates, crises, reforms and trust issues

Some examples of scandals in the data protection sector:

December 2020: UODO imposed on Virgin Mobile almost PLN 2 millions of penalties for leakage of customers' data¹⁰⁸.

November 2020: The University of Warsaw informed about a violation of personal data protection in the portal (www.mimuw.edu.pl) of the Faculty of Mathematics, Informatics and Mechanics. This includes information such as first and last names, photographs, PESELS, dates of birth, telephone numbers and addresses. As the university explained, the leakage is "a consequence of wrong actions of persons responsible for the preparation and configuration of the new service"¹⁰⁹.

September 2020: On 10 September UODO imposed a fine on Morele.net in the amount of 2 830 410 PLN (660 thousand EUR). In 2018 customers shopping in Morele.net (and other brands of the group, e.g. Digitalo) received text messages impersonating Morele.net immediately after shopping, informing about the need for a 1PLN surcharge for the order. The text messages contained a link which redirected the victim to a fake payment intermediary's website, and then stole the victim's login and password to the bank account and the transfer authorization code sent to the victim by the bank by SMS. As a result, the victim lost the money he had on his account¹¹⁰.

¹⁰⁸ <https://antyweb.pl/virgin-mobile-wyciek-danych-klientow-kara/>

¹⁰⁹ <https://tvn24.pl/tvnwarszawa/najnowsze/wyciek-danych-z-uniwrsytetu-warszawskiego-4756813>

¹¹⁰ <https://niebezpiecznik.pl/post/3-miliony-kary-dla-morele-net-od-uodo-za-naruszenie-rodo/>



6.2 The Polish Financial Regulatory Regime

Relevant regulative frameworks

Compared to other European member states, the history of the financial sector and financial regulations in Poland is relatively short. In Poland, the financial sector started to develop after the transition from a planned economy into a market one, in the early 1990s. The legal framework of the Polish banking system is contained in the Act of 29 August 1997. - Banking Law. The act defines the principles of conducting banking activity, establishing and organizing banks, branches and representative offices of foreign banks, as well as branches of credit institutions, and the principles of banking supervision, reorganisation proceedings, liquidation and bankruptcy of banks¹¹¹. Moreover, the activity of banks in Poland is regulated, among others, by¹¹²;

Act of August 29, 1997 on the National Bank of Poland,

Law of August 29, 1997 on mortgage bonds and mortgage banks,

Act of 10 June 2016 on the Bank Guarantee Fund, deposit guarantee system and forced restructuring.

In term of FinTech organisations in Poland due to the dynamics of FinTech entities, legislators have decided to introduce regulations of a subjective nature, i.e. relating to the area of activity of the entity itself¹¹³. Thus, the legal regulations are scattered among individual acts, and the most important ones include¹¹⁴:

Act of 19 August 2011 on payment services;

Act of August 29, 1997. - Banking Law;

Act of 11 September 2015 on Insurance and Reinsurance Activity;

Act of 27 May 2004 on investment funds and alternative investment fund management;

Act of 10 May 2018. The Personal Data Protection Act and the earlier Act of 29 August 1997;

Act of 23 April 1964. - Civil Code.

Overall, the Polish banking system was characterized by high stability and resilience.

Legislative bodies

Courts are divided into three divisions: Polish Administrative Courts; Voivodship Administrative Courts and Supreme Administrative Courts. Besides an administrative case, they may also constitute a commercial case, following a similar logic in the court's division. Commercial cases in Poland include corporate or business relations, damages against the board members, breach of company law or corporate rules, environmental cases against companies in Poland, contractual disputes.

Polish Parliament Committees with legislative functions:

Public Finance Committee - an organ of the lower chamber. Its tasks include matters of the monetary, credit and tax system, wages and income, state budget and financial plans, special purpose funds, agencies and foundations with the participation of the State Treasury, property insurance, customs and statistics.

Committee on Energy, Climate and State Assets - A lower chamber organ. The scope of her tasks includes matters of transformation of ownership forms, mainly in the state sector, and supervision over public property in the economy.

¹¹¹ <https://www.gov.pl/web/finanse/podstawa-prawna-funkcjonowania-bankow-w-polsce>

¹¹² Ibid.

¹¹³ Gawron, O. (2019). Otoczenie regulacyjne sektora fintech na przykładzie dyrektywy PSD2 i wybranych ustaw krajowych. *Journal of Finance and Financial Law*, Grudzień/December 2019, vol. 4(24), s.58.

¹¹⁴ Czugan M., Rogowski W. (red.), 2017, *Regulacje finansowe. FinTech – nowe instrumenty finansowe – resolution*, Wydawnictwo C.H.Beck, Warszawa, s. 29.



Economy and Development Committee - the scope of the Commission's activities includes economic policy, economic restructuring, industrial efficiency, international and domestic trade, technology, standardization, direct investment and foreign capital participation, as well as employee and economic self-government and employers.

National Economy and Innovation Committee - An upper chamber organ. The subject of the commission's activities is the state's financial system (including monetary policy, state budget revenues and expenses, special purpose funds, fiscal control), accounting, foreign exchange law, and the functioning of the financial market (including banking, insurance, investment funds, and securities).

Budget and Public Finance Committee - An upper chamber organ. The subject of the commission's activities is the state's financial system (including monetary policy, state budget revenues and expenditures, special purpose funds, fiscal control), accountancy, foreign exchange law, functioning of the financial market (including banking, insurance, investment funds, securities).

Regulatory bodies

Polish Financial Supervision Authority (KNF)

The Polish Financial Supervision Authority commenced its activities on September 19th 2006, i.e. the date when the Act on Financial Market Supervision of July 21st 2006 (Dz. U. of 2006, No. 157, item 1119, as amended) came into force. KNF is responsible for state supervision of the banking, capital, insurance and pension sectors, payment institutions and payment service offices, electronic money institutions and credit unions.

Office of Competition and Consumer Protection (UOKiK)

UOKiK carries out proceedings concerning competition restricting practices, i.e. abuses of a dominant position and prohibited agreements (cartels); it controls mergers; provides opinions on state aid schemes and individual state aid decisions before their notification to the European Commission. It also can run proceedings concerning practices infringing collective consumer interests and inspect prohibited clauses in B2C contracts; UOKiK also carries out proceedings concerning general product safety.

National Bank of Poland (NBP)

NBP is the central bank of the Republic of Poland. Its tasks are stipulated in the Constitution of the Republic of Poland, the Act on National Bank of Poland and the Banking Act. The fundamental objective of the NBP's activity is to maintain price stability. NBP develops and implements the monetary policy strategy and the annual monetary policy guidelines¹¹⁵.

The Ministry of Finance and the presidents of the Polish Financial Supervision Authority, the National Bank of Poland and the Bank Guarantee Fund¹¹⁶ coordinate their actions in the Financial Stability Committee - authority responsible for macroprudential supervision in Poland.

Executive bodies

The Ministry of Finance (MF) is a governmental administration office servicing the minister competent for the state budget, public finance and financial institutions. One of the fundamental tasks of the MF is preparation, execution and control over implementation of the state budget. Moreover, the Ministry deals with the financing system for local governments, the budget zone and state security and manages the public debt. The MF is also responsible for implementation of state income and expenses, including income from

¹¹⁵ https://www.nbp.pl/homen.aspx?f=/en/onbp/informacje/dzialalnosc_nbp.html

¹¹⁶ Bank Guarantee Fund (BFG; it guarantees banks and credit unions deposits and is responsible for the resolution of financial institutions at risk of bankruptcy).



taxes, as well as for financial, credit and payment cooperation with foreign countries and implementation of provisions regarding customs. The MF executes tasks related to the operation of financial markets, including banks, insurance companies and investment funds, and tasks related to trade in securities. Moreover, it initiates governmental policy with respect to the securities' market¹¹⁷.

Interest organisations

Polish Banks Association (ZBP)

ZBP is self-government organisation of banks, established in 1991, founded on the Chambers of Commerce Charter. Membership in the ZBP is voluntary and open for all banks created under the Polish law as well as for foreign credit institutions branches operating in the Republic of Poland¹¹⁸.

Debates, crises, reforms and trust issues

Some examples of challenges in the finance sector:

Lawsuits from Swiss Francs clients: Attracted by lower interest rates some 700,000 Poles took out mortgages in foreign currencies, mainly in Swiss francs, nearly a decade ago. They are now paying far bigger instalments than they expected after the Swiss franc soared 92 percent against the zloty since the start of the global financial crisis in 2008. Foreign currency loans total 124 billion zloty (\$31 billion), almost one third of all Polish mortgages, and Thursday's court verdict is expected to encourage more borrowers to sue for refunds¹¹⁹.

Banking Tax: The Banking Tax Act imposes a tax on selected financial institutions – domestic banks, consumer lending institutions and insurance companies, as well as the branches of foreign banks and insurance companies operating in Poland. The new banking tax is aimed specifically at the banking and insurance sectors and does not cover investment and pension funds. In January 2016, the European Central Bank criticized the plans for the introduction of the new tax in Poland. It warned the Polish government that the tax could have negative effects on the provision of credits and on financial stability.¹²⁰ The Entrepreneurship Council is against the high fiscal burdens on banks, which in practice make it impossible to finance the restructuring of Polish enterprises and adapt the Polish economy to the new realities of the global economy and in December 2020 appealed to the government to reduce the fiscal burden of the banking tax.

Some examples of scandals in the finance sector:

Amber Gold: one of the biggest financial scandals in Poland. Amber Gold launched in 2009. It promised guaranteed returns of 10 to 14 percent a year for what it claimed were investments in gold. The Polish Financial Supervision Authority (KNF) put Amber Gold on a "blacklist" of institutions that operate like banks without authorization. Amber Gold proved to be classic pyramid scheme, which scammed more than 18000 of its clients out of a total of PLN 851 mln (EUR 198 mln)¹²¹.

GetBack: The Polish Financial Supervision Authority delayed the notification of irregularities in GetBack to the public prosecutor's office for over two months. During this time, the company sold bonds to Poles for hundreds of millions of zlotys. Today they are worthless. GetBack was founded in 2012. Its founder was Leszek Czarnecki, majority shareholder of Getin Bank. The company developed rapidly. It purchased debt portfolios and was recovering debts. It also operated in Spain, Romania and Bulgaria. In 2017, the company

¹¹⁷ <https://www.gov.pl/web/finance/what-we-do-1>

¹¹⁸ <https://www.zbp.pl/?lang=en-us>

¹¹⁹ <https://www.reuters.com/article/us-eu-swissfrancs-poland-idUSKBN1WI0R5>

¹²⁰ <https://www.dlapiper.com/pl/poland/insights/publications/2016/03/global-tax-news-mar-2016/poland-new-tax-on-banks/>

¹²¹ <https://polandin.com/38084188/explainer-amber-gold-affair>; <https://www.pap.pl/en/news/news%2C528832%2Ccouple-behind-polands-major-pyramid-scheme-given-prison-sentences.html>



was newly listed on the Warsaw Stock Exchange and the stock exchange valued it at 2.5 billion PLN. It was the second largest company of this type on the market. From the beginning of 2018, the industry started to say that GetBack is in trouble. It was difficult to determine how big it was, because the company only gave some data and did not publish a financial report for 2017 - it finally did so on July 2, 2018¹²². According to Forbes¹²³: GetBack has perfected itself in masking actual losses with paper profits. It rolled up debts, redeemed them in exchange for a single payment, debts often changed ownership and even lent money to its own debtors.

6.3 The Polish Food safety Regime

Relevant legislative framework and regulations

The fundamental legal act in force in the Polish legislative system governing food law is the Act of 25 August 2006 on Food and Nutrition Safety, which sets out the conditions that constitute food safety¹²⁴. Other important Polish regulations are listed below:

- Act of 21 December 2001 on the commercial quality of agro-food articles (Journal of Laws of 2002, Number 5, Item 44 as amended),
- Act of 29 January 2004 on the veterinary requirements for products of animal origin (Journal of Laws of 2004, Number 33, Item 288).

The rules governing the circulation of food in Poland have changed considerably in connection with the adaption to European regulations, but also because of standardization efforts among European member states. Several legal acts incorporating the standards and requirements resulting from European legal regulations regulate the circulation of food, in particular: Regulation number (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Official Journal L 031), directive 93/43/EEC dated 14 June 1993 on the hygiene of foodstuffs (Official Journal L 139) and Regulation number 852/2004 of 29 April 2004 on the hygiene of foodstuffs (Official Journal L 139), which replaced the former directive, directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

The Act on the health conditions of food and nutrition is applied in parallel with the Act on the commercial quality of agro-food articles, which introduces specific regulations concerning the circulation of “**agro-food articles**”, in other words, agricultural products, undergrowth, wild game, marine and freshwater organisms in the form of raw materials, semi-finished products and finished products derived from these raw materials and semi-finished products, including foodstuffs.

Legislative bodies

The Polish parliament discusses legislative regulations regarding the food sector. The most important committee is Committee on Agriculture and Rural Development. The scope of the Committee's activity includes matters of agriculture, horticulture, fruit farming, purchase of agricultural produce, breeding, agricultural cooperatives, management and protection of agricultural and forest land, provision of means of production, including land reclamation and water supply to the countryside, food industry and fish processing, socio-professional organisations of farmers and the social and economic situation of the rural

¹²² <https://biqdata.wyborcza.pl/biqdata/7,159116,25480662,getback-glownny-bohater-afery-zeznal-ze-wspolpracowal-z-cba.html>

¹²³

¹²⁴ Owsiak, A. (2015). Regulacje organizacyjne i prawne warunkujące funkcjonowanie przedsiębiorstw przemysłu rolno-spożywczego w Polsce. *Progress in Economic Sciences*, 2, 257-269.



population; the scope of the Committee's activity also includes matters of determining the directions of demonopolization of the bodies and structures dealing with the above mentioned activity and development and modernization of rural infrastructure and issues related to education and agricultural consulting¹²⁵.

In addition, several departments in the Ministry of Agriculture and Rural Development are involved in policy development in food sector.

Department of Animal Breeding and Production Safety: performs the Minister's tasks concerning veterinary public health protection, animal health protection, feed quality and hygiene, animal protection and livestock breeding¹²⁶.

Department of Food Quality and Plant Production Safety: carries out the tasks of the Minister concerning the registration and protection of geographical indications, national food quality systems, commercial quality of agri-food products, standardization in agriculture and agri-food processing, organic farming, phytosanitary supervision and plant protection, registration of fertilizers and plant cultivation aids, as well as information and promotion activities in the field of food, and the subordination of the Inspection of Commercial Quality of Agricultural and Food Articles and the State Inspection of Plant Protection and Seed Protection not covered by other departments¹²⁷.

Department of Processing and Agricultural Markets: performs the Minister's tasks concerning agri-food processing, regulation of agricultural markets under the Common Agricultural Policy and markets in potatoes, spirits, aromatized wine products, fermented wine drinks and beer, agricultural cooperatives, agricultural producer groups and their associations, producer organisations and their associations, inter-branch organisations, as well as agricultural and agricultural market information statistics¹²⁸.

Department of Strategy, Knowledge Transfer and Innovation: carries out the Minister's tasks concerning the coordination of the implementation of national development strategies, the EUROPA 2020 strategy, analyses of the impact of EU and national policies on Polish agriculture and rural areas, innovation in the field of agriculture, rural development and agricultural markets, agricultural advisory services, science and supervision of research institutes not covered by the scope of other departments¹²⁹.

There are no specific, dedicated courts for food safety issues and regulations.

Regulatory bodies

Monitoring of the food trade processes at each stage of the food chain is monitored by official food control authorities, including the Sanitary Inspection and the Veterinary Inspection.

Sanitary Inspection - Initiating and supervising the activities of government administration aimed at preventing and minimizing the negative effects of events related to public health, in particular by supervising the conditions of: environmental hygiene, occupational hygiene at work, radiation hygiene, hygiene of teaching and upbringing processes, hygiene of rest and recreation, health food, nutrition and cosmetic products, hygiene and sanitation, which should be met by medical personnel, equipment and rooms where health services are provided¹³⁰.

¹²⁵ <https://www.sejm.gov.pl/Sejm9.nsf/agent.xsp?symbol=KOMISJAST&NrKadencji=9&KodKom=RRW>

¹²⁶ <https://www.gov.pl/web/rolnictwo/departament-bezpieczenstwa-hodowli-i-produkcji-zwierzecej>

¹²⁷ <https://www.gov.pl/web/rolnictwo/departament-jakosci-zywnosci-i-bezpieczenstwa-produkcji-roslinnej>

¹²⁸ <https://www.gov.pl/web/rolnictwo/departament-przetworstwa-i-rynkow-rolnych>

¹²⁹ <https://www.gov.pl/web/rolnictwo/departament-strategii-transferu-wiedzy-i-innowacji>

¹³⁰ <https://www.prawo.pl/kadry/zadania-i-uprawnienia-panstwowej-inspekcji-sanitarnej.187116.html>



Veterinary Inspection: The inspection performs tasks in the field of animal health protection; and b) the safety of animal products and food containing both non-animal and animal products in agricultural retail trade, in order to ensure public health protection¹³¹.

Other control authorities in food sector in Poland include:

Agricultural and Food Quality Inspection, which tasks are aimed at reducing the risk of harmful organisms, elimination of negative effects resulting from trade and use of plant protection products and supervision over the production of seed that fully meets health and quality requirements¹³²;

Inspectorate of Plant Health and Seed Inspection supervises the commercial quality of agri-food products in production and trade, including those exported abroad, controls the commercial quality of agri-food products imported from abroad, including the border control of these products, carrying out assessment and issuing certificates in the field of commercial quality of agri-food products¹³³.

Executive bodies

Research Institute of Horticulture - a governmental R&D organisation supervised by the Ministry of Agriculture and Rural Development. Its research programme covers all areas related to fruit, vegetable, ornamental plant and bee sciences. The Institute, besides research, is also involved in commercial activities, especially in food analysis¹³⁴.

National Research Institute of Animal Production - realizes the policy of the Ministry of Agriculture and Rural Development in the field of broadly understood animal production. The main subject of the Institute's activity is conducting research and development work, which comprise the breeding of all species of farm animals, production of safe food under animal and environmentally friendly conditions as well as the use of farm animals for biomedical purposes¹³⁵.

Institute of Agricultural and Food Economics - an independent scientific and research centre analysing economic and production processes in the Polish agriculture and food economy¹³⁶.

Interest organisation and associations

In Poland there are several interest organisations and associations representing regulates in the food sector.

Among them we can find:

National Poultry Chamber,

National Council of Agricultural,

Agricultural Economy Institute,

Polish Agricultural Society,

Polish Association of Processors and Producers of Ecological Products "Polish Ecology",

Polish Butchers and Meat Producers Association,

Polish Association of Poultry Breeders and Producers,

Federation of Industry Associations of Agricultural Producers,

Polish Media Group of Farmers and Consumers,

Association of Trade Unions of Farmers and Agricultural Organisations,

¹³¹ <https://www.wetgiw.gov.pl/inspekcja-weterynaryjna/organizacja-inspekcji-weterynaryjnej>

¹³² <http://piorin.gov.pl/o-inspekcji/o-inspekcji,4.html>

¹³³ <https://www.gov.pl/web/ijhars/inspekcja-jakosci-handlowej-artykulow-rolno-spozywczych>

¹³⁴ <http://www.inhort.pl/en>

¹³⁵ <http://www.izoo.krakow.pl/en/>

¹³⁶ <https://www.ictagrifood.eu/node/40302>



Foundation for Constructive Ecology Ecoprobono,
Polish Association of Sustainable Agriculture ASAP,
Association of Fruit Growers of the Republic of Poland,
Association of Juice Producers,
Association of Polish fruit and vegetable distributors - Unia Owocowa,
National Association of Fruit and Vegetable Processors,
National Union of Potato Producers,
National Union of Fruit and Vegetable Producers Groups,
National Agricultural Support Center,
Polish Meat Association.

Debates, crises, reforms and trust issues

Some examples of reforms in the food safety sector:

Prevention of food waste: it imposes an obligation on the food seller to conclude an agreement with a non-governmental organisation for the free transfer of food that meets the requirements of food law¹³⁷.

Restrictions on dispensing plastic bags at points of sale,

GMO-free" food labelling - the trend for organic products

"Sugar tax" - The tax is introduced by the Act of 14 February 2020 amending certain laws in connection with the promotion of pro-healthy consumer choices

Recent scandals:

In 2019, a journalistic investigation revealed that illegal slaughter of sick cows and trade in meat unfit for human consumption were commonplace in Poland.

¹³⁷ <https://businessinsider.com.pl/wiadomosci/ustawa-o-przeciwdzialaniu-marnowaniu-zywnosci/3p0vgdn>



7 Mapping the Israeli Regulatory Regimes

7.1 The Israeli Data Protection Regime

The Israeli data protection regulatory regime has its basis in two sources of legislation. First, the right to privacy gained in 1992 a constitutional status as a basic human right by the Basic Law: Human Dignity and Liberty. Second, the Protection of Privacy Act, 5741-1981 established the rules regarding the protection of privacy. Since 1981 the Act was amended several times and supplemented with regulations, but the Knesset (the Israeli Parliament) has yet to replace the Act with new legislation. In addition to legislation, as the constitutional right to privacy is not absolute, the Courts in Israel have been interpreting and balancing the right to privacy against other rights. As Israel has a Common Law legal system, decisions by The Supreme Court of Israel, the highest tribunal in the State of Israel, become precedent and therefore expand the legal and regulatory framework for data protection. Data protection in Israel is regulated at the national level through a national agency – the Privacy Protection Agency (PPA; in Hebrew: הרשות להגנת הפרטיות). In 2011, the European Commission had found that Israel is providing an adequate level of protection for personal data.

As for the sub-sectors our study covers, we find that telecommunications companies are regulated by the Communications Act (Bezeq and Broadcasting), 1982-5742. The Act set several licensing schemes, out of which only a few regulate internet service providers. Two companies, Bezeq and Hot Telecom, hold a general license to provide any immobile telecommunication services. Bezeq stationary domestic services. Five companies have a general license for providing mobile phone radio services in the RTN method, while 37 other companies hold either a unified or special license for providing internet access services. The Ministry of Telecommunications acts the regulator for the telecommunications sector.

Similarly, in the Health Sector, the Ministry of Health acts as the regulator. According to the Public Health Ordinance 1940 and the Public Health Regulations (Registration of Hospitals) 1966-5726, the Ministry has to approve the establishment of new hospitals and other medical institutions specified in the Ordinance. Before opening the hospital or institution must also receive a license in order to open, manage, and operate. In this mapping, we focus on the 42 general hospitals. In the past, the Ministry required hospitals to adopt data security certifications and established a committee for providing recommendation on secondary uses of health data.

Legislative bodies:

The Knesset, the Israeli Parliament, has only one chamber comprised of 120 members. The Knesset acts as both the Constituent Assembly that enacts Basic Laws and as the Israeli legislative branch. The Knesset is comprised of several permanent committees and several special committees. Out of the permanent committees, the Constitution, Law, and Justice Committee has jurisdiction to approve proposals for data protection legislation and to approve regulations proposed by the Minister of Justice. Three other permanent committees can have jurisdiction over data protection-related policies, depending on the subject matter of the relevant legislation: 1) the Labour, Welfare, and Health Committee for health-related policies; 2) the Economic Affairs Committee for telecommunication related policies; 3) the Foreign Affairs and Defense Committee for national security-related issues.

Three bodies have been established to aid the Knesset and its Committees during the legislative process. The Knesset Research and Information Center (RIC) provides in-house data, research papers, and background studies about legislation and parliamentary activities. The legislative and legal research branch in the Knesset legal bureau offers legal and professional assistance to the Knesset committees. Lastly, the Council for the



Protection of Privacy submits to the Constitution, Law and Justice Committee an annual report of the Data Protection Registrar, as well as the Council's comments on the report.¹³⁸ The Council also acts as an advisory council to the Minister of Justice on data protection and writes recommendations on proposals for legislation and regulation.

Regulatory agencies:

The data protection sector is regulated by the Privacy Protection Agency (the PPA). The PPA was initially established in 2006 by a government decision as the "Israeli Law, Information, and Technology Authority." In 2017 the government changed its name to the Privacy Protection Agency. The Privacy Protection Agency draws its regulatory authority from the two registrars that comprise it – the Database Registrar, which nationally regulates data protection based on the Data Protection Act, and the Certification Authority Registrar established in accordance with the Electronic Signature Act, 2001-5761. Until 2019, the PPA also housed the Registrar of Credit Data Services, which was found according to the Credit Data Service Act, 5772-2002. Primarily, the PPA has the authority to conduct criminal and administrative investigations and issue market guidelines.

The PPA is comprised of four departments. The Department for Legal Advice and Regulation is responsible for advising on legislative procedures and regulations, setting guidelines, and providing pre-rolling. The Department of Innovation and Policy Development is responsible for identifying trends and activities in the international arena, social and business technological trends and developing innovative regulatory policies. The Department of Public and Government Relations is responsible for promoting education, training, and instruction in the Authority, for making its policy accessible, communication and information, public inquiries, and government relations, and managing the registry of databases. And the Department for Enforcement is responsible for conducting criminal investigations, administrative investigations, audits, collecting and evaluating and managing the forensic laboratory.

Two additional executive bodies have responsibilities over the issues relating to data protection and are relevant to this mapping. First, the Ministry of Telecommunications has regulatory responsibility for the regulation of the telecommunication sector, including the registration of internet service providers. The Ministry of Communications is responsible for setting policy, opening up the communications market to competition and developing communications infrastructures. Second, the Ministry of Health has a regulatory responsibility to ensure the health of the population of Israel. Among others, it has direct responsibility for medical institutes.

Executive bodies:

In addition to the regulative agencies and ministries, the Ministry of Justice is also involved in data protection regulation in three capacities. First, the Ministry houses the PPA, and it has ministerial responsibility for the PPA. Second, the Minister of Justice and not the PPA hold the authority to issue regulations dealing with data protection. The PPA can only interpret the legislation and regulation by issuing guidelines. Second, the Ministry of justice also houses the Attorney General and the Office of Legal Counsel and Legislative Affairs. Consequently, it is involved in the development of all Israeli legal policies. Among the six sub-divisions of the Office of Legal Counsel and Legislative Affairs, the department for legislation is in charge of data protection. Lastly, the Ministry of Justice also houses the Council for the Protection of Privacy. Other than submitting the annual report of the Data Protection Registrar to the Constitution, Law and Justice Committee, the Council

¹³⁸ The Council for the Protection of Privacy is composed of public representatives from civil society, academia, and the private sector.



also acts as an advisory council to the Minister of Justice on data protection and writes recommendations on proposals for legislation and regulation.

Regulatory intermediaries:

The primary regulatory intermediary for data protection in Israel is the Standards Institute of Israel (SII). It is a state-owned corporation responsible for setting standards, as well as certifying organisations, products, and processes. It certifies according to several international and local standards, and specifically regarding data security in the organisation (e.g., the ISO 270XX standards). One of the services that the SII is offering is assessment and certification according to ISO 27799 Health informatics — Information security management in health using ISO/IEC 27002. In addition to the SII, there are few private companies that guide, assess, and certify in accordance with international and Israeli standards.

Regulatees:

Regulatees in the telecommunications sector are comprised of licensed telecommunications companies in different sizes, starting with the two major incumbents: Bezeq The Israeli Telecommunication Corp Ltd. the incumbent telephone company and Hot Telecommunication Systems Ltd. the incumbent cable company. Several telecommunications companies hold a general license for the provision of mobile phone radio services in the RTN method, which include the ability to provide mobile internet services. About 37 companies have a special license to provide internet access services.

Regulatees in the healthcare sector are comprised of licensed hospitals and medical institutions. Though we have focused our mapping only on general hospitals, a variety still exists between them, which might affect the level of compliance and visibility via an informative website. General hospitals can:

Be owned by the government.

Be owned by private actors.

Be operated by a non-profit or an Israeli medical organisation, such as the Hadassah Medical Centers.

Be owned by one of the four health care service providers.

Be administered by a missionary, an Islamic Charitable Society, or a Hasidic dynasty.

Be registered in Israel yet operate in East Jerusalem.

Or, be associated with one of the schools of medicine.

Interest bodies:

Due to the broad definition of regulated organisations under the Israeli Privacy Protection Act, which adopts the European approach to data protection, Israel has several interest bodies that act as repeated actors around issues of data protection. Only a few interest bodies operate around issues of healthcare and telecommunications:

The Israel Insurance Agents Association.

Israel Insurance Union in Israel and the Association of Life Insurance Companies (RA).

The Israeli Medical Association.

Non-judicial appeal or arbitration commission/body

In Israel, the PPA has no authority to settle disputes relating to data protection. The Israeli legal system allows litigants in civil matters to resolve disputes in arbitration or dispute resolution. The State Comptroller can audit the work of the executive and regulatory bodies, and investigate complaints from persons who have



personally been detrimentally affected by the actions of national and public authorities. Also, in healthcare, the Israeli Medical Association has both an ethics tribunal and board.

Sector-specific judiciary branch/courts:

The judicial branch of the State of Israel is comprised of three levels of courts: The Supreme Court, six District Courts, and the Magistrates' Courts. The Magistrates' Courts usually hear cases, including on data protection, of less than 2.5 million shekels and criminal cases of up to seven years. Other cases would be brought in front of the District Courts. A case can also be brought in front of the District Court when the District Court sits as Administrative Court. In recent years, most administrative cases that were brought in front of a district court on issues of data protection were brought in front of the District Court of Tel-Aviv. The Supreme Court, meanwhile, can also decide on cases pertaining to data protection. The Supreme Court can sit as the High Court of Justice empowering it to hear petitions against public bodies and governmental authorities.¹³⁹ The Supreme Court can also act as a court of appeals for the decisions of the District Courts. Lastly, some specialized tribunals and courts, for instance, the Labor Courts, can also have jurisdiction over data protection related cases.

Adjacent bodies:

As for adjacent bodies, it is possible to identify two relevant bodies: First, the Cyber Security Directorate. The Israeli government established the Directorate to take charge of protecting the national cyberspace from cyber threats. It coordinates policy on issues of data and cybersecurity, including regarding issues of critical infrastructure which includes hospitals and telecommunications. Second, the Consumer Protection and Fair-Trade Authority. The authority is responsible for handling complaints and monitoring the implementation of provisions of the Consumer Protection Act.

7.2 The Israeli Financial Regulatory Regime

The Israeli financial regulatory regime has its basis in several sources of legislation. First, Bank of Israel Law, 5770-2010- 2010 deals with the authority of Bank of Israel; Banking (Licensing) Law, 5741-1981 deals mainly with licenses and banking permits; the Banking Ordinance, 1941 which mainly authorized the Supervisor of Banks to regulate Banks. Regarding the activity of banks with securities, the Regulation of Investment Advising, Investment Marketing and Investment Portfolio Management Law- 1995 regulating the practice of investment advice, with the regulator responsible for regulating the field being the Securities Authority. Another major law that is particularly relevant to the field of banking is the Antitrust Law Business- 1988, with the regulator responsible for regulating this issue being the Antitrust Authority. In addition to legislation, the Courts in Israel have been expanding the

The responsibility of the banks and imposed on them broad obligations beyond those specified in the legislation. The most striking example of this is the imposition of a sweeping duty of trust on banks (Plato-Shenar 2006; 2007). One of the justifications for imposing a duty of trust on the banks is their perception as a kind of public institutions that provide the public with essential services. This perception is not unique to Israel but, its frequent application in case law makes it one of the unique features of the Israeli system (Plato-Shinar and Weber 2008).

¹³⁹ For instance, to appeal the decision of the Ministry of Communications (excluding decisions on administrative fines), a decision by the Ministry of Health, or request a decision pertaining for example to the appointment of a Commissioner for the PPA, one needs to appeal to the High Court of Justice



Legislative bodies:

The Knesset, the Israeli Parliament, has only one chamber comprised of 120 members. The Knesset acts as both the Constituent Assembly that enacts Basic Laws and as the Israeli legislative branch. The Knesset is comprised of several permanent committees and several special committees. Out of the permanent committees, two permanent committees can have jurisdiction over financial-related policies, depending on the subject matter of the relevant legislation: 1) the Finance committee; 2) the Economic Affairs Committee.

Regulatory agencies:

The finance sector is supervised by four regulatory entities:

1. The security authority- which was established under the Securities Law-1968, which defines its function as protecting the interests of the investor public.
2. Banking supervision unit located in Bank of Israel- Responsible for the stability of banking corporations, maintaining proper management, and maintaining the fairness of the business relationship between the banks and their customers. Also, credit card companies are restricted to their supervision.
3. The Capital Markets, Insurance, and Savings Authority- Independent authority, responsible for financial stability, consumer protection, promoting competition in the insurance industry. Supervising the fintech companies.
4. Competition Authority- The Competition Authority is responsible for maintaining the principles of competitiveness in the economy and for enforcing the Economic Competition Law. As part of its activities, the Authority supervises restrictive arrangements, monopolies, and mergers, and works against the formation of cartels in the economy.

Executive bodies:

In addition to the regulative agencies and ministries, the Ministry of Finance is also involved in financial regulation. The Ministry promotes economic reforms and structural changes in the financial sector to advise the Government on this issue. Another authority is the central bank which houses the Banking supervision unit. Also, the Israeli Money Laundering and Terror Financing Prohibition Authority, which belong to the Ministry of Finance Ministry, prevent and investigate money laundering offenses.

Regulatory intermediaries:

Few rating agencies serve as regulatory intermediaries for finance-related issues in Israel. Two of them responsible for rating public traded companies, among them the Bank. They publish economic analysis and research on stocks and bonds, with one of their main areas of activity being bond rating. They are supervised by the Security Authority. The other three intermediaries provide business and individual information for credit risk management, credit information, and marketing information: Dan and Bradstreet, Kav-Manhe, and BDI Coface. All intermediaries are private companies.

Regulatees:

Regulatees in the finance sector are comprised of licensed banks and Digital payment company companies (which are mostly owned by banks). There are 24 commercial banks, mortgages, and other business centres in Israel, four of them are international banks. There are 1,510 branches of all the banks in the State of Israel. The Israeli banking market is dominated by five large banking groups, which hold 94% of the total assets of the banking system. The two largest banking groups - Bank Leumi and Bank Hapoalim - alone hold about 58%



of the total assets, a situation that constitutes a duopoly. Another characteristic of the banking system in Israel is the low level of competitiveness.

Regarding digital payment companies. The three major companies: Bit, Paypal, and Paybox belong to Bank Hapoalim, Leumi, and Discount respectively. Another company is Wepay. The business of payment services is slowly developed in Israel and compared to other countries, Israel is lagging behind.

Interest bodies:

Israel has several interest bodies that act as repeated actors around issues of Finance. From the organisations representing businesses, the Bank Association is powerful. Two other institutions that relate more to the securities are The Federation of Israeli Chambers of Commerce (FICC) and The Association of Publicly Traded Companies.

Consumer organisations are considerably weak in Israel. Usually, these organisations are small and also active in a few areas, and not precisely in finance. Among the more common institutions are the Consumer Protection And Fair Trade Authority which is a government agency finance by the economic authority, and other civic organisations such as Lobi99 and The Movement for Quality Government in Israel (MQG).

Sector-specific judiciary branch/courts:

In the past decade, two courts have operated to deal with financial settlements: the District Court of Tel-Aviv and the District Court of Hifa court.

Challenges:

One of the main challenges facing financial regulators is the centralization of the banking system in Israel. The level of centralization of the banking system in Israel is high compared to developed countries. A few steps have been created in the past few years to account for this problem. The major change includes the Separation of credit card companies from banks: following the Strum Committee recommendations', the Knesset passed the law in 2017. The law determined that the two credit card companies would be separated from the Banks - Isracard from Hapoalim and Leumi Card from Leumi. That was one of the major steps included in the banking reforms program ran by Moshe Kahlon.

Another important step was the establishment of public credit data database as part of the credit data service law which was initiated in 2016 and authorized the Bank of Israel to manage the database and to share the data on consumers with private (licensed) companies. This law was initiated instead of the Credit Data Law from 2002.

New in the field of credit and increase competition between banks themselves or between them and other credit providers

Regarding securities, the most important change occurred In 2005, when the Bachar reform in the capital market was carried out to reduce the centralization of the banking system in the capital market. The main points of the reform were to end the banks' ownership of provident funds and mutual funds, to encourage competition in these areas of investment, to increase competition in the field of pension savings, and to increase the diversity of means of financing in the economy to create competition for those offered by banks. Regarding payment services- the barriers in the implementation of digital payment services in Israel has led to discussions about changing the regulatory entity so that the supervision on the fintech companies (among them-payment companies) would change from the Capital Markets, Insurance and Savings Authority to the security authority.



7.3 The Israeli Food Safety Regime

Overview and challenges:

The Israeli food safety regulatory regime is a disaggregated sector, which responsibilities are split between several governmental organisations. The main responsibility of assuring the safety of the food is divided between the agriculture ministry and the health ministry.

Regulatory oversight of food safety is scattered among various agencies. There are four main bodies whose direct responsibility is to take care of food safety. First, the Veterinary Food Service, which is part of the Ministry of Agriculture, supervises eggs, poultry and cattle and its slaughter. Second, the Plant Protection Services, also in the Ministry of Agriculture, is responsible for the safety of the crops. Third, the National Food Service, an arm-reach agency in the Ministry of Health, is responsible for food safety in production and import. Finally, the Department of Environmental Health, also part of the Ministry of Health, oversees food businesses. In addition, the local governance oversees sanitary supervision of food safety. However, the municipalities in Israel differ greatly in the resources available to them, which creates high non-uniformity in the supervision of food safety.

This disaggregation of responsibilities creates a situation where sometime responsibilities are neglected, and no agency takes responsibility. In addition, since these regulatory bodies create regulations with no coordination, the result is a regulatory burden for the market. For smaller food business, this has many severe implications on their easiness and ability to do business. However, and despite the extent of the regulation, food in Israel is less safe comparing to the European union which is evident in the higher number of sickness due to food contaminants. This is mainly due to insufficient enforcement which is due to insufficient number of regulatory supervisors and less enforcement in cases on non-compliance.

Background, actors and reforms:

Historically, Israel has established agriculture councils in most agriculture sectors and for different products, where the farmer themselves acted as regulators. These self-regulatory councils have led a socialist policy in the food sector through various regulatory tools; cultivation licenses, production quotas, statutory export monopolies and fix prices. After a big reform in the 90s, most of these councils have lost of their monopolistic powers, with an exception of the poultry council which still exists as a powerful entity in the food regime in Israel (Kachel and Finkelshtain, 2010). This council is responsible for poultry meat, eggs, and chicks. In this council there are several members who represent various interest groups including eggs cultivators and egg sellers. In addition, members of the Agriculture Ministry and the Finance Ministry, act as representatives of the state in the council. However, for most of the years, the acting Agriculture Minister was a Kibbutz member, affiliated highly with the interests of the farmers and cultivators of Israel. Therefore, it could be said that de-facto, the Ministry of Agriculture served the interests of the farmers. Hence, the Ministry of Agriculture has hesitated to impose regulations in the field of food safety. In addition, it should also be noted that the Ministry of Health is mostly occupied by the regulation of other tasks and is not dedicating sufficient resources for food safety issues (the Ministry of Health employs 33,067 people, of whom only 220 work in food safety).

In the last three years there have been three major reforms in the sector, which enlarged the responsibilities of the actors involved, reduced governmental intervention. These reforms rely much on trust. The first reform, in 2017, has moved most imported processed food to a self-regulation regime, based on pledges and random audits. The second reform, the licensing of businesses reform, created a differential licensing regime for food distributors. This reform reduced the regulatory burden especially for “low risk” businesses. Finally,



the Kosher reform in 2017, has also moved to a self-regulatory tool by allowing importers of kosher food to pledge that the food is kosher, with no need to go through the whole process of Kosher licensing.

It is still soon to know how these reforms will affect the safety of food in the country. Interviews with actors in the Israeli market suggest that perhaps these reforms have moved the burden for businesses from Pre-Market Surveillance to Post-Market Surveillance (after the import). Others suggest that these reforms might have a significant positive impact on the levels of trust within the regime and within the public.

In 2015, a new law was established- “the public health law (food)” which clearly divides the responsibilities of food safety between the Health and the Agriculture Ministers. It was finally made clear that the Agriculture Ministry is in charge of raw food ingredients, and that the Health Ministry is in charge of processed food. In addition, the Agriculture Ministry is officially responsible for regulating import and export of processed poultry and meat. Still, many of the products are in the joint responsibility of both Ministries including: frozen meat, slaughterhouse regulation and supervision and import of vegetable from the west bank.

More importantly, the new law has reformed the regime by defining regulation by product instead of regulation by process (which includes mostly a unified license for growing, distributing etc.). There have been multiple attempts to establish a food safety agency, which will regulate the sector aggregately, though these attempts have failed continuously.

Israel faces additional challenges. First, Israel faces difficulties in trading freely with the neighbor countries, while ensuring the safety of the food, due to foreign affairs and ongoing conflict. This creates “Island economy”, where most of the imported food is imported via air and sea. The extensive shipment times makes it hard to import food with short shelf life, such as eggs and milk. Second, in Israel there are several large minority groups which consume poultry and meat in different Kosher types. This leads to the need to regulate food safety in different operations. In addition, this also limits importation of food. Israel trades with the west bank and Gaza. However, the Military, civil administration and Israel Health ministry are failing to regulate the safety of the imported food (Israel’s Obudsmen report, 2020).

Regulatory agencies:

There is no singular regulatory agency that is in charge of the food safety, despite many attempts to establish one. Instead, there are several executive bodies that serve as regulatory agencies, and in which the responsibilities are divided between them. First, the National Food Service, an arm-reach agency in the Ministry of Health, is responsible for food safety in production and import. Second, the Veterinary Food Service, which is part of the Ministry of Agriculture, supervises eggs, poultry and cattle and its slaughter. Third, the Department of Environmental Health, also part of the Ministry of Health, oversees food businesses and acts throughout the local government system. Fourth, the Plant Protection Services, also in the Ministry of Agriculture, is responsible for the safety of the crops. An additional regulatory body is the Poultry Council which is responsible for quotas, prices, and licenses in the field of chicken and poultry.

Executive bodies:

Many executive bodies work in issues relevant to the food safety. First, the Competition Authority, which is responsible for increasing competition and dismantling monopolies works also on the food market. Second, the Business Licensing Division of the Ministry of the Interior, is responsible for supervising and auditing the licensing processes of food business in the local authorities. Third, the Regional Council Center works with government ministries to represent the needs of the rural authority, including the agriculture interests. Fourth, The Consumer Protection and Fair-Trade Authority. Fifth, the Federation of Local Authorities in Israel: Veterinary Department. Sixth, the Civil Administration in Judea and Samaria. Finally, the Israel Water



Authority is responsible for conserving water resources in Israel and ensuring the quality of the effluent water to maintain the quality of the agricultural crops.

Regulatory intermediaries:

There are several intermediaries to be identified. First, the Standard Institute of Israel, and second, the actors in the Kosher system and especially Badatz "Beit Yoseff", Badatz "Haeda Hacerdit" and the National Kosher administration.

Legislative bodies:

There are several legislative bodies in Israel which work on food safety issues. Three parliamentary committees which include the Economic Affairs Committee, the Labor, Welfare and Health Committee and Internal affairs and Environment Committee. In addition, the supreme Food Council which was established in 2004 and is jointly operated by the Ministry of Agriculture and Rural Development and the Ministry of Health. The role of the Council is to coordinate the policy and implementation actions, enforcement, supervision and control of the Ministries of Health and Agriculture regarding all topics connected with the food chain.

Interest bodies:

Multiple interest groups work in the sector of food safety including: The Israel Vegetables Growers Association; The Israel Fruit Growers Association; the Falcha Workers Union; The Agriculture Union; the Farmers' Federation of Israel; the Manufacturers' Association of Israel which aims to protect local food production in Israel from imports; the field crops workers organisation; the Poultry, Dairy and Crops Councils; the Cattle Breeders Association; the Restaurants and Bars Association; the Israel Hotels Association (IHA); the Federation of Israeli Chambers of Commerce (FICC) which represents the business interests of food corporations; The Moshav movement of Israel and more. In addition, several groups represent animal welfare interests including: SPCA; Animals Now; and Hai Meshek. Finally, the Israel Consumers Council represent the interests of consumers.



8 Mapping the Spanish and Catalan Regulatory Regimes

8.1 The Spanish and Catalan Data Protection Regime

Spain's legislative branch, called the Cortes Generales (Parliament), is bicameral, with a Congress of Deputies (Congreso de los Diputados) and the Senate (Senado). Both chambers are organized in different parliamentary committees, following a similar pattern of topics. The relevant parliamentary committees in both Congress and Senate for the data protection sector are the Committee for Justice (Comisión de Justicia), the Committee for Economic Affairs and Digital Transformation (Comisión de Asuntos Económicos y Transformación Digital) and the Committee for Health and Consumerism (Comisión de Sanidad y Consumo).

There are several relevant laws for the regulative framework of data protection. General data protection in Spain is regulated by the Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights, which implements the General Data Protection Regulation (GDPR) of the European Union to Spanish legislation. The law repeals the previous Organic Law 15/1999 on the Protection of Personal Data. Data protection is regulated at the national level through a national agency with enforcement capacity: the Spanish Data Protection Agency (Agencia Española de Protección de Datos - AEPD). In Spain, the GDPR has meant a shift in the compliance as the previous model was one of formal compliance to the law. The new model is based on proactive responsibility of all the actors involved (Gallardo-Messeguer, 2020).

As for the sub-sectors our study covers, telecommunication companies are subject to Law 25/2007 on the Conservation of Data relating to Electronic Communications and Public Communications Networks. This law obliges operators to keep the data generated or processed in the context of "the provision of electronic communications services or public communications networks, as well as the duty to transfer such data to authorised agents whenever they are required to do so by means of the corresponding judicial authorisation for the purpose of detecting, investigating and prosecuting serious crimes under the Criminal Code or special criminal laws" (ICLG, 2020).

The General Telecommunication Law 9/2014 specifies that telecommunication companies must adopt the appropriate technical and management measures to guarantee the protection of personal data. To this end, the AEPD may examine the measures adopted by the operators and may formulate recommendations on best practices related to the level of security that should be achieved with these measures. The law further specifies how telecommunication companies should deal with security breaches and how infractions are sanctioned. Sanctions are administered either by the Secretary of State for Telecommunications and for the Information Society, the National Commission of Markets and Competition or the Spanish Data Protection Agency, depending on the type and gravity of the infringement.

In the health sector, the legal framework is based on the General Law on Health 14/1986 and the General Law on Public Health 33/2011 that makes reference to the Organic Law on the Protection of Personal Data in what concerns data protection issues. Similarly, the Regulatory Law on Patient Autonomy 41/2002 regulates patient rights and refers to the Organic Law on the Protection of Personal Data for data protection matters.

In the executive branch, several ministries are relevant for data protection regulation. Most importantly, there is the Ministry of Economic Affairs and Digital Transformation (Ministerio de Asuntos



Económicos y Transformación Digital) - specifically, its Secretary of State for Telecommunications and Digital Infrastructures that has sanctioning power. The Ministry of Justice (Ministerio de Justicia) is also relevant for regulation in this sector. This Ministry suggests the presidency of the Data Protection Agency and its associate who are then appointed by the government. Within the Ministry of Health (Ministerio de Sanidad), the Directorate-General of Digital Health and Information Systems for the National Health System is concerned with information and communication technology within the health sector.

As for the judicial branch, the Constitutional Court, proclaimed in its Sentence 292/2000 that the right to data protection is a true fundamental right, autonomous and clearly differentiated from the others that are guaranteed in the same article 18 of the Spanish Constitution. Said judgment establishes that this right: "seeks to guarantee that person a power of control over their personal data, over its use and destination, with the purpose of preventing its illicit traffic and harmful to the dignity and right of the affected person."

Data protection violations can be brought before the judiciary. In fact, the judiciary has been involved in landmark decisions such as v. Google in 2014. Criminal law has to be applied as the last resource after using civil and administrative channels. There are no specific courts for data protection crimes and infractions. Disputes between the Spanish Data Protection Agency and companies are decided by the Administrative Litigation Chamber of the Spanish National High Court (Audiencia Nacional). Appeals can be directed to the Spanish Supreme Court (Tribunal Supremo Español). The State Attorney General holds the highest leadership and representation of the Prosecutor's Office. The Attorney General is independent and acts impartially. Among its functions are those of ensuring respect for constitutional institutions and fundamental rights and public liberties. To this end, the State Attorney General has been cooperating with the Data Protection Agency in order to protect citizens' data privacy.

b) Relevant actors (Spain)

Legislative bodies

The National Parliament discusses legislation regarding data protection and its related areas in committees of the **Senate** (Higher Chamber) the **Congress of Deputies** (Lower Chamber). Legislation and most parliamentary interpellations are handled in:

Committee for Justice

Committee for Economic Affairs and Digital

Committee for Health and Consumerism

Executive bodies

As for executive bodies, three ministries are relevant for regulation on data protection:

The **Ministry of Economic Affairs and Digital Transformation** is responsible for setting the guidelines to improve competitiveness, telecommunications, and the information society. The Ministry is especially responsible for the government's digital transformation and the development and promotion of artificial intelligence. Although the Ministry is not responsible for data protection per se, its role in digital transformation makes it a relevant actor in promoting and complying with data protection through digital means.

Its Secretary of State for Telecommunications and Digital Infrastructures is responsible for the functions of promotion and regulation of the telecommunications sector and audiovisual communication services,



dialogue with the professional, industrial and academic sectors, and inter-ministerial coordination or cooperation and with other Public Administrations regarding said matters. It also has sanctioning power over companies breaching data protection regulation.

The **Ministry of Justice** has, of course, the function of preparing and executing the Government's policy for the development of the legal system. However, it also has an important function within the data protection framework because it suggests the presidency of the Data Protection Agency and its associate who are then appointed by the government.

Within the **Ministry of Health**, the Directorate-General of Digital Health and Information Systems for the National Health System is concerned with information and communication technology within the health sector. Its responsibilities are the development of digital public services, the promotion of digital health and the electronic interoperability of clinical and health information, both nationally and internationally, as well as innovation in data analytics and exploitation information related to health.

Regulatory Agencies

The sector is regulated by the **Data Protection Agency (AEPD)**. Created in 1992, the agency is the public body responsible for ensuring compliance with the Organic Law on the Protection of Personal Data in Spain. It is a public law entity with its own legal personality and full public and private capacity that acts independently of the public Administration in the exercise of its functions.

Its main mission is to ensure compliance with data protection legislation by those responsible for the files (public entities, private companies, associations, etc.) and control their application in order to guarantee the fundamental right to the protection of personal data of citizens. It ensures compliance with the legislation on data protection and control its application (especially, rights of information, access, rectification, opposition and elimination of data). The AEPD carries out its powers of investigation fundamentally at the request of citizens, although it is also empowered to act *ex officio*. It has sanctioning powers against those who process data. It may require corrective measures and authorize international data transfers. It also attends requests and claims from citizens and provide information on the rights recognized by the law. The agency may develop standards and issue recommendations for the application of legal and regulatory provisions.

In the field of telecommunications, it has an explicit mandate to protect the rights and guarantees of subscribers and users in the field of electronic communications. This includes unsolicited commercial communications. It can also receive notifications of eventual security breaches in electronic telecommunications that may affect personal data.

The Agency is statutory and hierarchically independent and is related to the Government through the Ministry of Justice. Additionally, two Autonomous Communities have autonomous bodies responsible for data protection: Catalonia and the Basque Country. Their scope of action is limited to the files of public ownership declared by the autonomous and local administrations of their respective autonomous communities. For the rest of Autonomous Communities, the AEPD is the competent authority.



Regulatory Intermediaries

The **National Commission for Markets and Competition** (Comisión Nacional de los Mercados y la Competencia, CNMC) is the body that promotes and preserves the proper functioning of all markets in the interest of consumers and companies. It is a public body with its own legal personality. It is independent of the Government subject to parliamentary control. The CNMC is responsible for licensing, accreditation and certification, among others of internet service providers.

Interest organisations

Spain has a diverse landscape of interest organisations. There are market-oriented interest organisations of regulatees and professional organisations, as well as consumer associations.

In the telecommunication sector, there are professional organisations like the National Association of Operators and Internet Services, Spainwisp, and the Federation of Installers and Integrators of Telecommunications. These organisations provide a platform for internet service providers and defend their interests. There are also market-oriented interest organisations like the Association of Technology and Communication and the Spanish Association of the Digital Economy that promote the development of the sector. On the other side, there are interest organisations on the consumer side that protect users' interests. Examples for such interest organisations are the Confederation of Consumers and Users, the Organisation of Consumers and Users, the Association of Digital Consumers and Users of Spain, the Association of Media Users, Association of Internet Users, as well as the Spanish Confederation of Cooperatives of Consumers and Users.

In the health sector, there are interest organisations of doctors, hospitals and insurances, such as the Spanish Society of Primary Care Physicians, the Spanish Association of Hospitality, the Spanish Organisation of Hospitals and Health Services, the Spanish Union of Insurance and Reinsurance Entities, the general Council of the Associations of Insurance Mediators, the Business Association of Insurance Mediators, the Spanish Association of Risk and Insurance Management, the Independent Coordination Federation of Insurance Brokers, the Association of Insurance Brokers and the Spanish Association of Insurance Brokers.

More generally oriented interested organisations are the Spanish Alliance of the Privat Healthcare, the Spanish Public Health and Health Administration Society, the General Council of Official Medical Associations in Spain and the Spanish Private Health Alliance. The latter is the largest association for private health in Spain. It groups together almost 1,300 private health entities, among which we find hospitals and clinics, specialized centres, laboratories, health transport companies. Another important organisation is the Spanish Organisation of Hospitals and Health Services. This is a non-governmental, state-level, non-profit Spanish association that represents public and private healthcare centres in Spain made up of hospitals, clinics and other healthcare centres. On the patient side, there is the Spanish Patient Forum that defends patients' interests.

Regulatees

There is a considerable number of internet service providers (ISP) in Spain. For the Spanish mapping, the sample was reduced to ICPs that operate across the national territory. These ICPs differ of course substantially in size and popularity, with the most well-known (and also biggest, in terms of revenue) ICPs being Vodafone, Orange and Telefónica.

The hospital landscape in Spain is also quite diverse. There is a considerable number of private hospitals – some of them belong to the biggest hospitals in Spain. In our sample, we focus on public hospitals, but include



some private ones. We reduced the sample to general (as opposed to specialized) hospitals and made sure to include hospitals from all Autonomous Communities.

Non-judicial appeal or arbitration commission/body

There is no sector-specific ombudsman. However, citizens' complaints may be directed to the **Ombudsman** (Defensor de Pueblo). It is the High Commissioner of the General Courts in charge of defending the fundamental rights and public liberties of citizens by supervising the activity of Spanish public administrations. The Ombudsman is elected by the Congress of Deputies and the Senate, by a three-fifths majority. Its mandate lasts five years and it does not receive orders or instructions from any authority. It performs its functions independently and impartially, autonomously, and according to his criteria. He enjoys inviolability and immunity in the exercise of his office.

Sector Specific Judiciary branch/courts

While there is no sector-specific court, data protection violations can be brought before the judiciary. Criminal law has to be applied as the last resource after using civil and administrative channels. Disputes between the Spanish Data Protection Agency and companies are decided by the Administrative Litigation Chamber of the **Spanish National High Court** (Audiencia Nacional). Appeals can be directed to the **Spanish Supreme Court** (Tribunal Supremo Español). The **State Attorney General** (Fiscal General del Estado) holds the highest leadership and representation of the Prosecutor's Office. The Attorney General is independent and acts impartially. Among its functions are those of ensuring respect for constitutional institutions and fundamental rights and public liberties. To this end, the State Attorney General has been cooperating with the Data Protection Agency in order to protect citizens' data privacy.

c) Relevant actors (Catalonia)

Although not being federalist, Spain is a very decentralized country with important competences being given – in an asymmetric way – to its Autonomous Communities (Comunidades Autónomas, AC). Catalonia is an Autonomous Community with a strong regional identity and considerable amount of self-rule, which is why we to field the survey in this AC.

Legislative bodies

The structure of the Catalan Parliament follows the national one. The relevant committees for data protection regulation are:

Committee for Health

Committee for Justice

Committee for Digital Policy and Public Administration

Executive bodies

As for executive bodies, three ministries are relevant for regulation on data protection:

The **Ministry of Digital Policy and Public Administration** is responsible for implementing and coordinating government policies related to ICT, with the aim of achieving a smart digital society in Catalonia that is sustainable and inclusive. It also oversees the Catalan Cybersecurity Agency, which is responsible for preventing, detecting, responding to and investigating incidents or threats to electronic communications networks and public information systems, and for planning, manage, coordinate and supervise cybersecurity



in Catalonia, minimize damage and recovery time of networks and systems in the event of a cyberattack and collaborate with police forces and judicial authorities.

The **Ministry of Justice**'s ICT department aims to guarantee the alignment of information and communication technologies (ICT) with the strategic and operational objectives of the Ministry and with the ICT policies and strategies of the Catalan government, as well as disseminate and adopt its ICT norms, standards and protocols and cybersecurity.

The **Ministry of Health**'s ICT department aims to guarantee the alignment of information and communication technologies (ICT) with the strategic and operational objectives of the Ministry and with the ICT policies and strategies of the Catalan government, as well as disseminate and adopt its ICT norms, standards and protocols and cybersecurity. It has created the ICT Social Health Foundation (Fundació TIC Salut Social). This agency works to promote the development and use of ICT and networking in the field of health, acts as an observatory of new trends, innovation and monitoring of emerging initiatives, and offers standardization and product approval services. It also offers a data protection officer (DPO) for Catalan hospitals so that these don't have to provide their own DPO.

Regulatory Agencies

The **Catalan Data Protection Authority** is the Catalan equivalent of the Spanish Data Protection Agency. It is an independent body whose mission is to safeguard, within the scope of competences held by the Catalan government, the rights of protection of personal data and access to the information linked to such data. The institution provides advice about what rights exist in this area, how to exercise them and what to do if they are not respected. It also reports and advises on obligations established in the corresponding legislation and oversees entities to ensure they meet these obligations.

Interest organisations

There are also a number of Catalan interest organisations. In the telecommunication sector, there are professional organisations like the Catalan Federation of Telecommunication Installers that represents the telecommunication installation companies of Catalonia and defends and promotes their economic and social interests. The Catalan Association of Compliance promotes the transfer of knowledge between its members in order to achieve a more complete and in-depth view of the regulatory compliance function. There are also market-oriented interest organisations like the Catalan Chapter of the Internet Society that is dedicated to the development of the Internet and with the specific task of concentrating its efforts and actions on particular issues on the Internet. Promotes and disseminates related activities and telematics and telecommunications networks and services. On the consumer side, there are the Association of Consumers and Users in Action in Catalonia, the Organisation of Consumers and Users in Catalonia and the Consumer Union of Catalonia.

In the health sector, there are interest organisations of doctors, hospitals and insurances, such as the Catalan Hospital Union and the Catalan Association of Health Entities. The Catalan Hospital Union, for example, also helps its members by providing expertise on the implementation of the newest data protection regulation. On the patient side, there is the Catalan Association of Patient Safety that defends patients' interests.



Regulatees

For the Catalan sample, we considered ISP that operate within the Catalan territory, but not state-wide. Due to the limited number of such regional ISPs, we included all of them. As to hospitals, we restricted our samples to Catalan hospitals and included both private and public general hospitals.

d) Major debates/crises

One of the major legal cases in the Spanish history of data protection regulation is that of Google Spain SL, Google Inc. v the Spanish Data Protection Agency; and an individual plaintiff. It is a decision by the Court of Justice of the European Union (CJEU). It held that an Internet search engine operator is responsible for the processing that it carries out of personal information which appears on web pages published by third parties (BBC 2020). The outcome of the ruling is that an Internet search engine must consider requests from individuals to remove links to freely accessible web pages resulting from a search on their name.

As in other member states, the introduction of the European Data Protection Regulation (RGPD) was a major milestone in Spanish data protection regulation, which has to be applied since the end of May 2018. In Spain, the RGPD has meant a change of focus in the way to comply with the new obligations, since it has gone from a model based on the formal compliance of a law (the LOPD of 1999) to a model of proactive responsibility, in which it is not only about creating the conditions that allow adequate compliance with the regulations; but also about being able to demonstrate it if necessary (Gallardo-Messeguer, 2020).

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8.2 The Spanish and Catalan Financial Regime

Spain presents a fragmented structure for financial regulation, that has not changed substantially in the last 30 years, despite the policy pitfalls, tensions, and multiple banking crisis that occurred during this period. As to the regulatory framework, Spanish regulatory system governing financial institutions largely mirrors the legal framework in other EU Member States. Spanish regulation and supervision of the financial sector seeks as a general goal "to guarantee the correct functioning of its markets and to protect the consumers of financial services" (Royo, 2014). The main actors governing the activities of financial markets and institutions in Spain are the Government (as represented by the Ministry of Economy) and the Parliament, as the more relevant ones. As for supervisory and regulatory level, the most important entities are the Bank of Spain and the National Stock Market Commission (Comisión Nacional del Mercado de Valores, CNMV) (Royo, 2014). As for banking and securities, considering micro-prudential and conduct-of-business regulation, the abovementioned actors are the most relevant ones. FinTech companies are also included in their regulatory scope. They are regulated by the Royal Decree 19/2018 which nurtures from the Law 16/2009 on payment services as well as different EU directives that have led to the creation of the Single Euro Payments Area. Under the new law, the Bank of Spain is responsible for supervising the activities of FinTech companies in banking services, while CNMV oversees non-credit FinTech firms.



The most important crisis of the finance system in Spain since the 1980s occurred in 2011 when a large number of savings banks became bankrupt as they were unable to maintain capital ratios according to European directives, as a delayed effect of the housing bubble, and the banking crisis succeeded one after another in the period 2010-2012. The situation led the Spanish government to request up to €100 billion from the European Stability Mechanism (ESM) to rescue these banks, and to sponsor and finance several mergers and acquisitions, while in some cases acquiring assets and core capital of failed saving banks. In this context, some conditionally was introduced (by the UE) to adjust the regulatory framework in Spain. As a consequence the supervision of the Spanish financial system was put under the guidance of the so-called financial troika formed by the International Monetary Fund, the European Commission and the European Central Bank, and (Jordana 2014, EC 2012).

b) Relevant actors (Spain)

Executive bodies

The Ministry of Economic Affairs and Digital Transformation is the regulator of insurance and pension funds, with a dedicated Direction General, and still has some remaining responsibilities for financial/banking regulation, on the some issues related to macro prudential area, but also on consumer issues and banking's private foundations. Under the Ministry, the Directorate General for Insurance and Pensions Funds (DGSFP) is tasked with regulating the insurance and pensions sub-sector. Important bodies that are under the responsibility of the Ministry are:

Commission for the Prevention of Money Laundering and Monetary Offences

([CPBC](#)) which is responsible for promoting and coordinating measures for the prevention of money laundering, as well as the resolution of disciplinary proceedings for non-compliance with prevention obligations.

The Executive Service of the Commission for the Prevention of Money Laundering and Monetary Offences ([SEPBLAC](#)) which is under the CPBC and it is the Spanish Financial Intelligence Unit with supervisory authority in relation to the prevention of money laundering and terrorist financing.

There are other bodies organically linked to the Ministry but governed by different actors:

The Executive Resolution Authority (FROB) is the authority responsible for managing the process of resolution of credit institutions and investment services firms in the executive phase in Spain. It is integrated into the European network of authorities led from Brussels by the Single Board Resolution (JUR). The governing board has representatives from the Bank of Spain, the CNMV and the government.

The Macroprudential Authority Financial Stability Council (AMCESFI) is a collegiate body attached to the head of the Ministry of Economic Affairs and Digital Transformation, participated by high-level representatives of said Ministry and of the three authorities with sectoral responsibilities for regulation and prudential supervision of the system Spanish financial institution: the Bank of Spain, the National Securities Market Commission (CNMV) and the General Directorate of Insurance and Pension Funds (of the Ministry).

Legislative bodies

The National Parliament discusses legislation regarding finances (banking, micro-prudential regulation and fintech in a commission in the Senate (Higher Chamber) and a commission in the Congress of Deputies (Lower Chamber). Legislation and most parliamentary interpellations are therefore handled in:

Congress of Deputies

Commission for Economic Affairs and Digital Transformation



Senate

Commission for Economic Affairs and Digital Transformation

Regulatory bodies

[National Securities Market Commission](#) (CNMV)

Its objective is to ensure the transparency of the securities markets and the correct formation of prices in them, as well as the protection of investors. The action of the CNMV as a control body focuses mainly on companies that issue securities to be placed publicly in the primary market, the secondary securities markets and those that provide investment services.

[Bank of Spain \(BdE\)](#)

The BdE is the body that acts as the national central bank and, as the supervisor of the Spanish banking system together with the European Central Bank. The Bank of Spain supervises the solvency and compliance with the specific regulations of banks, savings banks, credit cooperatives, branches of foreign credit institutions, financial credit institutions, electronic money issuers, reciprocal guarantee and re-guarantee companies, currency exchange establishments and appraisal companies. Its supervisory role increased after the 2013-2014 crisis, because of the EU resolution mechanisms and transfer of wider responsibility from the Ministry of Finance. Regulatory powers of the BdE include micro-prudential and conduct of business regulation.

Interest organisations

The interest organisations (market-oriented) representing regulatees in this policy sector are:

Institute of Accountants and Auditors (ICAC)

Spanish Bank Association (ABA)

Spanish Mortgage Association (AHE)

National Association of Lending Institutions (ASNEF)

Spanish Confederation of Savings Banks (CECA)

National Union of Credit Cooperatives (UNACC)

Industry Association of Insurance (UNESPA)

Regulatees

The most important regulatees are the so-called 'Big Three' which represent the most important private Spanish banks: Santander, Banco Bilbao Vizcaya Argentaria (BBVA), and Caixabank (*La Caixa*). In general lines, the financial regulatees in Spain are (Tomillo and González, 2020):

Spanish Official Credit Institute (*Instituto de Crédito Oficial*) (ICO)

Banks, saving banks and credit co-operatives.

Electronic money entities (e.g. credit financial establishments, branches of foreign entities, payment institutions).

Investment firms (e.g. brokerage companies; broker dealers; portfolio management companies)

Management companies (e.g. management companies of collective investment schemes; management companies of closed-ended type collective investment entities; securitisation fund management companies; and pension fund management companies)-

Collective investment schemes (e.g. financial and non-financial schemes; investment companies and investment funds; and open-ended and closed-ended type schemes).



Closed-ended type collective investment schemes (e.g. venture capital entities including small and medium-sized enterprise (SME) venture capital entities; closed-ended type collective investment entities; European venture capital funds; and European social entrepreneurship funds).

Insurance and reinsurance companies and insurance intermediaries,

Others, such as mutual guarantee societies, counter-guarantee societies and valuation companies.

Sector Specific Judiciary branch/courts

There are not specialized courts on finance regulation in Spain, and the lawsuits should employ the general circuit, up to the Supreme Court. However, some local and regional courts specialize in particular economic topics that might have an impact upon finance litigation (i.e., mortgages, trademarks, competition). In the Spanish Supreme Court, there are different sections, as the section for civil conflicts, or the social one (Mejia 2020).

Relevant actors

Regional governments in Spain (autonomous Communities) had some regulatory power regarding the establishment and operating activity of saving banks there were active in their territories. However, after the 2012 crisis, most saving banks disappeared, and those remaining were include in the general regulatory framework in most cases. So, the regulatory capacities of regions in the savings banks area collapsed, and powers were assumed by the national regulatory and the Spanish government. This is the reason we did not identify any core actor in the finance area for the Catalan case.

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8.3 The Spanish and Catalan Food Safety Regime

This policy sector follows the European premises 'from farm to fork' where it seeks to follow food's chain of production, distribution, and consumption. At the national level is mainly responsible for setting the legal framework as well as coordinating controls, international relations, and transposing EU instruments (Palau, 2009). The 17 Autonomous Communities (regions) and the two Autonomous Cities may assume through their executive and legislative bodies some competences regarding food safety (mainly planning and implementation). However, they must respect the framework and coordinating powers allocated at the national level (Bourges et al. 2014). At the regional level, the management of their respective competences is done through regional ministries which to a large extent mirror those at the national level.



Spain has a legal framework induced from EU legislation in Food Safety at the start of the 21st century. The 2001 Spanish Food Law is a literal transposition of the European one (Todt, 2007). Most of the legislation is contained in the [Spanish Food Safety Agency \(AESAN\)](#)'s webpage. According to the law, Spain has to draft quinquennial plans for official control of the food chain. The last one is the 2015-2020 [National Plan for Official Control of the Food Chain \(PNCOCA\)](#). This document guides the enforcement of the controls in this policy sector according to the national legislation and the distribution of competences across different levels (see the Executive bodies below).

b) Relevant actors (Spain)

Executive bodies

The competences on the official control of the food chain are under the responsibility of three Ministries: Ministry of Health; Ministry of Agriculture, Fisheries and Food, and Ministry of Consumer Affairs. Control comprises activities related to rules and guidelines related to food and feed safety. All three develop coordinating functions, except for border control which is entirely under their responsibility. Planning and implementation of the national controls are under the responsibility of the Autonomous Communities ([Plan Nacional de Control Oficial de la Cadena Alimentaria](#)).

Specifically, the ministries are responsible for:

Official control in primary production and food and feed quality (Ministry of Agriculture, Fisheries and Food).

Official control of the subsequent phases of primary production (Ministry of Consumer Affairs). Under their attributions, the Ministry is responsible for the control system for food establishments and food produced or marketed in the internal market with repercussions on food security. It is also responsible for the food control system made available to the consumer without repercussions on food safety

Official control of goods for human use or consumption from third countries (Ministry of Health)

The executive work is carried out by General Directorates or Secretariat ascribed to some of the abovementioned ministries but also to the Ministry of Ecological Transition and the Ministry of Science. Accordingly, there are two directorates and one secretariat with competences in the area of food safety.

General Secretariat of Agriculture and Food - Ministry of Agriculture, Fish and Food.

It is responsible for the Common Agricultural Policy (PAC), rural development policy, irrigation policy and the development and coordination of multilateral relations in the framework of agri-food policies, innovation in the agricultural, food and rural sectors, and the food system.

General Directorate of Public Health, Quality, and Innovation - Ministry of Health

It is the directive organ of the Department that carries out the functions concerning public health, interterritorial coordination, high inspection, sanitary planning, organisation of the sanitary professions and development and execution of the pharmaceutical policy. It is responsible for the elaboration of information systems and the promotion of health strategies and quality programs in the National Health System, and the pertinent actions in the areas of food safety for human consumption, including nutrition and quality aspects with an impact on health; the security of the food chain, covering all its phases; as well as the promotion of consumer policy through the proposal of regulation, within the scope of state powers, that affects the protection and promotion of the rights of consumers and users, the establishment and promotion of effective procedures for the protection of the same, the interterritorial institutional cooperation in the matter, as well as the promotion of the associations of consumers and users and the support to the Council of Consumers and Users.



General Directorate for Quality and Environmental Assessment and the Natural Environment (Ministry of Ecological Transition)

The GD is responsible for the conservation of the Natural Environment and Biodiversity of the defunct General Directorate of Natural Environment and Forest Policy, counting on its management with the General Sub-directorates of Waste, Air Quality and Industrial Environment, Environmental Assessment and Natural Environment. It is a member of AESAN's Institutional Commission.

Subdirector General for Applied Services, Training and Research - Carlos III Health Institute (Ministry of Science and Innovation).

In Spain, these bodies tend to be formed by different state actors that work with the agri-food sector. They tend to lend support to the different industries in this area. The most relevant ones are:

Food Information and Control Agency (AICA). AICA is attached to the Ministry of Agriculture, Food and Environment, through the General Secretariat of Agriculture and Food, of measures to improve the functioning of the food chain, in order to control the rights and obligations established in the regulatory framework.

Spanish state agricultural insurance body (ENESA). This institution is dependent on the Ministry of Agriculture, Fisheries and Food through the Undersecretariat of the Department, acts as a coordinating and liaison body for the administration for the development of agrarian Insurance.

Spanish Agrarian Guarantee Fund (FEGA). FEGA is an autonomous body attached to the Ministry of Agriculture, Fisheries and Food through the General Secretariat of Agriculture and Food, whose main mission is to make the EAGF (European Agricultural Fund for Agricultural Guarantee) and EAFRD (European Agricultural Fund for Rural Development) Common Agricultural Policy (CAP) funds.

State Society of Agrarian Infrastructures (SEIASA). SEIASA, belongs to the Ministry of Finance and Public Function and is an instrumental company of the Ministry of Agriculture, Fisheries and Food, under the General Directorate for Rural Development, Innovation and Forest Policy.

Centre for Technical Farming and Food of Lugo (CETAL). The Lugo-CETAL Agro-Food Technology Center, FSP, is a state-owned public foundation whose governing body is the Board of Trustees, which is chaired by the Ministry of Agriculture and Fisheries, Food and Environment Ambient.

Legislative bodies

The National Parliament discusses legislation regarding food safety and its related areas in two commissions in the Senate (Higher Chamber) and two commissions in the Congress of Deputies (Lower Chamber). Food safety is a part of the policy domain of public health and agriculture and fishing. Legislation and most parliamentary interpellations are therefore handled in:

Senate

Commission of Agriculture, Fishing and Nutrition

Commission of Health and Consumption

Congress of Deputies

Commission of Agriculture, Fishing and Nutrition

Commission of Health and Consumption

Regulatory agencies

The sector is regulated by the Spanish **Agency for Food Safety and Nutrition (AESAN)**. AESAN is a regulatory agency with formal autonomy to promote food safety and guarantee objective information to consumers



and economic agents of the Spanish agri-food industries. It has risk-assessment, risk-management and communication tasks. The agency controls the food supply as well as the entire chain of production, distribution, and consumption as well as coordination with Autonomous Communities (regions) (Todt, et al. 2007). The agency is an autonomous body organisationally attached to the Ministry of Consumption. It is made up of more than 190 people. The agency has two bodies connecting it with other state and non-state actors.

Institutional Commission

The Institutional Commission is the body of the Agency in charge of establishing effective coordination and cooperation mechanisms between the Public Administrations with competences in matters of food security and nutrition. Therefore, it exercises inter-territorial and inter-departmental coordination functions in these areas of action of the Agency.

Advisory Council

The Advisory Council is the body for the active participation of society in matters related to food security and nutrition.

Interest organisations

Different regulatees are represented by interest organisations in areas related to food safety. Interest organisations can be divided in those representing consumers, bio-medical actors (e.g. physicians, veterinarians, biologists, agricultural engineers) and production, transformation, distribution and catering sectors (e.g. supermarkets, hospitality firms). In fact, relevant interest organisations have advisory status before the AESAN. The ones represented before the AESAN are:

Federation of Consumers and Independent Users (FUCI)

The Spanish Confederation of Consumer and User Cooperatives (HISPACOOOP)

The Organisation of Consumers and Users (OCU)

Small Farmers Association (UPA)

Business Association of Cultivated Sea Products (APROMAR)

General Council of Medical Associations

General Council of the Association of Official Pharmacists

General Council of the Association of Spanish Veterinarians

General Council of the Official Associations of Industrial Engineers

General Council of the Official Association of Biologists

General Council of the Official Association of Spanish Chemists

Agrarian Association of Young Farmers (ASAJA)

Organisation of Farmers and Ranchers Rural Initiative (COAG-IR)

Spanish Federation of Hostels and Catering (FEHR)

National Association of Medium and Large Sized Distribution Companies (ANGED)

Spanish Federation of Associations of Fruit and Vegetable Growers/Exporters (FEPEX)

Spanish Association of Distributors, Self-Service Stores and Supermarkets (ASEDAS)

Spanish Federation of Associations of Transformation Industries and Traders of Fish and Agricultural Products (FEICOPESCA)

Multi-sector Business Association of Food and Drinks (AME)



Regulatees

There is a considerable number of regulatees that participate in poultry production, processing and distribution, such as those working on slaughter and distribution of poultry meat, egg production and marketing, poultry distribution and wholesalers, manufacture of feed and sale of chicken meat, among others. In addition, our mapping also include regulatees participating in the production, processing and distribution of a wide range of fruits and vegetables, such as those working on marketing of agricultural products; production of cereals; cultivation of fruit and vegetables, collection; storage, conservation and packaging of fruits and vegetables; and manufacture and sale of fruits and vegetables; among others.

Non-judicial appeal or arbitration commission/body

Disputes or non-compliance with food safety regulation can be treated through the general directorates of consumption in each one of the Autonomous Communities and the Municipal Consumer Information Offices. They can also be placed by the consumers and users' associations as well as the Consumer Arbitration Boards. The compliance of food safety regulations is established in the National Plan for Official Control of the Food Chain (PNCOCA).

Sector Specific Judiciary branch/courts

There are not specialized courts on food safety regulation in Spain, and the lawsuits should employ the general circuit.

c) Relevant actors

Legislative bodies

Catalan Parliament (Committee of health)

Catalan Parliament (Committee of Agriculture, Livestock, Fisheries and Food)

Executive bodies

The competences on the official control of the food chain are under the responsibility of two regional Ministries (Departaments): Ministry of Agriculture, Livestock, Fisheries and Food and Ministry of health.

Ministry of Agriculture, Livestock, Fisheries and Food This regional ministry is responsible for proposing and carrying out the regional government policy on agricultural, livestock and fishery resources, food safety, among others.

Ministry of health. This executive body performs, among others, following functions: a) To establish the guidelines and priorities in public health, in accordance with the indications of the Health Plan of Catalonia, and to coordinate and supervise their implementation and execution; and b) To promote and coordinate the process of elaboration, evaluation, monitoring and updating of the Food Safety Plan.

IRTA - Institute of Agrifood Research and Technology. IRTA is a research institute owned by the Government of Catalonia ascribed to the Department of Agriculture. It is regulated by Law 04/2009, passed by the Catalan Parliament on 15 April 2009, and it is ruled by private regulations.



Public Health Agency of Catalonia. The Catalan Public Health Agency (ASPCAT) is responsible for both the promotion and protection of health, and the prevention and management of epidemiological and food alerts.

Prodeca - Promoters of Catalan Ailments. State-owned company created in 1986 as part of the Regional Ministry of Agriculture, Livestock, Fisheries and Food (Regional Government of Catalonia).

Catalan Agency for Health Quality and Assessment (AQuAS). The AQuAS is a public law entity attached to the Department of Health of the Generalitat de Catalunya that acts in the service of public policies and is subject to private law.

Regulatory agency

Catalan Agency of Food Safety. L'Agència Catalana de Seguretat Alimentària (ACSA) is a specialized area of the Public Health Agency of Catalonia, whose purpose is to obtain the maximum degree of food safety in Catalonia, handling the following lines of work: the evaluation and communication of risks for health related to food; support for the coordination of the actions of the competent Catalan public administrations in matters of food safety; promotion of collaboration between public administrations, universities and research centers, industrial sectors and consumer and user organisations; strategic planning and monitoring of the food safety situation in Catalonia.

Major debates/crises

Spain has experienced several major food safety crises that has contributed to the development of legislation but also to the creation of protocols to act in crisis moments. The last major crisis was related to the 2011 E.coli outbreak when Spanish vegetables were initially targeted as being the carriers of the pathogen (Jordana and Triviño-Salazar, 2020). This crisis as the BSE or the dioxin ones had European-wide implications that impacted Spain. However, we can go back to the 1980s when the issue started being politicized in the country due to the infamous crisis derived from the consumption of toxic oil sold as olive oil which killed over 900 people due to the toxic oil syndrome.

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9 Mapping the German Regulatory Regimes

9.1 The German Data Protection Regime

Relevant National Legislation

Federal Data Protection Act (orig. Bundesdatenschutzgesetz (BDSG) - The Federal Data Protection Act (BDSG) regulates data protection in Germany and provides instructions to public and non-public bodies on the collection and processing of personal data.

Regulations, e.g., on data to be stored under the Federal Criminal Police Office Act, Federal Cancer Registry Data Act. (orig. Verordnungen z.B. über die nach Bundeskriminalamtgesetz zu speichernden Daten, Bundeskrebsregisterdatengesetz.)

State data protection law regulating the work of public bodies (each state has its own), relating to the states of specific interest that are Baden-Württemberg, Berlin, Sachsen-Anhalt):

State Data Protection Act Baden-Württemberg (orig. Landesdatenschutzgesetz (LDSG) Baden-Württemberg)

Berlin Data Protection Act (orig. Gesetz zum Schutz personenbezogener Daten in der Berliner Verwaltung (orig. Berliner Datenschutzgesetz - BlnDSG))

State Data Protection Act Sachsen-Anhalt (orig. Gesetz zum Schutz personenbezogener Daten der Bürger (orig. Datenschutzgesetz Sachsen-Anhalt - DSG LSA))

Area-specific state laws and regulations (either integrated into the individual ordinances and state laws or separated, such as in the North Rhine-Westphalian Health Data Protection Act)Anordnung über den kirchlichen Datenschutz

EKD Data Protection Act (orig. EKD-Datenschutzgesetz)

Telecommunications Act (orig. Telekommunikationsgesetz)

Telemedia Act (orig. Telemediengesetz)

Other area-specific data protection regulations exist, for example, in the German Banking Act and Money Laundering Act, the Telecommunications Monitoring Ordinance, etc.

Overview of Supervision:

Federal government - At the federal level, **the Federal Commissioner for Data Protection and Freedom of Information (BfDI)** (orig. Bundesbeauftragte für den Datenschutz und die Informationsfreiheit (BfDI)) is an independent supervisory body responsible for monitoring data protection at federal public bodies and at companies in the telecommunications and postal services sectors (sections 21 and 24 of the Federal Data Protection Act (BDSG)).

State - For non-public bodies, such as companies, the supervisory authorities of the individual federal states, respectively the **State Commissioner for Data Protection (LfD)** (orig. Landesbeauftragte für den Datenschutz (LfD)), are responsible for monitoring compliance with the BDSG and other regulations on data protection (Section 38 (1) BDSG). At the request of the authority, non-public bodies must provide information without delay (Section 38 (3) BDSG). Furthermore, the supervisory authorities are authorized to enter properties and business premises during business hours and to conduct audits and inspections there (Section 38 (4)). In the event of violations, the authorities may order measures to be taken to remedy the situation or impose periodic penalty payments.

Companies - In addition to the state supervisory authorities at federal and state level, **company data protection officers** are to ensure compliance with the legal requirements. Since the resources of the state supervisory authorities are limited, a two-tier system was designed here and the state control at the company level was supplemented by self-monitoring. The task of a company data protection officer, who can also be



appointed externally, is to ensure compliance with data protection regulations (Section 4g (1) BDSG). Regardless of whether the data protection concerns are those of the employer or the employees, the institution of the data protection officer is a suitable first point of contact for assessing data protection risks. In Germany, a total of approximately 2.000 hospitals (~500.000 beds) are counted of which slightly less than 40 % are private. The corresponding umbrella association is the German Hospital Federation (orig. Deutsche Krankenhausgesellschaft e.V.).

Relating to the internet providers, beyond to the big ones, there is a large number of smaller regional providers that are represented by, e.g., eco Association of the Internet Industry which is the largest affiliated association in Europe.

Debates, Challenges, Crises and Reforms

Below you find some data protection scandals in – and also originating in (thus not Facebook, Cambridge Analytica, Google Plus, Marriott etc.) - Germany since 2010.

2012 – Illegal trade in patient prescriptions. With the data, pharmaceutical companies can track which doctor's office prescribed which drugs to which patients.

2013 - Pharmacy data center sells patient data to market research firm with inadequate encryption

2015 – DAK passes on patient data. The health insurance company DAK passes on confidential data of chronically ill patients to a company.

2018 - The social and dating website Knuddels.de reported a data breach of 1.87 million username and password combinations and 800,000 user email addresses in September.

2019 - Data scandal in the Bundestag. Data on around 1,000 former and current politicians and people in public life was published illegally.

2019 - Confidential health data freely available on the web. In Germany alone, at least 13,000 sets of confidential patient data were suddenly freely available on the Internet.

As of May 25, 2018, the redrafted BDSG supplements the directly applicable Regulation (EU) 2016/679 (General Data Protection Regulation) with the areas in which the EU Regulation leaves the member states room for maneuver. In addition, the BDSG implements significant parts of Directive (EU) 2016/680 (Data Protection Directive Police and Justice).

Some Current Debates:

Corona-App and data protection

General balancing of data protection vis-à-vis Covid-19 measures (Relaxing data protection for better pandemic response?)

Introduction of the electronic patient file (ePA)

Data retention: "It is incomprehensible that one year before the Bundestag elections, pending laws in the area of telecommunications are planned in a fast-track procedure that contradict the line of the ECJ (BfDI)."



9.2 The German Financial Regime

Relevant National Legislation

Legal basis of financial supervision - List of the most important laws for BaFin's supervisory activities (Source: BaFin).

Credit Institutions Reorganisation Act

Kreditinstitute-Reorganisationsgesetz (KredReorgG)

Shielding law

Abschirmungsgesetz

Winding-up Mechanism Act

Abwicklungsmechanismengesetz (AbwMechG)

Retirement Provision Contracts Certification Act

Altersvorsorgeverträge-Zertifizierungsgesetz (AltZertG)

Investor Compensation Act

Anlegerentschädigungsgesetz (AnlEntG)

Building savings bank act

Bausparkassengesetz (BauSparkG)

Company Pension Act

Betriebsrentengesetz (BetrAVG)

Stock Exchange Act

Börsengesetz (BörsG)

Money Laundering Act

Geldwäschegesetz (GwG)

Law on Private Equity and Venture Capital Companies

Gesetz über Unternehmensbeteiligungsgesellschaften (UBGG)

High Frequency Trading Act

Hochfrequenzhandelsgesetz

Capital Investor Model Proceedings Act

Kapitalanleger-Musterverfahrensgesetz (KapMuG)

German Banking Act

Kreditwesengesetz (KWG)

Mortgage Bond Act

Pfandbriefgesetz (PfandBG)

REIT Act

REIT-Gesetz (REITG)

Restructuring and Winding-up Act

Sanierungs- und Abwicklungsgesetz (SAG)

Asset Investment Act

Vermögensanlagengesetz (VermAnlG)

Insurance Tax Act

CRD IV Implementation Act

CRD-IV-Umsetzungsgesetz

Depotgesetz (DepotG)

Deposit Guarantee Act

Einlagensicherungsgesetz (EinSiG)

First Financial Market Amendment Act

Erstes Finanzmarktnovellierungsgesetz (1. FiMaNoG)

Financial Services Supervision Act

Finanzdienstleistungsaufsichtsgesetz (FinDAG)

Financial Market Adjustment Act

Finanzmarktanpassungsgesetz (FMAnpG)

Financial Stability Act

Finanzstabilitätsgesetz (FinStabG)

Financial Conglomerates Supervision Act

Finanzkonglomerate-Aufsichtsgesetz (FKAG)

Financial Market Stabilization Fund Act

Finanzmarktstabilisierungsfondsgesetz (FMStFG)

Trade regulations

Gewerbeordnung (GewO)

Capital Investment Code

Kapitalanlagegesetzbuch (KAGB)

Retail Investor Protection Act

Kleinanlegerschutzgesetz

UCITS-V Implementation Act

OGAW-V-Umsetzungsgesetz

Compulsory Insurance Act

Pflichtversicherungsgesetz (PflVG)

Restructuring Fund Act

Restrukturierungsfondsgesetz (RStruktFG)

Implementation Act for the Transparency Directive Amendment Directive

Umsetzungsgesetz zur Transparenzrichtlinie-Änderungsrichtlinie

Insurance Supervision Act

Versicherungsaufsichtsgesetz (VAG)

Insurance Contract Act



Versicherungsteuergesetz (VersStG)

Securities Trading Act

Wertpapierhandelsgesetz (WpHG)

Securities Acquisition and Takeover Act

Wertpapiererwerbs- und Übernahmegesetz (WpÜG)

Versicherungsvertragsgesetz (VVG)

Securities Prospectus Act

Wertpapierprospektgesetz (WpPG)

Payment Services Supervision Act

Zahlungsdiensteaufsichtsgesetz (ZAG)

Overview of Supervision:

With the creation of the European System of Supervisors (SSM), the European Central Bank (ECB) was entrusted with the direct supervision of the significant banks and banking groups (so-called significant institutions) in the respective member states of the euro area.

In principle, the national supervisory authorities remain responsible for less significant institutions.

The supervision of credit and financial services institutions is exercised by the **Federal Financial Supervisory Authority** in cooperation with the **Deutsche Bundesbank** (§ 6 Abs. 1 und § 7 Abs. 1 KWG).

The head office is the point of contact for banking supervision issues for all companies located in the respective federal state.

The Banking and Financial Supervision Regional Division is divided into "Ongoing Supervision" units and "Banking Audits" units.

The "Ongoing Supervision" units evaluate the notifications and reports submitted by the institutions, e.g. on significant organisational changes, the structure of the lending business, capital adequacy, and so on. Furthermore, the annual financial statements of the institutions, including the associated audit reports pursuant to Section 26 of the German Banking Act (KWG) and special audit reports, are analyzed here. The results and assessments are then forwarded to the German Federal Financial Supervisory Authority (BaFin), which bases its banking supervisory measures on them. In addition, regular supervisory meetings are held with the managers of the supervised institutions. Ongoing supervision also supports BaFin in the prosecution of unauthorized banking and financial services transactions.

The "Banking Audits" units are responsible for conducting the German supervisory authority's own banking audits. These include, in particular, the assessment of the institutions' adequate capital resources and risk management procedures on the basis of the Minimum Requirements for Risk Management (MaRisk). In addition, internal bank rating procedures, market risk models and advanced measurement procedures in the area of operational risk are reviewed if and to the extent that the institutions have submitted corresponding applications for approval to BaFin. In addition, audits in accordance with the German Investor Compensation Act (AnlEntG) are carried out at financial services institutions.

Companies that are affiliated with electronic payment are on the rise. Today, there is more than 50 trillion € annual cashless payment. The entire banking sector includes more than 1.700 in Germany registered banks and savings banks that are represented by large associations such as the Federal Association of German Public Sector Banks and the private counterpart that is the Federal Association of German Banks.

Debates, Challenges, Crises and Reforms

There is a large number of scandals to be found in the finance sector in Germany since 2010. Some of them are listed below:

Wirecard – Scandal (accounting scandal)

Wirecard – Implications: The case of Wirecard AG has shown that the current system of balance sheet controls for listed companies in Germany needs to be improved. To this end, the Federal Ministry of Finance



and the Federal Ministry of Justice and Consumer Protection (BMJV) presented an action plan on October 7 to strengthen financial reporting and financial market supervision.

Cum-Ex-Skandal / Clearstream (<https://www.welt.de/wirtschaft/article209965747/BaFin-Keine-Clearstream-Untersuchung-wegen-Cum-Ex-Geschaeften.html>)

FinCEN-Files, money laundering (<https://www.dw.com/de/fincen-files-wenn-die-aufsicht-der-banken-versagt/a-55005217>)

Over the past decades, the complexity of financial products has increased extremely, while the economic benefits of many of these products have remained dubious. The level and distribution of the risks assumed have been increasingly difficult to assess not only for supervisors but also for the financial market players themselves.

Regulation on Markets in Financial Instruments („MiFIR“)

Second Directive on Markets in Financial Instruments („MiFID II“)

EU Rating Regulation of 2013 („CRA III“)

...

Current challenges (Source: Bundesbank)

Digitization as a challenge and an opportunity. New competitors, digitized banking processes ...

Challenges posed by the Brexit

Joint deposit insurance

What has Germany achieved to prevent a major financial crisis? (Source: BMF)

Regulation and supervision of rating agencies: The German Implementation Act for the EU Rating Regulation, the core elements of which are mandatory registration of rating agencies in the EU, avoidance of conflicts of interest, better rating quality, improved transparency and internal governance structure, came into force back in June 2010. As of July 1, 2011, the new European Securities and Markets Authority (ESMA) will be responsible for the supervision of credit rating agencies.

framework for compensation systems: Compensation structures in the financial sector also contributed to the financial crisis. They were too focused on short-term earnings. With the Act on Requirements for Compensation Systems together with two legal ordinances in 2010, banks and insurance companies must have appropriate, transparent compensation systems that are geared to sustainable development.

This implemented international recommendations (standards of the Financial Stability Board, FSB) and requirements under European law. In addition, the Financial Supervisory Authority is authorized to prohibit the payment of variable compensation components in certain cases.

Ban on short selling: In the summer of 2010, uncovered short selling of German equities and eurozone sovereign debt and credit default swaps on eurozone sovereign debt that do not serve hedging purposes were generally banned. The German Federal Financial Supervisory Authority (BaFin) has been given new rights to prohibit further transactions in financial instruments in crisis situations.

Corresponding prohibitions apply at EU level under the EU Short Selling Regulation from November 2012. The national regulations and the EU Regulation also provide the power for national supervisory authorities or the EU securities regulator ESMA to prohibit further transactions in times of crisis.

- Second Regulation on the Further Implementation of the Amended Banking Directive and the Amended Capital Adequacy Directive: the Regulation of October 26, 2011 completes the national implementation measures previously taken under the Act on the Supervisory Requirements for the Remuneration Systems of Institutions and Insurance Companies of July 21, 2010 and under the Act on the Implementation of the Amended Banking Directive and the Amended Capital Adequacy Directive of November 19, 2010.



It essentially regulates the increase in regulatory capital requirements to cover risks from trading transactions, the increase in capital requirements for so-called re-securitizations (this refers to securitizations of original securitizations), and the expansion of regulatory disclosure requirements for said transactions.

Clear restructuring and insolvency procedure for banks: The Restructuring Act promulgated in December 2010 introduced suitable instruments for restructuring and orderly resolution for failing credit institutions that pose a threat to the stability of the financial markets. The banking supervisory authority will have a stronger right to intervene when banks are in a crisis situation. In the future, it will be possible to transfer business units of systemically important banks to a "bridge bank.

Special levy for German banks: With the entry into force of the Restructuring Fund Regulation on July 26, 2011 and the first collection of contributions to the Restructuring Fund in 2011, the bank levy now collects funds to finance measures under the Restructuring Act. This has created the conditions for the effective implementation of the measures envisaged therein to deal with the distress of a systemically important bank in the most budget-friendly way possible without jeopardizing the stability of the financial system.

Strengthening investor protection: The Act to Strengthen Investor Protection and Improve the Functionality of the Capital Market (Investor Protection and Functionality Improvement Act) of April 5, 2011 creates additional requirements for securities service providers to combat false advice.

In particular, there are plans to set up a database at BaFin in which investment advisors, sales managers and so-called compliance officers will be registered. It is expressly stipulated that this group of persons must meet minimum requirements in terms of expertise and reliability. Customers must also be briefly and comprehensibly informed about the essential characteristics of financial instruments by means of information sheets.

In addition, a minimum holding period is introduced for open-end real estate funds and a liquidation procedure for real estate funds where the redemption of units is suspended for a longer period. Finally, the transparency of shareholdings will be increased in order to prevent undetected "creeping up" on companies.

Strengthening investor protection in the area of the gray capital market: The Act Amending the Law on Financial Investment Intermediaries and Asset Investments of December 6, 2011, imposes stricter regulation of the so-called gray capital market (for example, closed-end funds). Gray market products ("investments") qualify as financial instruments within the meaning of the German Banking Act (Kreditwesengesetz) and the German Securities Trading Act (Wertpapierhandelsgesetz), so that their distribution by securities service companies is directly subject to the investor-protection provisions of the German Securities Trading Act and to supervision by the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht).

The approximately 80,000 so-called "independent" (commercial) intermediaries who distribute investment funds and investments will continue to be subject to supervision by the trade authorities of the federal states. In the future, they will have to fulfill information, advisory and documentation obligations comparable to those of bank advisors when providing investment advice. Another measure is the stricter regulation of the public offering of asset investments. Finally, the special statute of limitations for defective or missing prospectuses was abolished, so that the general BGB statute of limitations of up to ten years applies here as well.

Better framework conditions for investment fund business: The Act on the Implementation of the Recast Investment Fund Directive (UCITS IV Implementation Act), which entered into force on July 1, 2011, is intended to increase the efficiency of the investment fund business for fund providers and create attractive and competitive framework conditions. Uniform protection standards are to be created for fund investors



throughout the EU (e.g. introduction of a two-page sheet containing key investor information on the main features of the investment fund).

Relieving securities issuers of administrative burdens: In implementation of the EU Directive amending the Prospectus and Transparency Directives, the draft law currently in the parliamentary process on the implementation of Directive 2010/73/EU and the amendment of the Stock Exchange Act is intended to reduce administrative burdens for issuers and financial intermediaries. In addition, the clarity and efficiency of certain regulations are to be improved and investor protection enhanced.

The deadline for the implementation of the Directive is July 1, 2012. In addition, the draft law provides for further selective amendments in the area of the Securities Prospectus Act and the Stock Exchange Act, as well as amendments to the Restructuring Fund Act and the Restructuring Fund Regulation (RStruktFV).

Licensing and supervision of alternative investment fund managers: Managers of alternative investment funds (including hedge funds and private equity funds) will be subject to licensing requirements in the future and will be supervised on an ongoing basis. In return, fund managers will receive an EU passport allowing them to distribute funds throughout the EU. The Alternative Investment Fund Managers (AIFM) Directive is to be transposed into national law by July 2013.

9.3 The German Food Safety Regime

Relevant National Legislation

In total, Germany has more than 700 relevant regulations within the food sector. Law on food security is composed by EU, federal and state law. Most important legislation in Germany (exclusive EU legislation) is listed below:

Law:

The German Food and Feed Code (orig. "Lebensmittel- und Futtermittelgesetzbuch (LFGB)") is the major framework legislation and is the foundation for the entire German food law.

Other important regulation (orig. Verordnungen):

Regulation on the implementation of provisions of Community food hygiene legislation (orig. Verordnung zur Durchführung von Vorschriften des gemeinschaftlichen Lebensmittelhygienerechts),

Publication of the Explanatory Memorandum to the Ordinance on the Implementation of the Provisions of Community Food Hygiene Law (orig. Bekanntmachung der Begründung zur Verordnung zur Durchführung von Vorschriften des gemeinschaftlichen Lebensmittelhygienerechts),

Announcement of the Basic Statements of the Project Group "Development of Risk-Based Requirements for the Approval of Establishments" of the Working Group on Meat and Poultry Meat Hygiene and Technical Issues of Food of Animal Origin of the Working Group of the Federal States on Consumer Health Protection (orig. Bekanntmachung der Grundsätzlichen Ausführungen der Projektgruppe "Erarbeitung risikobasierter Anforderungen an die Zulassung von Betrieben" der Arbeitsgruppe Fleisch- und Geflügelfleischhygiene und fachspezifische Fragen von Lebensmitteln tierischer Herkunft der Länderarbeitsgemeinschaft gesundheitlicher Verbraucherschutz (AFFL)),

Food Hygiene Regulation (orig. Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von Lebensmitteln (Lebensmittelhygiene-Verordnung – LMHV)),

Animal food hygiene regulation (orig. Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von bestimmten Lebensmitteln tierischen Ursprungs (Tierische Lebensmittel-Hygieneverordnung – Tier-LMHV)),



Animal Food Monitoring Ordinance (orig. Verordnung zur Regelung bestimmter Fragen der amtlichen Überwachung des Herstellens, Behandelns und Inverkehrbringens von Lebensmitteln tierischen Ursprungs (Tierische Lebensmittel-Überwachungsverordnung – Tier-LMÜV)),

Ordinance containing food law provisions on the monitoring of zoonoses and zoonotic organisms (orig. Verordnung mit lebensmittelrechtlichen Vorschriften zur Überwachung von Zoonosen und Zoonoseerregern),

Food Import Regulation (orig. Verordnung über die Durchführung der veterinärrechtlichen Kontrollen bei der Einfuhr und Durchfuhr von Lebensmitteln tierischen Ursprungs aus Drittländern sowie über die Einfuhr sonstiger Lebensmittel aus Drittländern (Lebensmitteleinfuhr-Verordnung – LMEV)),

Food Law Penalty and Fine Ordinance (orig. Lebensmittelrechtliche Straf- und Bußgeldverordnung (LMRStV))

Overview of Supervision:

Precautionary consumer protection, quality assurance, and environmentally and animal-friendly production are the three main objectives of the consumer, food and agricultural policy of the **Federal Ministry of Food and Agriculture**. In addition to the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL), the ministry's portfolio includes the Federal Plant Variety Office and four federal research institutes. In addition, the ministry supervises five legally independent institutions under public law, including the Federal Agency for Agriculture and Food and the Federal Institute for Risk Assessment, in addition to the sales funds for agricultural products, wood and wine.

The **Federal Office of Consumer Protection and Food Safety** (BVL) participates in the preparation of general administrative regulations and monitoring programs and is available to the federal states as a coordinating office. The BVL is also the office for the working groups of experts for food chemistry and for food hygiene and food of animal origin.

In Germany, **responsibility for official food monitoring lies with the federal states**. Monitoring is coordinated by the competent state ministry or the competent senate administration in the city states. The **food monitoring and veterinary offices** of the districts and independent cities take samples on site and inspect businesses. The official controls cover all stages of food production: production and manufacturing companies are inspected, as well as the storage, transport and sale of foodstuffs and the catering industry. The establishments are inspected without prior notice, either at regular intervals or on the basis of information provided by consumers or third parties. Establishments that have already attracted negative attention are inspected more frequently. In addition to these so-called planned samples, a food inspector can take further samples at any time if there is suspicion, for example if a business makes an untrustworthy impression during the inspection.

Agriculture in Germany is a very huge sector with a total of 267.000 agricultural companies. This number is constantly decreasing ever since the reference year of 1975 when a total of approximately 905.000 affiliated companies was counted. Within the wider area of agriculture, poultry/eggs and vegetables/fruits are important pillars. Affiliated companies are represented by a large number of associations at the national and the regional level such as the large umbrella associations such as the Central Association of the German Poultry Industry and the Federal Association of the German Food Industry.

Debates, Challenges, Crises and Reforms

As a matter of fact, the entire system as it is today, was established against the backdrop of major crises (above all, the BSE crisis) in the 1990s and as an answer to such in early 00s.



Current public warnings and information: <https://www.lebensmittelwarnung.de/bvl-lmw-de/liste/alle/deutschlandweit/10/0>

Scandals and large-scale crisis such as BSE, H5N1, “Gammelfleisch-Skandale” etc. are rarely to be found within the past 10 years. However, there are some crises that hit the German food sector (see <https://www.sueddeutsche.de/panorama/lebensmittelindustrie-fipronil-im-ei-pferdefleisch-in-der-lasagne-1.3616834>) :

2019: Large-scale recall of low-fat milk from Milchkontor DMK and Fude + Serrahn. Milk products from ten different supermarket chains are contaminated with the germ "Aeromonas hydrophila".

2019: 1100 different products of the Wilke company are affected by listeria. Among them organic and halal meat as well as vegetarian and even vegan products. Three people die as a result of listeriosis caused by Wilke products.

2017 - Fipronil in eggs

2015: Investigators find 280 kilos of meat contaminated with e-coli bacteria in the canteen of the LKA and statistics office in Düsseldorf at the beginning of November. The meat, which was supposed to be disposed of, came from an animal feed manufacturer in NRW. He further processed it into dog food and then falsely passed it on to a butcher in Düsseldorf, who eventually supplied the canteens.

2014 – Salmonellosis scandal (Bayern-Ei)

2013 – horse meat scandal

2011 – EHEC infections

2011 – Dioxin scandal

Recently: Problems and challenges of farmers relating to “Billigpreise” (too cheap prices). The wider context includes farmers and the four large retailers in Germany (Edeka, Rewe, Aldi, and Lidl) that are said to – due to their enormous market power - dictate low prices. As response, legislation shall be adopted and an ombudsman shall be installed. However, the four bigshots argue that low prices are a result of the global surplus and, thus, decreasing prices. Furthermore, they argue that the majority of agricultural goods produced in Germany are exported and not distributed in Germany.

Animal welfare is becoming more and more prominent. Recently, high position politicians repeatedly recognized bad conditions in stables and slaughterhouses. In this context, a.o., federal minister of agriculture Julia Klöckner criticized very low prices for meat.

Tierwohlkennzeichen: The animal welfare label is an award for products that go beyond the legal requirements to stand for more animal welfare in livestock farming. The label makes this difference clearly visible to consumers. In 2019 Supermarkets introduce husbandry labelling.

Ethical perspective of food waste became very important in the recent past (<https://www.welt.de/debatte/kommentare/article216966816/Julia-Kloeckner-Lebensmittelverschwendung-ist-unethisch.html>) .

Nutri-Score: The new labeling makes it possible to compare the nutritional quality of foods at a glance.

Biodiversity: Protecting bees and insects: The BMEL advocates improved measures to protect biodiversity and landscape structural diversity in agricultural areas as well as in forests without jeopardizing the sustainable use of these ecosystems, e.g. for the production of food or raw materials.

Business associations accuse food safety regulators of overregulation and consumer advocacy (“Überregulierung und Verbraucherbevormundung bei Lebensmitteln verhindern!”) largely as response to a potential traffic light labels of the Nutri-Score (Ampelkennzeichnung) regarding nutritional values etc.



In 2020, the LFGB was overhauled in large parts to incorporate EU legislation. Major changes are to be found in the context of rules on food additives and cosmetic products, official control rights, traceability information, monitoring of online trade in perishable foods, cosmetics and consumer goods.

2020 - Feasibility study on the optimization of food monitoring and consumer health protection. At the same time, the study shows that the potential of digitization and new technologies has so far been insufficiently exploited for data management in consumer health protection.



10 Mapping the Norwegian Regulatory Regimes

10.1 The Norwegian Data Protection Regime

The Norwegian Data Protection Authority is a core actor for data protection in Norway. As an independent, supervisory body, the Norwegian Data Protection Authority works to protect the individual right to privacy. The Authority ensures that Norwegian and EU data protection legislation is adhered to by handling complaints and inspections (Datatilsynet a). They are in charge of fining and taking other measures against actors who breach Norwegian data protection law. They also act as an ombud and provide the public with information about data protection. While the Norwegian Data Protection Authority is independent, meaning that its rulings and decisions cannot be reversed, it is administratively subordinate to the Ministry of Local Government and Modernisation and is financed by the Norwegian government (Datatilsynet b).

Data protection is not a clearly defined sector. Thus, there are many actors who work with data protection, but whose sole focus is not data protection. Below is a list of actors who work, in varying degrees, with data protection (focusing on health data and electronic communication).

Legislative Bodies

- The Standing Committee on Justice
 - Works with data protection laws, such as the Personal Data Act (Stortinget a)
- The Standing Committee on Health and Care Services
 - Responsible for matters relating to health services (Stortinget b)
- The Standing Committee on Transport and Communications
 - Responsible for matters relating to telecommunications and electronic communication (Stortinget c)

Courts

There are no specialized courts in Norway.

Regulatory Agencies

- The Norwegian Data Protection Authority (as described above)
- Norwegian Communications Authority
 - Executive supervisory and administrative authority for services within electronic communication
 - Subject to the Ministry of Local Government and Modernisation (Norwegian Communications Authority 2020)

Regulatory Intermediaries

- There are currently no public or private certification bodies in Norway for data protection (Datatilsynet 2020a).

Executive Bodies

- Ministry of Local Government and Modernisation
 - Works with Personal Data Regulations
 - Administratively responsible for the Norwegian Data Protection Authority, the Privacy Appeals Board, and for the Norwegian Communications Authority (Regjeringen a)
- The Ministry of Justice
 - Works with the administration of the Personal Data Act (Regjeringen b)
- The Ministry of Health and Care Services,
 - The section for E-health works with the protection of health data (Regjeringen c)
- The Norwegian Institute of Public Health



- Government agency under the Ministry of Health and Care Services
- The Division of Health Data and Digitalisation has responsibility for registries, IT/e-health activities and digitalization (Norwegian Institute of Public Health 2017)
- The Directorate of eHealth
 - Sub-ordinate institution of the Norwegian Ministry of Health and Care Services (Directorate of eHealth 2021)
 - Has responsibility for the health data program (Datatilsynet 2020b).
- Norwegian Directorate of Health
 - Works with the Norwegian Data Protection Authority at the director and case level (Datatilsynet 2020b).

Interest Organisations

- ICT Norway
 - Norway's largest interest group for ICT (IKT Norge)
- Norwegian Medical Association
 - Professional organisation and trade union for Norwegian doctors (Legeforeningen 2018)
- The Norwegian Hospital and Health Service Association
 - Independent interest organisation for hospitals and health care (generally) (NSH)
- The Norwegian Dental Association
 - Professional association and trade union for dentists in Norway (Den norske tannlegeforening)
- Norsk forening for helse- og treningsterapeuter
 - Interest organisation for health workers and physical therapists (NFHT).
- Nelfo
 - Interest organisation for ekom/ICT (Nelfo)

Ombud

- Privacy Appeals Board
 - Administratively subordinate to the Ministry of Local Government and Modernisation (Personvernemnda)

The Main Regulations

The main regulations are the Personal Data Act (personopplysningsloven) and GDPR (personvernforordningen). The Norwegian Data Protection Authority also has several specific laws for the justice and health sectors (Datatilsynet c). More information about these laws can be found (in Norwegian) on the Norwegian Data Protection Authority's website.¹⁴⁰

Scandals

A recent survey, conducted in 2019 by Opinion for the Norwegian Data Protection Agency, found that in general Norwegians have high levels of trust in public bodies' handling of personal data. The exception was with NAV, the Norwegian Labour and Welfare Administration, schools, and kindergartens. Lower levels of trust were reported for the aforementioned bodies. Trust levels were lowest, according to the study, among social media companies and those running messaging services and search engines (Datatilsynet 2019/2020, 4) The lack of trust in schools could be due to several breaches students' personal data over the past few years.

Below is a list of breaches in Norwegian data protection law between 2010 and 2020. The majority of these cases come from the Norwegian Data Protection Authority's register of cases considered as "key

¹⁴⁰ <https://www.datatilsynet.no/regelverk-og-verktoy/lover-og-regler/>.



decisions".¹⁴¹ Not all cases on this register are included, only ones which include large data breaches. Moreover, this register is only for the past five years (2015-november 2020). Therefore, to find cases for the first part of the decade, it was necessary to refer to news articles.

2019-2020

- The Norwegian Data Protection Authority placed a temporary ban on the COVID tracing app, Smittestop, stating that the Norwegian Institute of Public Health had not adequately documented the need for location data from GPS for contact tracing (Datatilsynet 2020c).
- Rælingen municipality failed to carry proper risk assessments on the special needs learning platform, Showbie. The platform allowed for those in the group to access the personal health data of students with special needs (Datatilsynet 2020d).
- The Norwegian Public Roads Administration used personal data for reasons other than originally stated and failed to erase video footage after seven days (Datatilsynet 2020e).
- Østfold HF Hospital improperly stored report extracts from patient records from 2013-2019. Led to a personal data breach (Datatilsynet 2020f).
- Bergen Municipality's personal data security for students in primary and lower secondary schools was insufficient. Led to a data breach (Datatilsynet 2020g).

2018

- Oslo Municipality illegally stored patient records outside the medical system from 2007-2018 (Datatilsynet 2019).

2017

- Oslo University Hospital illegally gathered and used blood tests and health data (Datatilsynet 2017).

2013

- Before the 2013 elections, the Conservative party had a Facebook campaign, which the Norwegian Data Protection Authority declared illegal. The party took two years to answer the claims (Olsson, Lydersen & Tomter 2018).

2011

- The Institute for Forensic Medicine (Rettsmedisinsk institutt), which is no longer in existence, had an illegal DNA register (Færaas 2011).
- The Norwegian Ministry of Foreign Affairs improperly used the personal data of Norwegians living abroad (Rønneberg 2010).

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10.2 The Norwegian Financial Regime

The financial system in Norway is regulated by various laws and regulation. Those include both micro prudential regulation (supervision of financial institutions) and conduct of business regulation (consumer/customer relations of financial institutions) for banking and securities markets. The financial supervisory authority – Finanstilsynet – provides an overview of relevant laws and regulations in financial regulation, including English translations for most documents (<https://www.finanstilsynet.no/en/laws-and-regulations/>). The Act on Financial institutions and Financial Groups (last revised in 2016) defines different types of financial institutions, such as banks, mortgage companies, and payment companies. They are primarily supervised by the financial supervisory authority. In international comparison, the banking sector in Norway is small, though, which results from Norwegian banks' limited activities abroad (Norges Bank 2020). Following the financial crisis of 2008, a public committee reviewed the country's crisis response and developed policy suggestions (see <https://www.regjeringen.no/no/dokumenter/nou-2011-1/id631151/>), but according to an involved expert only few policy suggestions were implemented.

Legislative bodies

The **Norwegian parliament** (Stortinget) has a **Standing Committee on Finance and Economic Affairs**, which has responsibilities regarding financial markets (<https://www.stortinget.no/en/In-English/Standing-Committees/The-Standing-Committee-on-Finance-and-Economic-Affairs/>). In Norway, minority governments



are common, which means that the government has to make compromises with opposition parties in parliament to get approval for policy proposals.

Courts

There is no specialized court system in Norway, which means that lawsuits are handled by regular courts.

Regulatory agencies

The main actor in financial regulation is **The Financial Supervisory Authority of Norway** (Finanstilsynet) (<https://www.finanstilsynet.no/en>). It is a unified regulator and covers all three major financial sectors. Amongst other things, it performs risk-based supervision (based on banks' own reporting) and on-site inspections with individual banks (micro-prudential regulation) in banking and securities. In addition, it has supervisory functions in insurance and pensions, the supervision of auditors and audit firms, real estate agents and real estate agencies, and financial institutions' use of ICT and payment services systems.

The **Norwegian Central Bank** (Norges Bank) "has executive and advisory responsibilities in the area of monetary policy and is responsible for promoting robust and efficient payment systems and financial markets" (<https://www.norges-bank.no/en/topics/about/Mission-core-responsibilities/>). The Central Bank performs macro prudential supervision and "monitors financial institutions, securities markets and payment systems to identify trends that may weaken the stability of the financial system" (<https://www.norges-bank.no/en/topics/financial-stability/financial-stability-primary-objective/>, 18.12.2020). Another main task of the Central Bank is asset management, more specifically managing the "Government Pension Fund Global", which invests the country's massive revenues from oil and gas in the North Sea.

Regulatory intermediaries

The **Norwegian Banks' Guarantee Fund** (Bankenes sikringsfond) is a legally independent organisation created to guarantee for bank deposits up to NOK two million (approx. 200,000 EUR) (https://www.bankenessikringsfond.no/om-oss_2/). Its tasks also include the monitoring of the member banks' financial situation.

The Norwegian Investor Compensation Scheme is a private body, regulated by Norwegian law, in accordance with Directive 97/9/EC (ICS-directive). Client's funds and financial instruments dealt with by a Norwegian investment firm are covered by the guarantee up to NOK 200.000 per client. (<https://www.verdipapirforetakenessikringsfond.no/en/about/>).

The **Finance Industry Authorisation schemes** (Finansnæringens autorisasjonsordninger, FinAut) is a national scheme, which aims to safeguard the finance industries' authorisation and accreditation schemes. (<https://www.finaut.no/finaut-english/>). This is an industry self-regulating body that sets standards for consumer relations, runs examinations, and supervises financial businesses. It is owned by Finance Norway and the Norwegian Fund and Asset Management Association.



Executive bodies

The **Ministry of Finance** (Finansdepartementet) has the overall responsibility for financial sector, has tasks within rule-making and single-case decisions, and has oversight functions towards the financial supervisory agency and the central bank.

The **Consumer Authority** (Forbrukertilsynet) “is an independent administrative body with the responsibility of supervising measures in the market and seek to exert influence on traders to observe the regulatory framework” (<https://www.forbrukertilsynet.no/english>). In financial services, it supervises the marketing of for example savings products, and it supervises providers of new payment solutions (<https://www.forbrukertilsynet.no/english/financial-services>).

Interest organisations

Finance Norway (Finans Norge) is the interest organisation of the financial industry in Norway (<https://www.finansnorge.no/en/about-finance-norway-new/>).

Norwegian Fund and Asset Management Association (Verdipapirfondenes forening) is the interest organisation for the fund and asset industry (<https://www.vff.no/about-the-norwegian-fund-and-asset-management-association>).

The **Association of Norwegian Finance Houses** (Finansieringsselskapenes Forening) was founded in 1984 taking over the responsibilities of the former specialist associations for leasing, factoring and other methods of financing. The association is the branch organisation for companies that carry out business of special financing, i.e. leasing, factoring and credit cards. (text from their website, <https://www.info.no/about-us/>)

Finansforbundet is the largest labor union within the finance sector, representing around 32 000 members from 300 companies (<https://www.finansforbundet.no/>).

The **Consumer Council** (Forbrukerrådet) is an independent public body that works towards pushing consumer interests in political decision-making, that assists consumers in obtaining their rights, and that supports consumers in making informed choices, for example by providing information on financial services through a dedicated website (www.finansportalen.no).

Non-judicial appeal or arbitration commission/body

The Norwegian Financial Services Complaints Board (Finansklagenemnda) “deals with disputes that arise between finance companies and their customers in service areas such as insurance, banking, financing, securities funds and debt collection.” (<https://www.finkn.no/English>). This organisation was created based on an agreement between the Consumer Council and various business interest organisations.

Scandals in financial regulation

The finance sector is highly international. Therefore, there is only limited value in focusing on national problems and scandals in financial regulation, as scandals often cross borders. There have been no major



scandals in the past years in banking and finance in Norway. That said, one issue that gained some attention was the practice of some banks – one pertinent example being *Bank Norwegian* – to offer consumer loans to individuals much more easily than other banks. In many cases, customers were unable to repay their debt. This practice was labelled “immoral” by one expert <https://e24.no/boers-og-finans/i/J1dyvJ/jeg-oensker-aa-komme-med-en-sterk-advarsel-mot-bank-norwegian>, last accessed 12.02.2021).

Another pertinent issue is the regulation of loans to prevent housing bubbles and ensure financial stability. The Financial Regulator in Norway is in charge of setting standards for the regulation of loans - how much money can individuals borrow from banks (usually in terms of annual income) to prevent the creation of bubbles. With continuously increasing prices in the housing market, the financial regulator for instance proposed to lower the maximum limit of a borrower’s total debt (for housing and borrower loans) relative to annual income (<https://www.finanstilsynet.no/en/news-archive/press-releases/2020/finanstilsynet-proposes-new-lending-regulations2/>, last accessed 12.002.2021).

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10.3 The Norwegian Food Safety Regime

Norway’s regulatory regime for food safety looks very different today than it did fifteen years ago. Today, the main regulator is the Norwegian Food Safety Authority. Founded in 2004, the Norwegian Food Safety Authority took over the responsibility for food safety, which previously lay with five different agencies. In 2015, the Norwegian Food Safety Authority itself underwent reorganisation, going from having a three-level model with eight regional offices to a two-level model with a main office and five regional offices (Renø 2020, 10). The Norwegian Food Safety Authority is a subordinate agency of the Ministry of Agriculture and Food, the Ministry of Health and Care Services, and the Ministry of Trade Industry and Fisheries. The Ministry of Agriculture and Food is responsible for the Norwegian Food Safety Authority’s administration and budget (Mattilsynet 2021a).

As the main actor in the Norwegian food sector, the Norwegian Food Safety Authority carries out a wide range of tasks. The Authority both drafts legislation and provides advice regarding existing legislation. It is responsible for supervision and enforcement; it performs risk-based inspections and monitors both the safety of food and the health of plants, fish, and animals (Mattilsynet 2021a). The Norwegian Food Safety Authority works closely with other bodies, the police and research organisations (Mattilsynet 2017, 3).

Below is an overview of actors in the Norwegian food sector. The ministries and research organisations work especially closely with the Norwegian Food Safety Authority.

Legislative Bodies

- The Norwegian Parliament’s Standing Committee on Business and Industry
 - Responsible for food policy, the Agricultural Agreement (jordbruksavtalen), fisheries, whaling, aquaculture, and salmon fishing

Courts

There are no sector specific courts in Norway.



Regulatory Agencies

- The Norwegian Food Safety Authority
 - The main actor in the Norwegian food sector (as described above)

Regulatory Intermediaries

- Debio
 - Sole certifier of organic food
 - Debio's Ø-label is found on all organic food in Norway
- Norwegian Accreditation
 - The national accreditation body for Norway
 - Provides accreditation for laboratories dealing with food
- Eurofins Norway
 - Provides analyses of food and feed
- Aquatiq Consult
 - Provides certification
- Matmerk
 - Owns the labels "Nyt Norge" (label for Norwegian-produced food and drink) and "Spesialitetet" (label for local food and drink)
 - Provides quality assurance through their internal control system, KSL
 - Farmers can check to make sure they are in compliance with food safety regulation
- Fairtrade Norway
 - Provides certification and a label for fair trade products

Executive Bodies

- Ministry of Agriculture and Food
 - Responsible for food and agricultural policy
 - The Norwegian Food Safety Authority is a subordinate agency (and this ministry is the main superior authority of that agency)
- Ministry of Trade, Industry and Fisheries
 - Responsible for seafood policy
 - The Norwegian Food Safety Authority is a subordinate agency
- Ministry of Health and Care Services
 - Has a department of public health which works with food safety
 - The Norwegian Food Safety Authority is a subordinate agency

Research organisations working with the Norwegian Food Safety Authority (Regjeringen 2018)

- The Norwegian Veterinary Institute
 - Biomedical research institute for animal health, fish health and food safety
- The Norwegian Institute of Public Health
 - Has a section for zoonotic, food- and waterborne infections
- Institute of Marine Research
 - Provides research-based advice on seafood and aquaculture
- NIBIO
 - One of Norway's largest research institutes working with food safety
- The Norwegian Scientific Committee for Food and Environment
 - Assists the Norwegian Food Safety Authority by conducting scientific risk assessments regarding food safety and food production



Interest organisations

- Norwegian Agricultural Cooperatives
 - Interest organisation for 17 farmer-owned cooperatives
- FoodDrinkNorway
 - Large interest organisation, representing more than 1600 businesses
- Consumer Council
 - A large consumer organisation with a section working with food
- Kore
 - Interest organisation in the food sector
- Økologisk Norge
 - Interest organisation for organic farmers, companies, and consumers
- Biologisk-dynamisk Forening
 - Interest organisation for organic farmers
- Norsk bonde- og småbrukarlag
 - Politically independent interest organisation working to improve Norwegian agriculture
- Norges Bondelag
 - Large interest organisation for farmers

The Main Laws

As a member of the European Economic Area (EEA), Norway is bound to the European Union (EU) food safety regulation. Thus, according to the Norwegian Food Safety Authority, most national regulation is based upon EEA/EU law (Mattilsynet 2021b). Norway also actively participates and cooperates in the efforts to adapt and develop food safety regulation at the European level (Regjeringen 2018).

The main law, Matloven, pertains to all matters in connection with the production, processing and distribution of goods and foodstuffs, including drinking water. Other relevant laws include the law on animal welfare (Lov om dryrevelferd) and the law on plants (Lov om planteforedlerrett). Information on these laws, as well as several others can be found on the Norwegian Food Safety Authority's website.¹⁴²

Scandals

According to the Norwegian Food Safety Authority, Norwegian food and drinking water is some of the safest in the world. The Authority credits this to their long-term preventative work and the lack of infection in Norwegian livestock (Mattilsynet 2016, 9). In their 2017 annual report, then Director General, Harald Gjein, wrote that he was pleased with the Authority's work. "The positive status in most of our areas, as well as our second place in the reputational survey of 88 public bodies, goes some way to confirming this" (Mattilsynet 2017, 3).

However, the recent 2019 mink scandal and the 2016 fish scandal, described below, have led to a so-called "trust-crisis" (KPMG 2019, ii). Because of these scandals and the following debate regarding the Authority's methods, the Norwegian Parliament called for an independent investigation of the Food Safety Authority in 2019 (KPMG 2019, ii). The investigation identified a number of systematic weaknesses and made recommendations for correcting them. The new Director General, Ingunn Midttun Godal, addressed this report, stating: "The Norwegian Food Safety Authority is faced with a great need to change and develop, both due to the weaknesses pointed out in KPMG's report and as a result of great changes taking place in society as a whole" (Mattilsynet 2019, 5).

Over the last decade, 2010-2020, there have been several food related scandals. These scandals are described below.

¹⁴² https://www.mattilsynet.no/om_mattilsynet/gjeldende_regelverk/lover/



2019

The Norwegian Food Safety Authority published a report about the maltreatment of mink on a farm in the Rogaland district. Several animals were malnourished. The report was later found to be full of factual errors, and the Authority admitted to the errors (KPMG 2019, ii).

In addition to the mink scandal, there were two deaths associated with *Campylobacter* bacteria in the drinking water. After the incident, the Norwegian Food Safety authority was commissioned by the Ministry of Health and Care Services to map the drinking water situation in all municipalities (Mattilsynet 2019, 5).

2016

The Norwegian Food Safety Authority made claims against Lerøy, a Norwegian Seafood Corporation. The Authority said that poor conditions led to sickness/damage in fish. They chose to report the head of the board and the CEO to the police for breaches in law. According to the Norwegian Food Safety Authority, between 1.5 and 2.0 million fish showed sickness/damage due to unhealthy conditions. However, the Authority was later only able to document damage/sickness in a small number of fish, and the company was acquitted because the Authority could not prove its claims (KPMG 2019, ii).

2013

Food fraud was a large focus because of the horsemeat scandal in the European Union. No products with horsemeat were found in Norway, but the investigation revealed that some products labeled as beef included pork (Mattilsynet 2013, 3).

In addition to these larger incidents, the Norwegian Food Safety Authority's yearly reports (2010-2019), describe a few cases of food borne illness each year. The Authority maintains that food safety is high in Norway, especially compared to other countries.

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11 Mapping the EU Regulatory Regimes

11.1 The EU Data Protection Regime

In 2018, the European Union's (EU) Regulation 2016/679, commonly known as the General Data Protection Regulation or GDPR, came into force. GDPR regulates the processing of personal data by companies, organisations and individuals. Like other EU regulations, GDPR applies to all Member States. GDPR strengthened data protection regulation within the European Union. You can find more about GDPR as well as new legislation on this webpage: https://edps.europa.eu/data-protection/data-protection/legislation_en Below is a list of organisations that work, though in various capacities, with data protection. There are only two actors at the EU level that work solely with data protection. These actors are the European Data Protection Board, which was established under GDPR, and the European Data Protection Supervisor. The legislative and executive bodies listed below only partly work with data protection. In other words, data protection is one of their many focus areas. The TiGRE project looks at the data protection "sector" through the lens of two sub-sectors: health data and the electronic communication of personal data. The selection of interest groups is based on these two sub-sectors. Therefore, interest groups from the health and telecommunications sub-sectors are included.

Legislative Bodies

- The **European Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE)** is responsible for data protection and privacy in a digital age.
- The **Council of the European Union's Justice and Home Affairs Council configuration (JHA)** worked on GDPR. The Economic and Financial Affairs Council configuration (Ecofin) also contributed (European Parliament).

Regulatory Agencies

- Established by GDPR, the **European Data Protection Board (EDPB)** replaced the Article 29 Working Party, which consisted of representatives of EU Member State supervisory authorities, representatives from the Commission and the European Data Protection Supervisor. A main task of the European Data Protection Board is to ensure that data protection rules are applied consistently throughout the EU (European Union Agency for Fundamental Rights and Council of Europe 2018, 199-200).
- As an independent data protection authority, **the European Data Protection Supervisor (EDPS)** is tasked with monitoring the processing of personal data by the EU institutions, bodies, offices and agencies. They have investigation, corrective powers and sanctions, and authorisation and advisory power. They also provide advice on policies and legislation (European Data Protection Supervisor).

The two regulatory agencies, described above, often work together and the EDPS provides the EDPB with an independent secretariat (European Data Protection Board).

Executive Bodies

- The EU's executive body is the **European Commission**, which consists of several Directorates-General. They develop, implement and manage EU policies, laws and funding programmes. **DG Justice and Consumers (JUST)** is responsible for, among other things, data protection. Within DG JUST is the Directorate for Data Protection.
- The **European Union Agency for Cybersecurity (ENISA)** is the EU's cybersecurity agency.



- **The European Union for Agency Fundamental Rights (FRA)** provides EU institutions and Member States with independent, expert advice for policy and decision makers. One of their focus areas is data protection (European Union Agency for Fundamental Rights).

Interest Groups

- Confederation of European Data Protection Organisations*
- DIGITAL-EUROPE*
- European Telecommunications Network Operators' Association (ETNO) – GSMA* Europe
- Access Now Europe*
- HOPE - European Hospital and Healthcare Federation
- European Association of Senior Hospital Physicians
- European Internet Services Providers Association
- European Association of Data Protection Professionals

The interest groups above directly deal with data protection or represent the health and telecommunications sub-sectors. Interest groups that have a star (*) next to them were part of a multistakeholder expert group to support the application of GDPR (European Commission 2019).

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11.2 The EU Financial Regime

The current structure of the institutions for financial regulation at the European Union (EU) level results from a series of reforms in the wake of the financial crisis in the 2000s, which led to the establishment of the European System of Financial Supervision (ESFS). The ESFS is a regulatory architecture that includes the



European Central Bank (ECB), the three European Supervisory Authorities (ESAs), the European Systemic Risk Board (ESRB) and national supervisors. The three ESAs are: for banking the European Banking Authority (EBA), for securities the European Securities and Markets Authority (ESMA) and for insurance the European Insurance and Occupational Pensions Authority (EIOPA).¹⁴³

As of 2020, the authority responsible for the macroprudential oversight of the EU financial system is the ESRB. The ESRB supervises all areas of financial activity and has the macro-prudential oversight for the financial activities in the EU. The general board of ESRB is composed by the president and vice-president of the ECB, governors of the national central banks of the Member States, representatives of the three major financial EU agencies (EBA, EIOPA and ESMA), one member of the EU Commission, and technical and scientific advisers.

Mapping of relevant actors at the European level

Legislative bodies:

- After a legislative initiative by the Commission, policy proposals are discussed in committees of the **European Parliament**. Financial services regulation falls within the responsibility of the European Parliament's **Committee for Economic and Monetary Affairs**.
- The Council of the European Union, along with the European Parliament, is a main decision-making body at the European Union level. The Council of the European Union's meetings are attendant by ministers from each national government. Legislation on the regulation of financial services financial services issues are discussed in the **Economic and Financial Affairs Council** configuration (**Ecofin**). The General Secretariat¹⁴⁴ provides advice, assistance and help with the Council of the European Union's work. For finance, the relevant body within the General Secretariat is ECOMP (Economic Affairs and Competitiveness).

Regulatory agencies:

- **European Central Bank (ECB)**: The ECB is an official EU institution at the heart of the Eurosystem as well as the Single Supervisory Mechanism for banking supervision. The ECB is responsible for the Single Supervisory Mechanism, in cooperation with national supervisors. Under this umbrella, the ECB directly supervises 115 significant banks operating in the EU. ECB also is in charge of the Single Resolution Mechanism. The ECB created a banking supervision area and also established a supervisory board to perform the ECB tasks in this field.
- **European Banking Authority**: The EBA is an independent EU Authority, which works to ensure effective and consistent prudential regulation and supervision across the European banking sector. The EBA, in coordination with national banking regulatory authorities, also contributes to banking regulation at the EU level, for example in areas such rule harmonization and supporting the implementation of Basel III in Europe. The EBA focus on most of the issues related to the development of banking regulation at the EU level, including money laundering, new fintech activities and other financial innovations. Importantly, the board of supervisors, the main decision making body of EBA, is composed mainly by the heads of national regulatory agencies. Its overall objectives are to maintain financial stability in the EU and to safeguard the integrity, efficiency and orderly functioning of the banking sector

¹⁴³ Insurance is not a focus area of the TiGRE project.

¹⁴⁴ The Council of Europe and the Council of the European Union share a secretariat.



- **European Securities and Markets Authority (ESMA):** The ESMA is an independent EU Authority that contributes to safeguarding the stability of the European Union's financial system by enhancing the protection of investors and promoting stable and orderly financial markets. It assesses risk to investors, markets and financial stability. It promotes supervisory convergence and directly supervises credit rating agencies and trade repositories.

Executive bodies:

- **EU Commission Directorate-General for Financial Stability, Financial Services and Capital Markets Union (FISMA):** The Directorate-General for Financial Stability, Financial Services and Capital Markets Union is the Commission department responsible for EU policy on banking and finance.
- **European Systemic Risk Board - European System of Financial Supervision:** The ESRB is responsible for the macro-prudential oversight of the EU financial system and the prevention and mitigation of systemic risk. The ESRB therefore has a broad remit, covering banks, insurers, asset managers, shadow banks, the infrastructure of the financial market and other financial institutions and markets.

Stakeholders and interest groups:

- Association for Financial Markets in Europe (AFME)
- European Banking Federation (EBF)
- European Association of Cooperative Banks
- European Fintech Association
- European Association of Public Banks and Funding agencies AISBL
- European Association of Co-operative Banks
- International Securities Lending Association
- European Central Securities Depositories Association
- Federation of European Securities Exchanges
- International Capital Market Association
- European Fund and Asset Management Association
- Electronic Money Association

Legal framework

A comprehensive overview of the system of financial regulation can be found here:

https://ec.europa.eu/info/business-economy-euro/banking-and-finance/financial-supervision-and-risk-management/european-system-financial-supervision_en

11.3 The EU Food Safety Regime

The organisation of the regulatory regime for food safety at the EU level is based on the idea of separating risk assessment and risk management (Heims 2019). The current regime was established in the wake of the BSE (“mad cow disease”) in the 1990s. The main institutions dealing uniquely with food safety are the European Food Safety Authority (EFSA), in charge of risk assessments, and the Directorate Health and Food Audits within DG SANTE (formerly FVO – Food and Veterinary Office), which is in charge of risk management, more specifically inspection and control of member states’ compliance with EU regulations (BfR 2017). The EU regulatory regime has multiple connections to the national regulatory regime. As mentioned, DG SANTE



supervises national food safety regimes' compliance with EU legislation (Heims 2019). Moreover, one of EFSA's main competences is to advise national regulatory agencies and provide them with independent scientific knowledge. Cooperation with EFSA goes both ways; national regulators also provide advice to EFSA through its advisory forum and individual experts working for national regulators are regularly involved in EFSA's risk assessment exercises (Bach and Ruffing 2014). Risk management, audit and control competencies are located at the national level, however most member states established some food safety risk assessment bodies as well.

The food industry can be split up in several ways. One way is to look at the nature of the product: dairy, meat, fish, vegetables, etc. Another way, and the method utilized in this mapping, is to divide up the sector according to the production chain "**from farm to fork**" (BfR 2017). This takes into account agriculture, fisheries and other actors in the primary sector (1), the food handling and production sector (2), food storage (3), the distribution, hotel and catering industries (4), and lastly the consumers (5). Food safety regulatory bodies at the European level generally look at the production chain as a whole, calling on experts of the different links in the production chain of food products. For this mapping, we therefore opted to look at the different actors from a policy and regulations viewpoint.

We distinguish the development of legislation and regulation, the execution and implementation of policies, the control of compliance with said legislation and regulation and the enforcement of non-compliance. Not all of these elements are present at all policy levels. Interest groups are included at different phases of this regulatory process. They usually represent particular sub-industries or certain links in the food production chain.



12 Mapping of relevant actors at the European level

12.1 Legislative bodies

- Legislation regarding food safety and food regulations is harmonized across the European Union. These rules and laws are, like any European legislation, adopted in a **co-decision procedure** wherein the legislation is proposed by the commission and then approved and adopted by both the European Parliament and Council of the European Union.
- Legislative initiatives on the European level are initiated by the **European Commission**. In the current constellation, the commissioner for food safety is Stella Kyriades.
- After a legislative initiative by the Commission, the proposal is discussed in the committees of the **European Parliament**. Food safety legislation is discussed in the **Committee on the Environment, public health and food safety (ENVI)**.

Members: <https://www.europarl.europa.eu/committees/en/envi/home/members>

- The **Council of the European Union, along with the European Parliament, is a main decision-making body at the European Union level**. The Council of the European Union's meetings are attendant by ministers from each national government. Which minister attends is dependent on the topic at hand. Food Safety issues are discussed in the **Agriculture and Fisheries Council Constellation (AGRIFISH) (BfR 2017, 9)**. The General Secretariat¹⁴⁵ provides advice, assistance and help with the Council of the European Union's work. For food safety, the relevant body within the General Secretariat is LIFE (Agriculture, Fisheries, Social Affairs, and Health).

12.2 Executive bodies

- The executive body of the European Union is the **European Commission**. The commission is made up of several Directorates-General, who are responsible for one policy department. They develop, implement and manage EU policies, laws and funding programmes. Food Safety policies are executed by the **DG Health and Food Safety (SANTE)**. This DG is tasked with EU policy regarding the safety of food and feed, the health and wellbeing of animals, plant health, pesticides and genetically manipulated organisms (GMO) 'from farm to fork'. One of the tasks of the DG SANTE is to control and audit the food safety controls and inspection systems of member states 'from farm to fork' (Heims 2019). As mentioned above, DG SANTE's Directorate Health and Food Audits performs audits of the regulatory agencies of member states and non-EU countries (BfR 2017, 10). DG SANTE does not perform audits of companies or organisations (that is, regulatees), which is the task of the regulatory agencies of member states and non-member states. The DG SANTE is also tasked with guaranteeing that food and feed that is imported in the European Union complies with the minimum standards regarding food safety and animal and plant health (BfR 2017, 8).

¹⁴⁵ The Council of Europe and the Council of the European Union share a secretariat.



- Executive agencies of the European Union are tasked with the support and management of specific funding programmes. The **Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)** manage the Better Training for Safer Food programme. This is an initiative that aims to develop a harmonised training strategy of food law, food safety, animal and plant health controlling officials, based on the ‘train-the-trainer’-principle.
- The **European Union’s Customs authorities** play an important role as well. They control food and feed that enters the European Union.

12.3 Regulatory agency

- On the European level the **European Food Safety Authority (EFSA)** is the independent regulatory agency. To be precise, this agency is only involved in risk assessment and its role is providing scientific advice and scientific and technical support in all fields with direct or indirect effects on food safety. This is peculiar to food safety regulation, with its clear institutional separation between risk assessment and risk management. In practice, this means EFSA assesses and detects (emerging) food risks and, in so doing, supporting the commission and member states to take on these risks. One of EFSA’s most important outputs are scientific opinions. The commission, member states and the European Parliament can raise questions about food safety on which EFSA formulates an independent, scientifically grounded opinion (Groenleer 2009).

Besides the delivery and communication of scientific advice, EFSA also evaluates products that require a safety assessment before they can be authorised to enter the EU market.

EFSA is led by a director and a management board. The management board is responsible for allocation of the budget, the adoption of the work programme and the annual report. Contrary to other European Agencies, EFSA’s management board is not made up of representatives of member states. The fourteen members of the management board are nominated by the European Parliament out of a list, drawn up by the Commission. The members of the management board are selected for their personal background and expertise. Four of the fourteen members are representatives of consumer organisations, one is a representative of the Commission (Groenleer 2009).

Members of the management board: <http://www.efsa.europa.eu/en/people/mbmembers>

12.4 Stakeholders and interest groups

- As the communication of its scientific knowledge is one of the key mandates of EFSA it has an active dissemination strategy and a registration of stakeholders. Organisations who are interested in EFSA’s work can apply for an accreditation as a registered stakeholder. Stakeholders have to comply with some criteria to be accredited. They have to operate at an EU level, they have to have a track record in the food or feed industry, they have to be a representative organisation, they have to be non-profit making and they have to be registered in the EU transparency register. This means that EFSA



only disseminates directly to stakeholders who represent a certain part of the European food and feed industry, on an EU level.

The stakeholders are divided into seven categories:

- Consumers: organisations representing the interests of consumers.
- Environmental/Health NGO's and advocacy groups: Organisations with an interest in public health, safe food or environmental sustainability
- Farmers and primary producers: Representatives of those who provide agricultural, fishery and forestry materials.
- Business and food industries: Representatives of companies belonging to an industry of relevance to ESFA's work.
- Distributors and horeca: stakeholders trading or selling of final food products
- Practitioner's associations: Representatives of professionals working in the field of food safety and public health.
- Academia

Stakeholders can also provide advice to ESFA through two standing bodies: the stakeholder forum, who gather annually, and the stakeholder bureau, made up of seven representatives of the stakeholder forum, they also help shape the agenda of the annual stakeholder forum.

Registered stakeholders: <http://www.efsa.europa.eu/sites/default/files/stakeholders-registered-list.pdf>

12.5 Legal Framework

There are two main regulations for food safety at the European Union level: Regulations (EC) No. 178/2002 and No. 882/2004. These regulations apply to all European Union Member States. Regulation (EC) No. 178/2002, which covers all stages of the food chain, sets the general principles and requirements for food safety law within the European Union (BfR 2017, 8). Regulation (EC) No. 882/2004 sets the general principles to ensure compliance with food safety law (BfR 2017, 8).

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