Guiding food safety authorities in inspection strategy design

A systems approach to food safety regulation

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by

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TU Delft

Preface

In the last couple of years, I have developed a strong interest in the application of technologies by the government for the public good. The increased use of technology has shown to have the potential to be of large impact, positive or negative. The Toeslagenaffaire showcased the discriminatory algorithm of the tax services that led to disastrous consequences, becoming one of the most discussed political topics in recent years. On a personal note, after my time as a Red Cross volunteer, during which we transitioned from paper-based data storage to online data storage, a cyberattack was reported, compromising the data of the beneficiaries I aimed to help, making me question the impact of my efforts. This motivated me to contribute to finding responsible ways to implement new technologies for the public good. That's why the Dutch food safety authority project appealed to me. Risk-based algorithms have become increasingly popular among food safety authorities because of efficiency considerations. With this thesis, I hope to contribute to implementing these algorithms in a manner that ensures a positive impact rather than a negative one.

Even though the thesis itself was an untroubled research process with a topic that excited me from beginning to end, I was personally challenged by an unlucky bike accident that left me with a concussion. I was used to being busy with many things simultaneously, but in the last half a year, I had to learn to slow down. I want to thank my family, Jip, Carlo and my housemates, for their support during this time. Furthermore, I want to thank my supervisors, Haiko and Alexander, for their proactive guidance, elaborate feedback, fast email replies and consideration of my personal circumstances. Altogether, this made my thesis a pleasant experience.

Coming to the end of the master's, I can genuinely say that I have thoroughly enjoyed it. I gained various skills and perspectives that I consider highly valuable. I made the radical change from Industrial Design as a bachelor to Engineering and Policy analysis as a master, and I never regretted it for a second. One of the reasons my master's was highly enjoyable was because of Suus, a previous member of my rowing team, who became my team member in many exciting projects during the master's. Now, with my concussion healed, I am looking forward to apply the gained knowledge, aiming to make a positive impact

Lidewij Maria Heerkens
Delft, October 2023

Summary

The Nederlandse- Voedsel en Warenautoriteit (NVWA) asked the at-first-sight simple question of how to combine risk-based and random methods for inspection. Risk-based and random inspection methods have contrasting incentives. Risk-based inspection increases efficiency and allocates resources efficiently but fails to regulate low and emergent risks. Random inspection tackles unforeseen and emerging risks, ensures representativeness and prevents bias but fails to detect food hazards and non-compliance with food safety laws efficiently. A void in the literature exists on how to address the question of the NVWA. The supposedly simple question thus appeared to be a rather complex one. The research develops guidance for food safety authorities in combining risk-based and random methods through a design science approach combined with a systems view to retrieve a complete understanding while allowing it to narrow down to practical guidance.

To address the literature void, the construct of inspection strategy is developed based on literature and interviews with regulatory authorities. The following definition of the construct is retrieved: an inspection strategy entails selecting and combining methods based on inherent considerations and operationalization on contextual considerations. The construct of inspection strategy is placed between method selection and food safety regulation (see Figure 1). The construct serves as a common language and shared understanding for food safety authorities.

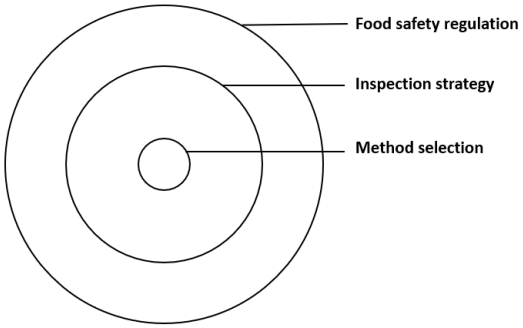

Figure 1: Position inspection strategy

The systems view is introduced to understand why inspection strategy design is complex for food safety authorities because of its context. Literature shows there is value in taking a systems view to regulation. In fact, the complex systems view applied to food safety regulation brought forward systems characteristics to consider in inspection strategy design, including adaptive, emergence, unpredictable and goal-seeking. The systems view showed that an inspection strategy is to be designed within the context of food safety regulation that is continuously changing in an unpredictable manner because of emerging food safety risks. Consequently, the complex systems view provided direction on how guidance for food safety authorities designing an inspection strategy within food safety regulation is to be developed.

Following the definition of inspection strategy and the exploration of the system complexities of the food safety regulation context, the requirements for an inspection strategy are identified. The requirements originated from the systems map, interviews and literature. Fourteen requirements are defined with corresponding categories and priorities. Based on the requirements, a visual framework is constructed, providing an overview of the considerations for food safety authorities designing an inspection strategy (see Figure 2). The framework, when applied to strategies, exposes potential trade-offs. The

framework respects the complexities of the previously uncovered complex system characteristics by providing insight without imposing rigid standards.

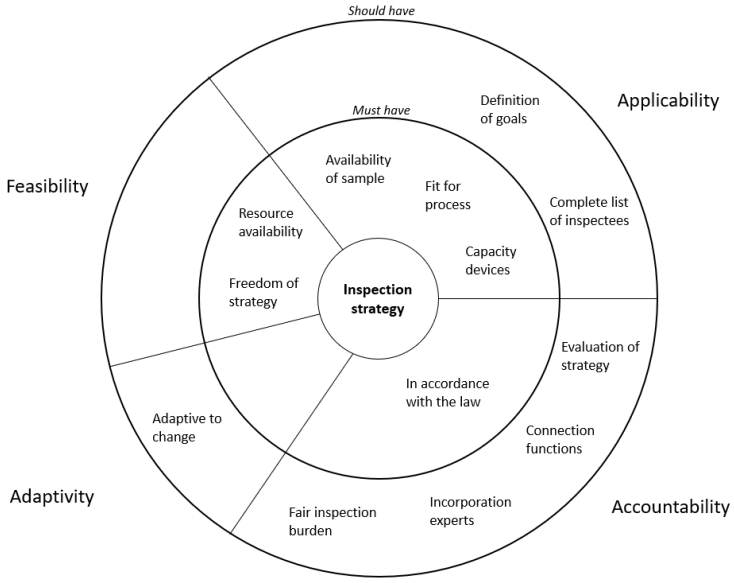

Figure 2: Requirements framework

Guidance for food safety authorities is developed based on the previous findings. The guidance is twofold. First, a scale of encountered inspection strategies from random to risk-based (see Figure 3) is evaluated based on the requirements framework, guiding food safety authorities by providing insight into the associated trade-offs and helping them in the selection of a strategy. Second, questions are developed to guide food safety authorities before, during and after the design of an inspection strategy. Food safety authorities have to implement the guidance themselves.

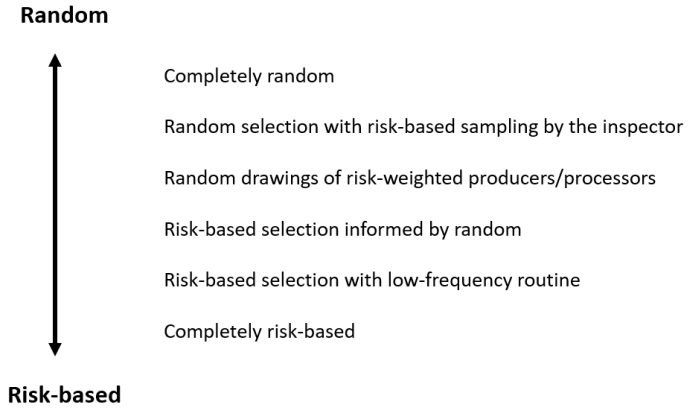

Figure 3: Scale of inspection strategies

Ultimately, the research holds potential for food safety authorities to improve their inspection strategies combining risk-based and random methods when implementing the guidance. Consequently, improving the state of food safety in an accountable, applicable, feasible and adaptive manner. Through validation is confirmed that the guidance is helpful for the NVWA. Furthermore, the research produces academic value by creating a common language in the academic field through the construct of an inspection strategy and by demonstrating the utility of systems thinking for regulation. The recommendation stands to implement the guidance, include participatory methods, validate with various food safety authorities and continue applying systems thinking in food safety regulation for future research.

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List of Abbrevations

Abbreviation	Definition
NVWA	Nederlandse Voedsel- en Warenautoriteit
AGES	Austrian Agency for Health and Food Safety
CAS	Complex Adaptive System

1

Introduction

Safe food is essential for sustaining life and good health (World Health Organization, 2023). Unsafe food consists of food containing harmful bacteria, viruses, parasites, or chemical substances and can be the cause of harmful diseases (World Health Organization, 2023). In the Netherlands, a regulatory authority called the Nederlandse Voedsel- en Warenautoriteit (NVWA) exists to establish national food safety. One of the core tasks of the NVWA is to regulate companies and organizations producing and processing food based on laws and instructions (Nederlandse Voedsel- en Warenautoriteit, 2023).

Inspection is the most important and visible action in regulation (OECD, 2014). Inspection can be executed in various ways to regulate the safety of food. The NVWA strives to plan and execute inspections utilizing the advantages and compromising the disadvantages of random and risk-based inspection methods. The two common inspection methods have conflicting incentives. Risk-based inspection increases efficiency and allocates resources effectively (van Asselt et al., 2021) but fails to regulate low and emergent risks (Black & Baldwin, 2012; Delft University of Technology, 2023). Moreover, risk-based inspection methods withhold food safety authorities from making statements about the complete inspected population. Random inspection, on the other hand, addresses unforeseen and emerging risks and prevents bias but fails to detect food hazards and non-compliance with food safety laws efficiently (Delft University of Technology, 2023; Presi et al., 2008). Random inspections allow for the creation of a representative picture of the inspected population.

The NVWA asked a research team from the TU Delft how to combine risk-based and random methods for inspection. This research is employed to help answer that question. The question of the NVWA appeared quite simple at first, but no straightforward answer came forward in the literature. A gap in the existing literature was discovered while searching literature on inspection strategies combining random and risk-based methods. The construct of inspection strategy, which considers both the inspection context and the methods, appeared to be non-existent while that was expected to help address NVWA's question, leaving a void in knowledge. Consequently, the construct of inspection strategy is first to be defined by employing the design science approach. Following, exploration is conducted to understand why NVWA's question is complex rather than simple. The systems view is incorporated into the design science approach to create a complete understanding of the complexities. The systems view uncovers why the design of an inspection strategy is complex based on the system dynamics in which food safety regulation takes place. The design science approach allows to narrow down the insights to rather practical knowledge for answering the question. Last, guidance is formulated to support the NVWA in addressing their question. Ultimately, the research aims to provide valuable insights for food safety authorities looking to combine risk-based and random methods within an inspection strategy.

The thesis is structured as follows. In the second chapter, the research approach and methods are defined to fit the purpose of the study. In the third chapter, the construct of inspection strategy, its components and necessity is defined. In the fourth chapter, the complex system context in which inspection

strategies are to be designed is explored. In the fifth chapter, the requirements for an inspection strategy are defined through further investigation of the inspection strategy and its systems context. In the sixth chapter, the previous findings are translated into guidance for an inspection strategy for the NVWA and/or other food safety authorities. Then, in the discussion, the findings, the social and academic relevance, limitations, and recommendations for future research are appointed. Last, in the conclusion, the main research question and the sub-questions are answered.

2

Research approach and methods

A transparent and structured approach to research is at the base of the creation of scientific value. Therefore, the research approach and methods are clarified and elaborated on in this section. The section begins with the research problem. Second, the research questions are aligned. Then, the selected research approach, the design science approach, is substantiated. Last, the methods employed to answer the main research question are discussed.

2.1. Research problem

The research follows a problem-based research approach. The research problem at the base of the research is provided through the question of the commissioner, the NVWA. The question of how to combine risk-based and random methods for inspection seems quite practical at first. However, no straightforward answer or method to solve the problem has been shown to exist in the literature (see Chapter 3 for literature discussion). The literature on the combination of risk-based and random methods is scarce, and the construct of inspection strategy, which was expected to be found in the literature, appears to be rather undefined, leaving a void in knowledge for addressing the question of the NVWA. The question is framed as the problem of designing an inspection strategy that combines random and risk-based methods when one lacks the knowledge to do so. Leading to a three-fold knowledge gap: the lack of the construct of an inspection strategy, the unknown complexities for food safety authorities in the design of an inspection strategy and the undetermined way food safety authorities ought to design an inspection strategy combining risk-based and random methods.

The research problem of food safety authorities having to design an inspection strategy that combines random and risk-based methods while lacking the knowledge to do so requires a learning-by-doing route. The learning-by-doing route allows the research to start with a broader and explorative approach to uncover the unknowns and complexities of the problem. The end goal of the research is to help the NVWA in the design of an inspection strategy that combines risk-based and random methods. To provide actionable help in the design of an inspection strategy, guidance is to be developed in designing an inspection strategy with a risk-based and random method for food safety regulation. Guidance is formed depending on the uncovered unknowns and complexities of the problem.

As mentioned before, the problem of the lack of knowledge to design an inspection strategy combining risk-based and random methods has been written very little in the literature, let alone on how to solve it. Nevertheless, the European Union set a requirement for food safety authorities of its member states to design a partly risk-based strategy (Borraz et al., 2022). The problem is, therefore, likely to be shared by food safety authorities within the European Union. Thus, knowledge creation on the problem itself and the development of guidance in dealing with the problem could be valuable for food safety authorities across the European Union.

2.2. Research question and sub-questions

To first understand and explore the construct of inspection strategy along with its context and to later find a way to support food safety authorities in designing an inspection strategy, the following research question is constructed:

How can guidance be developed for food safety authorities aiming to design an inspection strategy that combines risk-based and random methods based on the process of understanding the complex context?

Following the main research question, the sub-questions are formulated. The four sub-questions are aligned below, accompanied by their aim and their employed method(s). The methods for answering the sub-questions are already mentioned to give a structured overview of the research. The argumentation on the selection of the methods is clarified throughout the research since the research follows a learning-by-doing route and methods were employed based on previous findings throughout the research.

1. *What is an inspection strategy and why is it necessary?*
   The aim of this sub-question is to address the first part of the knowledge gap, namely the lack of construct of inspection strategy. The inspection strategy and its components and necessities are to be defined. To answer this question, interviews and literature are employed.
2. *Why is the design of an inspection strategy complex based on its context?*
   The aim of this sub-question is to address the second part of the knowledge gap on the unknown complexities of inspection strategy design. The complex context of food safety regulation is explored with a systems view to answer this question.
3. *What are the requirements for an inspection strategy?*
   The aim of this sub-question is to identify what an inspection strategy needs for food safety authorities to combine a risk-based and random method based on further investigation of the system. To answer the question, interviews, literature and a system map are used to retrieve the requirements.
4. *What guidance can be developed for food safety authorities designing an inspection strategy?*
   This sub-question aims to operationalise the findings of the previous sub-questions to provide guidance for food safety authorities. To answer the question, the format of the guidance is defined, and the guidance itself is developed.
5. *Is the guidance applicable for food safety authorities?*
   The aim of the sub-question is to establish whether the guidance is applicable to food safety authorities and if adjustments are still to be made to improve the guidance. To answer this sub-question, another interview is conducted focused on validation.

2.3. Design science approach

The previously defined research problem requires a rather practical problem-based approach and a learning-by-doing route. First, the problem is to be understood before the approach can be defined to deal with the problem. Johannesson and Perjons (2014) state that ”practical problems are often wicked problems in the sense that they are difficult or impossible to solve due to incomplete knowledge, contradictory and changing requirements, and the complex interplay between related problems”. The design science approach is intrinsically iterative and explorative and thus suitable for the undefined practical problem of this research. Practical problems are to be solved by means of design artefacts (Johannesson & Perjons, 2014)

Furthermore, the design science approach has its roots in engineering and is a fundamentally problem-solving paradigm (vom Brocke et al., 2020). One of the goals of design science is to push the boundaries of organisational capabilities through the design of artefacts (vom Brocke et al., 2020). The artefact can take many forms, including constructs, models, methods, and instantiations. Design science creates knowledge on how things are to be arranged to achieve certain goals, referred to as design knowledge. In the design science approach, the design artefact is central in the creation of knowledge (vom Brocke et al., 2020).

In this research, the design artefact is the inspection strategy, and thus design knowledge is to be created on how the inspection strategy is to be arranged to serve the goal of food safety regulation taking into account the organizational capabilities of food safety authorities. The inspection strategy can be categorized as a construct, which ought to create a formalized language and shared knowledge of a discipline (Jacob et al., 2022). The design science approach translates to exploring and understanding the current problem of inspection strategy design and providing rather actionable guidance to help the food safety authorities design an inspection strategy.

2.3.1. Design science framework

The design science research framework exhibits the iterative design science processes. The design science research framework is built upon three bases and three cycles (Hevner, 2007). The bases represent environment, design, and knowledge. The three cycles represent the iterative processes between the bases; relevance cycle, rigor cycle, and design cycle. The relevance cycle provides the research with an application context. The application context translates to directions as research input and indications of fitness of the design in its environment (Hevner, 2007). The rigor cycle ensures past knowledge is included and new knowledge is created in the research project. In the end, the knowledge contributions are added to the knowledge base through the rigor cycle. The design cycle is the heart of the design science process. The design cycle represents the iterations between research activities and the development of the design artefact (Hevner, 2007).

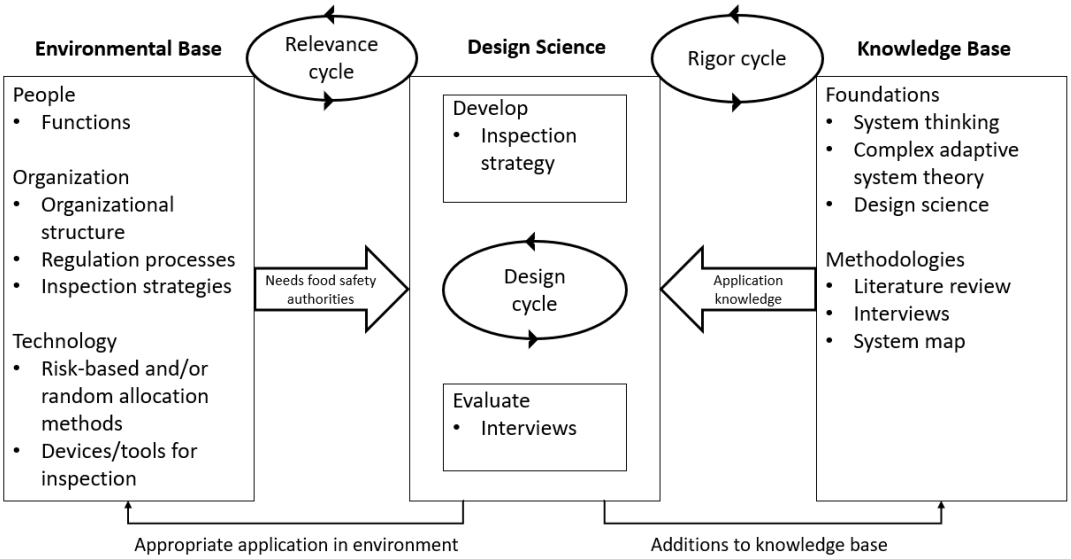

Figure 2.1: Design science research framework

Figure 2.1 represents the design science process applied to this specific research. The figure is inspired by the framework of the study 'Introduction to Design Science research' by vom Brocke et al. (2020). The environmental base is the context of the design, so in this case, the organization of food safety authorities, the technologies available to use in inspection strategies, and the people within the organization that take part in designing an inspection strategy. The knowledge base contains the foundations in literature and the knowledge of methods to support the design science research process. Through the rigor and relevance cycle, the input of these bases is added to the design cycle of the inspection strategy. The design science framework represents the iterative processes within design science to create applicable and scientific design knowledge. Following the framework and its processes, a more practical research plan is created to operationalize the design science approach.

2.3.2. Design science plan

The framework represents the iterative and rather chaotic process of design science. The design research process is to be structured to make the research executable. Johannesson and Perjons (2014)

provided an introduction to design science to support researchers undertaking comprehensive, understandable, and actionable design science research. Johannesson and Perjons (2014) clarified the activities in design science in the form of a five-step plan. In the complete design science plan, the researcher takes the role of observer, artefact designer, and evaluator (Jacob et al., 2022). Johannesson and Perjons (2014) listed the following five activities to be executed by the researcher:

1. Explicate problem
2. Define requirements
3. Design and develop artefact
4. Demonstrate artefact
5. Evaluate artefect

However, Johannesson and Perjons (2014) state that most design science researchers do not undertake all of the five activities of the five-step plan in depth but that researchers tend to focus on one or two of the activities.

The research problem directs the focus to the first two activities: explicate the problem and define requirements. The first activity of explicating the problem consists of two steps in this research. The first step is to define what an inspection strategy entails and why the absence is problematic, and the second step is to uncover how the context makes the inspection strategy design complex. The two steps together explicate the problem of inspection strategy design. The second activity aims to retrieve what an inspection strategy requires. The food safety authorities design and implement the inspection strategy within their organizational and technical capabilities themselves. A food safety authority has in-house knowledge of the inner workings of their organization and the specifics of every sector (e.g. animal health, plant health, industrial production, chemicals, etc.). The available time within this research is too limited to obtain complete knowledge of the organizational structure of every department and technical specifics of sectors to design multiple concrete and ready-for-use inspection strategies.

Nevertheless, the research aims to provide guidance for the food safety authorities to implement and design their own inspection strategies. An additional step is required in the design science plan to make the plan applicable to food safety authorities, including the commissioner (NVWA). An additional step is added to the design science plan of Johannesson and Perjons (2014), namely the guidance for the design of the artefact. Figure 2.2 shows the design science plan of Johannesson and Perjons (2014) adjusted to this specific research. The additional step of guidance for designing an inspection is developed based on the problem explication and the design requirements.

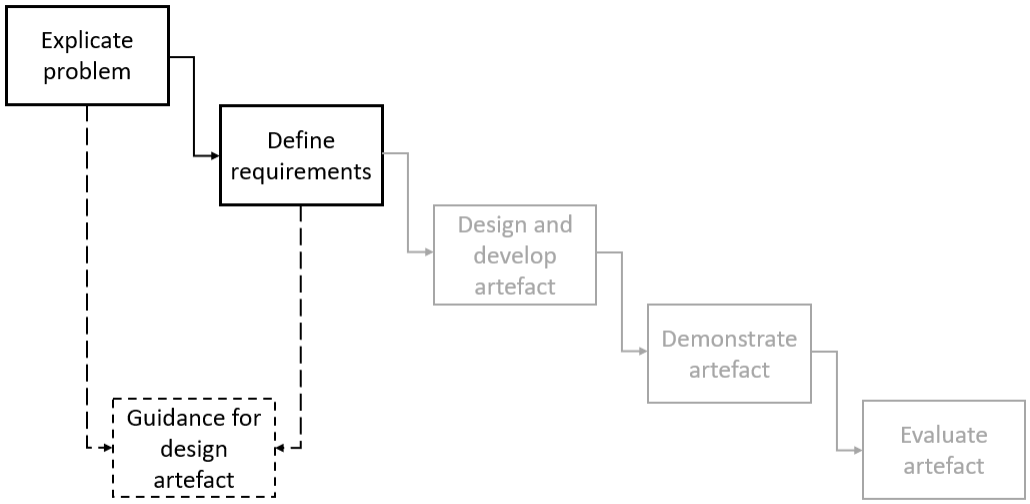

Figure 2.2: Design science plan

2.4. Research methods

In the description of the sub-questions, the methods are already briefly mentioned. Within the design science approach, multiple research methods are employed to fuel the design of an inspection strategy through the relevance and rigor cycle. The selection of the methods occurred while executing the design processes, so not all methods are predefined at the start of the research but chosen based on the continuous findings within the design science research process. Nonetheless, an overview of the methods is provided in this section to ensure a clear and transparent research approach. The reason for the selection of some methods is further substantiated in upcoming chapters.

2.4.1. Literature reviews

The literature review is purposed to build upon knowledge from previous research and to put the research in its academic context. Literature reviews are considered specifically useful when the literature is complex and multidisciplinary, which is the case for the research problem of designing an inspection strategy for food safety. Additionally, reviews can lead to insights into how components relate to one another within a research area (Campbell et al., 2014).

The academic literature is gathered through search engines and selected based on keywords and publishing date. Keywords include but are not limited to regulation, inspection, regulatory governance, risk-based, random, surveillance, and monitoring. Preferably in relation to food safety regulation. Engines that are included are ResearchGate, Springer, Google Scholar, and ScienceDirect. Academic literature in the context of inspection strategies, such as systems thinking and regulation theories, are expected to be relevant throughout the years. However, the risk-based focus in inspection strategies is a more recent approach, so more literature within this academic area is preferred.

The literature review adds to the knowledge base through the rigor cycle within the design science approach throughout the research. First, the literature review serves as a foundation for the research by the academic interpretation of the research problem. Second, literature reviews are employed throughout the research to substantiate thought processes and findings. The method is employed to help answer the first, second, third and fourth sub-questions.

2.4.2. Interviews

The interviews aim to investigate the environmental base of inspection strategies. Interviews are employed to generate knowledge on the construct of inspection strategy and its complex context to expli-

cate the problem. Additionally, interviews are employed for the identification of the design requirements in relation to food safety regulations and other regulation fields where inspection is present. At the end of the research, one last interview is conducted with the purpose of validation. Interviews allow for deeper knowledge, understanding, and exploration of a research problem that is relatively undefined. The method leaves room for the perspectives on the inspection strategy of the interviewee.

The selection of the interviewees is dependent on the willingness of the commissioner to participate. The aim is to make an interviewee selection with the largest part of the interviewees related to inspection strategies within the field of food safety regulation. However, to limit the dependence on the commissioner, interviews on inspection strategies in other fields are included on top of the ones within food safety regulation. Furthermore, the inclusion of interviews in other fields provides context for the state of inspection strategies across regulatory fields. The approach to the interviews is semi-structured to guide the interviewee to discuss the direction of the research problem but allow for associations that the researcher had not thought of beforehand. The interviews are analyzed methodologically through coding because bias can be reduced through a methodological and transparent approach (Kalu & Bwalya, 2017).

The outcome of the interviews is knowledge creation on the design environment and serves as input for the design artefact through to the relevance cycle. The interview protocol can be found in Appendix A, and the interview analysis in Appendix B. The method is employed to help answer all the sub-questions.

2.4.3. System map

System maps are included in the research because it is considered a useful method in investigating complex systems (Cavill et al., 2020). Chapter 4 demonstrates the complex systems environment of food safety regulation and inspection strategies, leading to systems mapping as the chosen method. System maps are employed to map the interaction and dynamics of factors constituting a system. The value of system maps has been demonstrated in the public field of complex health problems already (Kiekens et al., 2022). Moreover, system mapping can help researchers gain deeper insights into the causes of a problem and identify opportunities within the complexities of the system (Kiekens et al., 2022).

The system map is developed based on qualitative data from the interviews with the food safety authorities and in collaboration with experts. A system map can take different forms. For this research, a system map is developed based on causal components and interactions to understand how an inspection strategy is arranged, what components impact the strategy, and in what way.

The design of the system map is an iterative process. The outcome of the method is a visualization of the system map, including the impactful components and the dynamics of the system. After the system is mapped, the map is evaluated to identify inspection strategy requirements that can be translated into guidance for designing an inspection strategy. The method is applied to predominantly answer the third sub-question.

3

What is an inspection strategy?

As stated in the research problem, the undefined construct of inspection strategy leaves a void in knowledge for addressing the question of the NVWA. The first step in this research is to define an inspection strategy precisely. Alongside this, the necessity and components of an inspection strategy are established. The definition of inspection strategy forms the basis for addressing the challenge: the lack of knowledge in designing an inspection strategy employing random and/or risk-based methods. This section adds to the problem explication, the first activity in the design science plan (see Figure 2.2).

The inspection strategy's definition, necessity, and components are explored through the discussion of the literature on inspection strategy, inspection strategies in practice and goals of inspection strategies. The discussion fuels the design science framework's rigor and relevance cycle (see Figure 2.1). The literature discussion on inspection strategy contributes to the rigor cycle, while interviews to uncover the inspection strategies in practice provide input through the relevance cycle. The interview protocol can be found in Appendix A, and Chapter 5 elaborates on the interview questions in detail. In the end, the chapter concludes by providing the final definition of the construct of inspection strategy in relation to the problem, offering a clear and definitive overview.

3.1. Literature on inspection strategy

Because of the scarce literature on the construct of inspection strategies, a preliminary definition is established by the definitions of 'inspection' and 'strategy.' A food safety regulating authority such as the NVWA can take different actions to detect non-compliance with national food safety laws. Inspection is the most visible and important action in food safety regulation (OECD, 2014). Inspection entails an inspector visiting a producer/processor of food. The inspectors can take samples or check for certain standards at the producer/processor. A strategy is defined by Hambrick et al. (2005) as the approach to achieving objectives. Without a strategy, time and resources can be wasted easily (Hambrick et al., 2005). The preliminary definition of inspection strategy is thus defined as the approach to inspection to serve the objective of safe food. The definition of inspection strategy is iterated and refined at the end of this chapter.

Within an inspection strategy, methods are selected for inspection to serve the intended objective. A variety of methods can be utilized within inspection strategies, including random and risk-based methods. The two methods, random and risk-based for inspection strategy, are central in the research since the question of the NVWA is to find a combination of the two. Even though the literature on inspection strategies is scarce, literature on risk-based and random methods and their implications for an inspection strategy can be found. Especially, risk-based methods have been increasingly discussed as a favourable part of the inspection strategy over the last couple of years,(OECD, 2014; van Asselt et al., 2021; World Health Organization, 2019). The literature on methods is discussed to contribute to the definition of an inspection strategy, establish the need for the broader concept of inspection

strategy and identify the components that should be integrated into this definition. The literature fuels the construct of inspection strategy through the rigor cycle.

An overview of risk-based methods for inspection in food safety regulation is provided by van Asselt et al. (2021). van Asselt et al. (2021) stated that risk-based methods for inspection are upcoming because of the proportionate allocation of resources and their effectiveness. In spite of that, van Asselt et al. (2021) pointed out that the selection of a method is indeed not as straightforward as one might initially expect. In fact, van Asselt et al. (2021) noted that no global consensus on the methods for risk-based inspections exists and that the selection of the method is highly impacted by the time and budget available as well as what output is preferred. The dependence for method selection on budget, time and preferred output confirms the need for a broader construct of an inspection strategy that involves these components.

Another study that touched upon risk-based methods for inspection in food safety regulation is by Ferri et al. (2023). Ferri et al. (2023) provided an overview of features, opportunities, and challenges of a risk meat safety assurance system within Europe and the role of official veterinarians as risk managers. Ferri et al. (2023) argued that the implementation of a risk-based method should be a slow and careful process followed by consistent development and comes with challenges such as dealing with knowledge gaps and opposition of actors. In addition, Ferri et al. (2023) concluded that a strong commitment of all actors in the food system is required to ensure positive change and proper allocation of resources. The study by Ferri et al. (2023) demonstrated the impact of actor influences, knowledge gaps and resource allocation on the success of a method. Again, this confirms the need for a broader construct of an inspection strategy that considers the components like actors, knowledge and resources.

Along with van Asselt et al. (2021), Blanc and Faure (2020) similarly noticed the upcoming usage of risk-based methods in regulation and inspection strategies. In the study, three cases are analyzed, showing varying degrees of EU involvement with risk-based methods. One of the case studies focused on food safety. In the area of food safety, European legislation specifically mandates the use of risk-based enforcement practices. Blanc and Faure (2020) stated that the European Commission worries about the differences in the actual implementation of risk-based methods by national authorities because of differences in institutions, resources, approaches, etc. Furthermore, limits to risk-based methods for inspection strategies were appointed. Risk-based methods would only focus on visible and larger risks and thus ignore small violations of which the cumulative impact could also be considerable. Blanc and Faure (2020) argued to complement risk-based methods with random methods to have at least some frequency of inspection for low-risks. From the study of Blanc and Faure (2020), three relevant conclusions are drawn for inspection strategies combining a risk-based and random method. First, a combination of a risk-based and random method is a strategy direction to pursue. Second, a risk-based method is inherently limited because of the sole focus on larger risks. Third, considerations on the actual implementation of a method are significant for the success of a method. The three conclusions establish the need for a broader construct of inspection strategy that considers the actual implementation in its context and method limitations and combines both random and risk-based methods.

The inherent limitations of risk-based strategies have been highlighted by Black and Baldwin (2012) likewise. Black and Baldwin (2012) developed a strategic framework for regulators to use when selecting intervention strategies for dealing with low risks. Black and Baldwin (2012) provided an explanation of why risk-based regulation aims low. The goal of risk-based inspection as a strategy is to calculate risks so that resources can be allocated accordingly. On the face of it, a risk-based inspection strategy appears to be a rationalistic solution to a complex problem. However, a risk-based strategy has limitations and fails to provide a plan of what regulators are ought to do because it a false assumption that low risks only require low resources to be dealt with effectively (Black & Baldwin, 2012). Risk-based regulation is not to be viewed in any way as the one practical solution that targets the highest risks and allocates priorities accordingly (Black & Baldwin, 2012). The study by Black and Baldwin (2012) demonstrated that an inspection strategy requires more than just selecting a risk-based method and that the limitations of risk-based methods must be considered in the inspection strategy design.

The literature on risk-based and random methods for inspection in food safety regulation provides two indications for inspection strategies. First, the inspection strategy needs to be defined broader than just the method selection, as the strategy heavily relies on components including actors, resources and knowledge. Second, risk-based methods within the inspection strategy have constraints that are to be dealt with accordingly in the design of an inspection strategy. Even though risk-based methods are considered an upcoming opportunity for an effective inspection strategy by food safety authorities. Risk-based methods also show complexities considering practical implementations and methodological limitations, such as the sole focus on high risk. At this point, ambiguity exists around the most appropriate method combination within an inspection strategy to use in different contexts. Random methods as part of an inspection strategy in food safety regulation have been less popular in the literature discussion. Nonetheless, the combination of a risk-based method with a random method in an inspection strategy is stated as a direction to pursue by Blanc and Faure (2020). The literature on methods revealed that the definition of an inspection strategy should encompass both methodological considerations and contextual components.

3.2. Inspection strategies in practice

After fueling the construct of an inspection strategy through the rigor cycle with literature, the construct is further developed through the relevance cycle with interviews. The relevance cycle fuels the construct through interviews on inspection strategies as they are applied in practice. Throughout the research, interviews serve different purposes; in this chapter, the purpose is to enhance the definition of the inspection strategy construct. Chapter 5 elaborates on the interview questions, and the interview protocol can be found in Appendix A. In practice, food safety authorities often implement inspection strategies using risk-based and random methods without explicitly labelling them as inspection strategies. The interviews shed light on these inspection strategies in practice, contributing to the definition of an inspection strategy, demonstrating the need for a broader concept of inspection strategy and identifying the essential components that should be incorporated into this definition.

3.2.1. Practice of the NVWA

In the interviews with NVWA employees, current inspection strategies in practice are uncovered. The NVWA is actively seeking an inspection strategy that appropriately combines both risk-based and random methods. Nevertheless, at this time, they have operational inspection strategies that require further discussion to explore the current state of the inspection strategy and the current inclusion of risk-based and random methods for possible future design directions integrating risk-based and random methods in the inspection strategies. The current inspection strategies and their components that emerged from interviews with NVWA employees are discussed.

In the interviews, the method selection in combination with the resource allocation is often mentioned as a large consideration in the inspection strategy by the interviewees from the NVWA. Interviewee 2 stated that the amount of samples taken during inspections is very small, so it is very important to select the right places to take samples. Interviewee 5 specified as the largest challenge where you should inspect; the capacity is limited, so choices need to be made. Interviewee 7 is responsible for making inspection plans and expressed that limited resources play a significant role in the planning of inspections. The method used to determine the places where to inspect is closely tied to the constraints of resources. This underscores the importance of considering both method selection and resource constraints in the design of an inspection strategy.

Another determinant in the inspection strategy by the NVWA that came forward in the interviews is the differences in inspection strategy required per sector. The inspection strategy heavily depends on what is to be inspected: an animal, a supermarket item, or a packaging process. The NVWA is responsible for a wide variety of sectors; some examples are animal health, plant protection, and the food service industry. In the case of the NVWA, the microbiology sector tends to select the producers/processors to be inspected risk based on the location in the food chain, and then the inspector takes the samples randomly (Interviewee 3). In the animal health sector, however, producers/processors to be inspected are selected mostly randomly, but the inspector looks for risks when inspecting animals when sampling for antibiotics or hormones (Interviewee 2). For instance, a sick-looking animal is more likely to have

received antibiotics, or a fat animal has more chance to have received hormones. In addition to the differences per sector, the goals per sector for an inspection strategy differ accordingly. The differences in practice per sector reveal that an inspection strategy is to be designed specifically per sector.

NVWA showed to design inspection strategies while considering resources in combination with methods and demonstrated to execute different strategies in different sectors. Current inspection strategies are dependent on resources and the specifics per sector. Making the design of an inspection strategy a rather context-dependent undertaking rather than a solely methodological one. An inspection strategy is thus to take into account not only the risk-based or random methods but also the sector specifics and available resources.

3.2.2. Practice of AGES

The Austrian Agency for Health and Food Safety (AGES) was introduced into the research by the NVWA because of the shared interest in finding a combination of risk-based and random inspection methods. AGES has, similar to the NVWA, the ultimate goal to ensure food safety. Additionally, an official requirement from the European Union exists to have some form of a risk-based method included in the inspection strategy (Borraz et al., 2022). So, both AGES and NVWA share the same ultimate goal and the same requirement by the European Union.

Two employees from AGES were interviewed to discuss the inspection strategy in practice. Important to note before going into the inspection strategy is that the organizational structure of the food safety authority is different in Austria compared to the Netherlands. AGES collaborates with the Federal Office for Food Safety to ensure food safety. AGES defines the inspection plan, the statistical part, and the calculations, and the Federal Office executes the inspections and makes management decisions (Interviewee 7). The design is separated from the execution of the inspection strategy. AGES makes the planning based on drawing weighted samples of the list of producers/processors (Interviewee 4). The samples are weighted through risk factors (Interviewee 4).

When interviewing AGES employees, components to be considered in inspection strategies arose. Namely, AGES struggles with the concrete formulation of the goal of inspections, which impacts where to put the focus (Interviewee 7). The NVWA named the dependence on the formulation of goals similarly but in relation to inspection method selection (Interviewee 2). Furthermore, Interviewee 4 specified the little data available to identify risk factors and model the risks to serve as input for selecting the producers/processors (Interviewee 4). Interviewee 3 from the NVWA also stated to have relatively little data available, leading to an inspection strategy predominantly based on experts. The availability of data or experts and goals are impactful components to be included in the construct of an inspection strategy.

The discussion on the practice with AGES exposed an inspection strategy design based on the drawing of risk-weighted samples, potential variations in the organizational structures of food safety authorities to be considered, and overlap in components in relation to inspection strategy design between food safety authorities. The inspection strategy of AGES demonstrates that differences exist between inspection strategies of food safety authorities in practice, even though they deal with similar components, have the same ultimate goal of ensuring food safety and the same European Union requirement of the inclusion of a risk-based method in the strategy. The inspection strategy is to be mindful of the organizational structure, goals and constraints, such as data availability.

3.2.3. Practice of Dutch inspection of education

One interview was conducted with the inspection of education. The inspection of education is similar to the NVWA, a Dutch regulating governmental authority that is funded by a ministry (Rijksoverheid, 2023). A different ministry than the NVWA, nonetheless. The inspection of education has as its goal to assess the quality of education in schools and other educational institutions (Rijksoverheid, 2023). Inspections are part of their activities to assess the quality of education and serve the goal of ensuring good education. The inspection of education employs an inspection strategy in practice similar to the NVWA and AGES.

With a data scientist from the inspection of education, an interview was conducted. From the interview, recent changes in inspection strategy design came forward. The inspection of education first predominantly employed a risk-based approach within the inspection strategy. The problem with this approach was that only predefined high-risk groups were inspected, and no inspections were executed for the low-risk group, leading to a gap in information about the entire population (Interviewee 8). With this strategy, the inspection of education had no clue how many poor education schools they missed and whether the allocation of inspection resources was effective.

The inspection of education recently decided to include a significant number of random inspections. The number of random inspections was defined based on the confidence interval of the entire population to be able to make statements about the entire population. The inspection of education authority deals likewise with a variety of sectors. For instance, primary education, secondary education, newcomer education, and special needs education. The amount of needed random inspection differs per sector. Smaller sectors, for instance, special needs education, need relatively more random inspection to be able to make representative statements about the entire population of inspectees.

In the interview, the possibility of weighing risk-based inspection results instead of random inspection results to be able to make statements about the entire population was discussed. Interviewee 8 stated that the approach did not seem favourable to retrieving representative results based on executed research. However, Interviewee 8 said to have received a significant budget in recent years at the inspection of education and that they might reconsider such an approach if the budget is cut.

The inspection strategy in practice by the education of inspection showed the impact of the allocated budget by the concerned ministry. Furthermore, the limitations of a solely risk-based approach for an inspection strategy and the differences in the number of required random inspections between sectors to be beneficial for the inspection strategy were exposed. Collectively, these findings further underscore the necessity for the construct of an inspection strategy that incorporates resource constraints, considerations of implementation in specific sectors and limitations of risk-based methods.

3.3. Goals of inspection strategies

In the inspection strategy discussion by AGES and the NVWA, the influence of the goals is briefly mentioned. Consequently, this section aims to elaborate on the goal of inspection in relation to the inspection strategy. Interviewee 7 from AGES stated to struggle with a concrete formulation of goals and Interviewee 2 from NVWA stated that the trade-offs between risk-based and random methods depend on the goal of the inspection. The impact of the defined goal of the inspection on the strategy is to be discussed to gain further understanding of the implications.

The goals of inspections came forward in multiple interviews conducted by various members of the TU Delft research team working on NVWA's question. Together with the research team, the inspection goals were discussed, aligned and visualized (see Figure 3.1). As previously mentioned, the ultimate goal of food safety authorities is to ensure food safety, but the approach to achieve the ultimate goal involves pursuing different intermediate goals (see Figure 3.1). The figure commences with the ultimate goal positioned on the left, followed by the goals and subgoals, and ending in the action of inspection. The inspection strategy depends on what goals and subgoals are to be pursued. For instance, a different inspection strategy is required to map sectors versus to catch violations. If the goal is catching violations, a predominantly risk-based method focusing on violation risks might be favourable while when the goal is to map the sector, a predominantly random method would be favourable to include the entire inspected population.

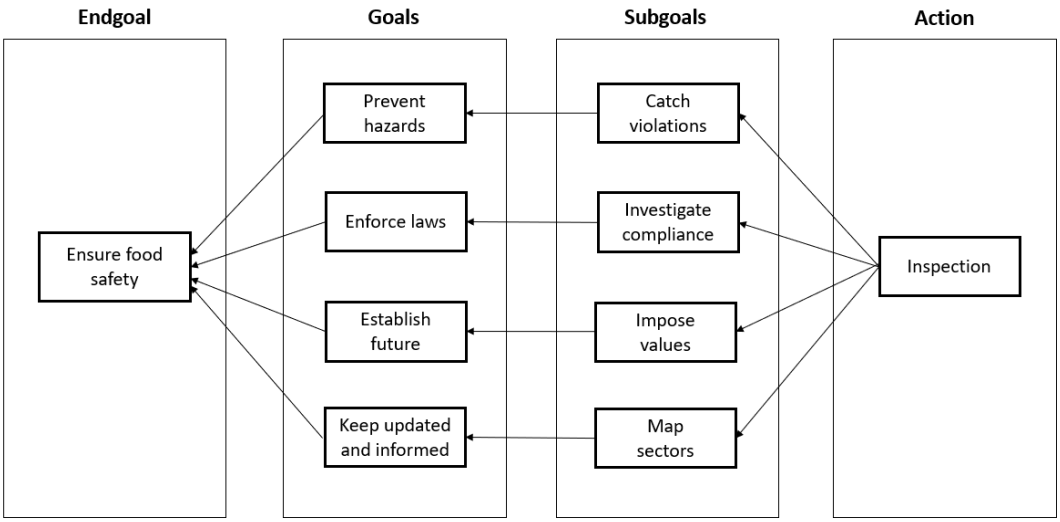

Figure 3.1: Inspection goals

The variation of goals and subgoals impacts the inspection strategy aiming to achieve the end goal of ensuring food safety. Without the definition of the intermediate goals, the right method cannot be selected to achieve these goals. The strategy of inspection, including the selection of the method, is thus to build upon these goals. The inspection strategy is to incorporate the definition of goals in the design process.

3.4. Final construct of inspection strategy

In this section, step by step, an understanding is created of the construct of inspection strategy, including its necessity and components. A compilation is made to provide an overview of all the components of inspection strategies that came forward in literature, interviews and discussions within the research team. The construct of inspection strategy is defined based on the literature on inspection methods, inspection strategies in practice and the goals of inspection.

Literature demonstrated the need for an inspection strategy that incorporated limitations of risk-based methods, knowledge limitations, willingness of the actors and resource constraints. The inspection strategies in practice further confirmed the impact of resources and limitations of risk-based methods but also brought forward the necessity to include specifics per sectors, data availability and organizational structures in inspection strategies. The goals of the inspection strategy were shown to be a determinant of the direction an inspection strategy is to pursue and is thus the be considered in the inspection strategy design as well. Altogether, the need for a broader construct of inspection strategy that includes the previously mentioned components is confirmed. Furthermore, the dependence on many components demonstrates the design of an inspection strategy is a rather complex undertaking.

At the start of the chapter, a definition of an inspection strategy is given, namely: 'An inspection strategy is the approach to inspection to serve the objective of safe food'. In this chapter, the inspection strategy demonstrated to rely on two key elements: method selection, which involves selecting and/or combining random and risk-based methods while keeping the limitations in mind, and the context, which includes components like available resources, sector-specifics, data availability, willingness of actors, goals and organizational structures. Coming to the end of the section, an iteration of the construct of inspection strategy is provided to create a common language and a shared understanding throughout this research.

An inspection strategy entails the selection and combination of methods based on inherent considerations and operationalization based on contextual considerations.

To further comprehend the construct of an inspection strategy, the position of an inspection strategy is appointed. The inspection strategy is positioned between food safety regulation and method selection, as illustrated in Figure 3.2. The inner circle of method selection entails selecting and/or combining risk-based and random inspection methods. The outer circle of food safety regulation entails the broader context within which an inspection strategy is designed to operate, including all rules, developments and actions aimed at ensuring the overall safety of food beyond inspections. The inspection strategy is right in the middle, representing both the selection of method and the operationalization in the context of food safety regulation. It's important to recognize that no perfect combination of methods fits every context. The selection of methods depends on various previously mentioned inherent considerations. Furthermore, contextual considerations, for instance, changing resource constraints for food safety regulation, can significantly impact the inspection strategy. Chapter 4 will provide a more in-depth exploration of the food safety regulation context. This research predominantly aims to provide guidance in the design of an inspection strategy, where the impacts of method selection and food safety regulation are considered whenever they are directly relevant to the inspection strategy design.

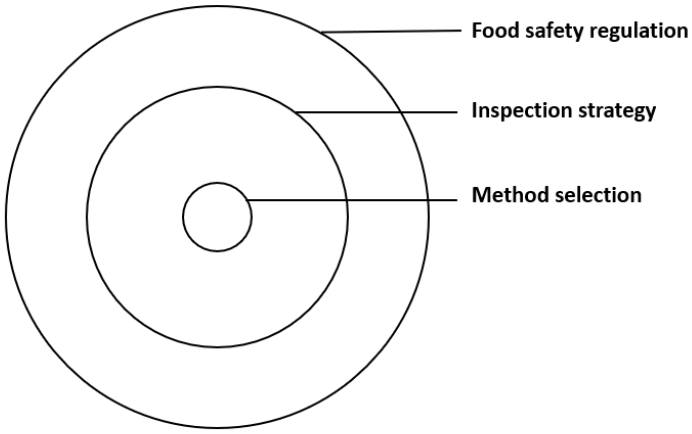

Figure 3.2: Position inspection strategy

Ultimately, the definition of an inspection strategy has been developed to create a common language in the field of food safety. Furthermore, the inspection strategy has been placed in between method selection and food safety regulation and is to be used to answer the question of the NVWA. An inspection strategy holds the potential to deal with weaknesses of methods and put the methods into their organizational and technical context of food safety regulation. The construct of inspection strategy is thus essential for food safety authorities since the discussion on method selection is too limited to serve input for answering the question of combining risk-based and random inspection methods. The definition of the inspection strategy is the first step to explicate the research problem fueled by the question of the NVWA and tackles the first part of the knowledge gap on the lack of the construct of an inspection strategy. The second part of the knowledge gap on the contextual complexities of inspection strategy design will be further determined in the next chapter.

4

Complex system context of inspection strategy

In the previous chapter, 'What is an inspection strategy?', the large impact of the food safety regulation context came forward. An inspection strategy becomes complex because of the context a strategy is to be designed within. The contextual complexities are rooted in the dynamics of food safety regulation. This chapter aims to establish the complexities of the food safety regulation context impacting the inspection strategy. Based on the complexities, insight is provided into how inspection strategies are to be designed and into the following research path. The systems approach is introduced, and the complexities are explored by literature on the systems context, the complex adaptive systems view and the discussion on risk perception in the multi-actor system. This section is the second step in the problem explication and is still part of the first activity in the design science plan (see Figure 2.2). Both the rigor and relevance cycle are employed to explicate the complexities of inspection strategy design (see Figure 2.1).

4.1. Literature on systems context of inspection strategy

An inspection strategy combining risk-based and random methods has shown to be heavenly dependent on the context, including specifics of the sector, the inspection goals, the available resources, practical implications, and the willingness of the actors. Since the design of an inspection strategy depends on its context, the context is to be investigated first before an answer can be formed to guide the NVWA on how to design an inspection strategy combining both methods. A step back must be taken to retrieve insight into the system dynamics of food safety regulation. A systems approach allows for a more holistic view of the contextual complexities of food safety regulation impacting inspection strategies. The potential of a systems approach to food safety regulation has been discussed in the literature.

Food safety is seen as a complex adaptive system by Nayak and Waterson (2019). Nayak and Waterson (2019) took a complex adaptive system approach to create an understanding of food safety. Food safety has the characteristics of complex adaptive systems, such as interaction between many entities, variabilities, and context dependence. Accordingly, adopting a systematic approach to food safety is essential to gain insight into the entire system. Furthermore, the food system is defined as a system with many subsystems, namely government regulation, private sector, educational, and consumer systems (Nayak & Waterson, 2019). Thus, food safety regulation can be considered to take place in a system itself, and a system approach can be taken similarly. Additionally, given that the inspection strategy has been shown to deal with complex adaptive system characteristics such as context dependence and many components, the complex adaptive systems approach appears to be a logical step.

The systems approach has been previously applied to regulation. Corbett (2015) argued that a systems approach is essential for regulatory excellence. Corbett (2015) stated that understanding how

to change the dynamics of systems and influence systems is necessary to create greater public value. The system approach to regulation is applied to the case study of a non-governmental organization that seeks to regulate the complex systems problem of poverty. The system approach includes trial and error, makes use of interactions and adapts to the circumstances. The system approach shows success in influencing the complex problem of the case study. The food system is also mentioned as a complex system that could use a system approach to open up important pathways for impactful regulation. Consequently, the systems approach can contribute to understanding complexities in the design of an inspection strategy based on the system nature around food safety regulation.

Since regulation combined with system thinking has been discussed in literature before, van der Heijden (2022) was able to synthesize the academic literature on systems thinking for and in regulatory governance. van der Heijden (2022) presented the main findings, including challenges and opportunities of systems thinking applied to regulatory governance. The first challenge is that system thinking is always difficult work with a large variety of possible approaches and a lack of knowledge on what systems approach is specifically suitable for what kind of regulation. The second challenge is that even though system thinking is used to capture the complete picture of a regulation problem, it still cannot find a way around using the contrasting reductionist approaches and tools (van der Heijden, 2022). Nevertheless, van der Heijden (2022) stated that system thinking can lead to a broad and deep understanding of regulation problems and solutions. System thinking applied correctly to regulatory governance can improve regulatory authorities' flexibility, adaptability, and resilience. Finally, van der Heijden (2022) ended with the goal of creating larger knowledge on the practical application of systems thinking for and in regulatory governance to start understanding how systems thinking can be utilized as an approach to regulatory governance and other approaches, such as risk-based approaches (van der Heijden, 2022). Demonstrating the need for knowledge creation on the practical application of the systems approach on regulation approaches like an inspection strategy combining a risk-based and random method.

The complex adaptive system view demonstrated the potential to understand the complexities of inspection strategies for food safety regulation and holds the potential to give direction to the research. Nevertheless, as demonstrated van der Heijden (2022), this field remains relatively unexplored territory. Canyon (2018), on the other hand, provides a more practical approach in the article on simplifying complex adaptive challenges. Canyon (2018) stated that complex adaptive systems can be strategically dealt with through, among other things, continuously improving the awareness of information, broadening the analysis at first, and later narrowing the focus through identifying the forces of the system. This approach by Canyon (2018) is taken along in this research. Because of the context dependence, the analysis is broadened to the view of the entire system within which food safety regulation operates. By analyzing the entire system, the research can then focus on identifying the driving forces and complexities shaping the inspection strategy.

4.2. Food safety regulation within complex adaptive system

The complex adaptive systems view is chosen first to understand the dynamic context of food safety regulation with the aim to later narrow down to the complexities of inspection strategies. As previously shown in the literature, complex systems thinking showed potential for gaining insight into the forces and complexities of inspection strategies for food safety regulation. Corbett (2015) stated that complex system thinking is essential for regulation to be successful since the components of the systems complicate the problem of regulation (Corbett, 2015), and thus the components and the dynamics should be considered in regulation and accordingly in the inspection strategy. Within the design science approach, the complex adaptive systems (CAS) view is considered part of the knowledge base (see Figure 2.1). The view of complex adaptive systems is chosen to explore the impact of food safety regulation by understanding its surrounding system. First, the complex adaptive system view is discussed. Second, the view is related to food safety regulation through its defined characteristics. Last, the implications of CAS to food safety regulation for inspection strategies are elaborated upon.

4.2.1. Complex adaptive systems view

Before going into depth on complex adaptive systems, a short definition of how complex adaptive systems are seen in this research is to be given. Throughout literature, complex adaptive systems are seen differently: as a view, perspective, theory, or even as a framework. For the purpose of this research, complex adaptive systems are chosen to be used as a view for identifying complexities for inspection strategies. Extensive research could be conducted to explore the nature of complex adaptive systems (CAS) in depth. However, due to the need for specific and focused research based on the question of the NVWA, the assumption is made that complex adaptive systems are to be seen as a view.

The use of the CAS view is utilized as a foundation of the design science process as part of the knowledge base. Corbett (2015) already emphasized the need for a systems approach to regulation (Corbett, 2015). Carmichael and Hadžikadić (2019) explained complex adaptive systems more elaborately in the book chapter 'The Fundamentals of Complex Adaptive Systems'. Complex adaptive systems are exploited to study and describe systems (Carmichael & Hadžikadić, 2019). CAS challenges that systems are stable and persistent. Instead, Carmichael and Hadžikadić (2019) suggests that systems are rather dynamic, unpredictable, and nonlinear. These kinds of systems require non-traditional approaches to create understanding, highlighting the importance of the CAS view in navigating the system complexities. Complex adaptive systems are described through multiple roughly defined characteristics, including one or more levels of feedback, emergent properties, self-organization and non-linear dynamic behaviour. Taking a complex adaptive systems approach allows to focus on understanding the entire system and its dynamics (Carmichael & Hadžikadić, 2019).

CAS can be used for different purposes and can be applied to different fields in the public sector. Chaffee and McNeill (2007) proposed CAS as a way to gain insight for reform in the model of nursing. According to Chaffee and McNeill (2007) CAS provides a framework to study systems that display complex behaviour, and they stated that CAS holds the potential to increase understanding of a fluctuating and confusing work environment and consequently improve the decision making and increase the effectiveness in the case of nursing (Chaffee & McNeill, 2007). Chaffee and McNeill (2007) stated that CAS can be predominately seen as a powerful opportunity to design research, decisions, policies, and practices with a new view. Similarly, Sturmberg et al. (2012) used the CAS view to set directions for health care reform. The study defines the health care model as a complex adaptive system and critically analyzes the CAS health care model. Sturmberg et al. (2012) emphasizes the need for the CAS view to understand how a desired outcome in the system can be achieved (Sturmberg et al., 2012).

Wallis (2008) studied the state of CAS in literature over the last years through content analysis. The findings include that various different understandings of CAS, including variations of its characteristics, exist. The practical recommendation stands for academics to specify their CAS definition and its characteristics for their case to improve their research clarity when working with a CAS view. Consequently, CAS is to be defined for the purpose of understanding the contextual complexities of food safety regulation in the next section.

4.2.2. Food safety regulation in complex adaptive system

Before establishing that food safety regulation takes place in a complex adaptive system, the CAS definition and its characteristics are to be defined and applied to this research. Wallis (2008) mapped the various descriptors. Out of 26 descriptors, the following eight are the most popular: unpredictable, many agents, co-evolutionary, self-organizing, goal seeking, emergence, and interaction (Wallis, 2008). To support consistency in the academic field, these eight descriptors are used to describe the system context of food safety regulation. In addition, Wallis (2008) stated that the flexibility of the definition and descriptors allow for valuable insights for different studies. In the case of the food safety regulation, the descriptor adaptive is added to the popular descriptors because two studies encountered early on in the research process showed the presence of this descriptor in the system of food safety regulation (Devaney, 2016; Fung et al., 2018).

Characteristics

The eight selected characteristics are argued to fit the system context of food safety regulation. Literature and logical reasoning are predominantly used to substantiate that the CAS characteristics are also characteristics impacting food safety regulation. In addition, from the interviews (see Appendix A), complex adaptive system characteristics have emerged. These have been included to highlight the actuality of the characteristic. Below, the characteristics and their substantiation are aligned.

1. **Unpredictable**: Focker et al. (2022) reviewed safety hazards in circular food systems in Europe. According to Focker et al. (2022) food hazards are often hard to predict since so many microbiological and chemical hazards are present in food production and processes, new and unknown hazards can quickly arise. Because food hazards are difficult to predict, the regulation of food safety deals accordingly with unpredictability. Interviewee 2 also mentioned that every year, an annual plan is made, but around a quarter of the plan changes throughout the course of the year because of new risks arising. Unpredictability is clearly a system characteristic that is present in the regulation of food safety.
2. **Many agents**: In the global strategy for food safety by the World Health Organization (2022), the many agents are considered to have significant impact. World Health Organization (2022) named that food safety is a shared responsibility among multiple agents. National authorities predominantly drive food regulation, but food safety itself is a joint effort of all agents. These agents include national authorities, private food producers and processors, consumers, academia and many more. The many agents are at the base of the system that national authorities aim to regulate.
3. **Co-evolutionary**: Luo et al. (2019) studied the evolutionary dynamics of information disclosure of food safety regulations from the consumer perspective. Luo et al. (2019) found that if consumers are more sensitive to health food safety regulatory information, the producers that provide high-quality food increase profits and then urge the government to prioritize disclosure of health food safety regulatory information. Demonstrating that the dynamics between consumers, regulators and producers/processors lead to co-evolutionary behaviour within the system of food safety regulation.
4. **Self-organizing**: Sharma et al. (2010) discussed the past self-regulatory undertakings by the food industry, including their strengths and weaknesses. 'The food industry threatened by possible government regulation and critical public opinion, industries often undertake self-regulatory actions, issue statements of concern for public welfare, and assert that self-regulation is sufficient to protect the public' (Sharma et al., 2010). Sharma et al. (2010) focused on healthy food in terms of nutrition and not in terms of safety. Additionally, the study is from the United States, and differences between European and American food industries exist. However, one can envision similar opportunities for self-regulation within food safety regulation. Public opinion on unsafe foods can potentially lead to producers/processors taking action to ensure ongoing profit. Accordingly, food safety regulation could be self-organized within the system.
5. **Goal seeking**: Leistikow et al. (2022) discussed the goal of regulation and the role of inspections. The proposal stands to take a value-driven regulation approach because the goal is to contribute to societal value, and compliance is to be seen as a means and not a goal in itself of regulation. The NVWA named four different goals: prevent food hazards, enforce laws, sustain welfare and monitor the field. AGES mentioned having an ongoing discussion to find a concrete formulation of the goal of inspection (Interviewee 7). The dilemma was whether the goal should be to find the non-compliant producers/processors or to go and take samples (Interviewee 7). A few different perceptions of what is to be the goal of regulation have been mentioned. Demonstrating the lack of consensus on the goal and the continuous search in the system of food safety regulation.
6. **Emergence**: The rise of the risk-based method for regulation is an example of an emergent characteristic impacting food safety regulation. New possibilities and trends emerge depending on the availability of data and the development of tools within the field of regulation. Interviewee 4 mentioned that risk-based strategies started to pop up and that the term became more prevalent, so their organization started looking into risk-based strategies as well. Food safety regulation is subject to emerging trends in the system.
7. **Interaction**: Lin (2014) noticed the growing influence of private regulators (e.g. producers/processors) in the food safety sector. Lin (2014) stated that the interactions between the public and

the private regulators are constructive to global food safety governance and that the interactions help build scientific knowledge, exchange of information, expert cooperation, and coordination of activities. The characteristic of interaction is thus present in food safety regulation and even holds the opportunity to ensure safer food.

8. **Adaptive**: Devaney (2016) investigated food safety governance of the Food Safety Authority of Ireland (FSAI) through the perspective of the consumer. An outcome of the study was that the regulation of food safety needs to be continuously adaptive because of consistently emerging food risks and hazards (Devaney, 2016). Interviewee 2 stated that the inspection plan is constantly shifting because of changes in seasons or import trends. The adaptive characteristic is impactful for food safety regulation.

Food safety regulation has been argued to take place in a complex adaptive system, and thus, food safety regulation takes place in a system that is not easy to understand and to make changes in. This impacts the way inspection strategy can be designed and executed. Nonetheless, one complex adaptive system is not the other complex adaptive system. Naturally, differences exist between complex adaptive systems since they are endlessly complex and large. The nursing system of Chaffee and McNeill (2007) and the health care system of Sturmberg et al. (2012) are not the same as the system of food safety regulation. The characteristics of food safety regulation that are especially dominant are those that have also shown presence in the interviews. Namely, the characteristics of adaptive, emergence, goal-seeking and unpredictable. These characteristics are the ones that interviewees are quick to think of when discussing food safety regulations in relation to inspection strategy. Indicating their strong presence in nature and the dynamics in the system in which food safety regulation takes place.

Food safety regulation takes place in a complex adaptive system, where the food safety regulation continuously has to be adaptable to unpredictable and emerging food hazards and safety risks. In addition, food safety regulation must remain up-to-date and adapt to new and emerging methods to improve the efficient detection of food hazards and safety risks. Food safety regulation is thus subject to continuous and unpredictable change over time. Besides, the lack of consensus on the goal of the regulation and inspection remains a complicating factor, and the variety of goals can lead to a lack of alignment in the systems context of food safety regulation.

Ultimately, the dynamics of the system within food safety regulation take place, are difficult to grasp. An image is sketched of the highly complex and continuously changing context wherein food safety regulation takes place, and, consequently, an inspection strategy is to be designed within. Furthermore, the system characteristics that should be given considerable significance in food safety regulation of adaptive, emergence, goal-seeking, and unpredictability are appointed. The next section further discusses the implications of the CAS context for inspection strategies.

4.2.3. Implications for inspection strategies

Food safety regulation has been demonstrated to deal with complex adaptive system characteristics, but what does that mean for the inspection strategy design combining risk-based and random methods for food safety authorities? Before discussing the implications for the inspection strategy, first, the limitations of CAS are discussed to understand that CAS cannot be seen as the sole solution to the research problem of not knowing how to design an inspection strategy combining risk-based and random methods but rather as a direction to find a solution to the problem for food safety authorities.

Wallis (2008) stated that a lack of consensus on the definition of complex adaptive systems exists, leading to freedom for interpretation by researchers and, therefore, not providing a straightforward and reusable method across the academic field. Researchers have difficulty using insights from studies with CAS because of the different approaches taken through the lack of definition. The actual value of the application of CAS for inspection strategies in food safety regulation is difficult to define because of the differences across researchers. Discussing CAS with experts leads to the following insight: CAS is not to be used as a method to tackle a problem but rather as a way to view the problem. (Warnier, 2023). Therefore, CAS alone will not provide all the knowledge required for food safety authorities to design an inspection strategy.

CAS demonstrated that the challenge of designing inspection strategies lies within the context of food safety regulation. Complexities are evident, as the characteristics of CAS demonstrate the dynamic and continuously changing nature of food safety regulation. Consequently, designing an inspection strategy within that system is not an easy task. The inspection strategy is subject to system characteristics of food safety regulation. The system's adaptive, emergence, goal-seeking, and unpredictability characteristics are especially to be considered in the inspection strategy design. An inspection strategy design that employs risk-based and random methods must be resilient and adaptive to the continuous change of the food safety regulation system context. The CAS behaviour regarding food safety regulation impacts how inspection strategies are to be designed to ensure food safety. This is because designing a 'best' inspection strategy is impossible. Such an approach would provide only short-lived guidance to food safety authorities; as the system of food safety regulation is continuously evolving, the inspection strategy requires ongoing adaptation and improvement. The CAS view inspires the research to aim to provide guidance on the design of an inspection strategy while respecting current complexities and future changes of the system and not to develop the best inspection strategy for a specific case at this moment in time.

The CAS view cannot be seen as a solution to the problem of the NVWA but as a view that provides valuable input for dealing with the problem in the next research steps. The CAS view serves as a foundation for building the research upon to uncover how inspection strategies should be designed. As previously mentioned Canyon (2018) stated, complex adaptive systems can be strategically dealt with through continuously improving the awareness of information, broadening the analysis at first, and later narrowing the focus through identifying forces of the system with tools such as system mapping. This approach by Canyon (2018) is being applied to the research since food safety regulation has been demonstrated to occur beyond doubt within a complex adaptive system. Creating awareness of information and broadening the analysis are done through exploratory and continual interviews and the inclusion of the food safety regulation context throughout the research. The narrowing down and identifying forces of inspection strategies is to happen in the next chapter while keeping in mind the CAS characteristics.

Ultimately, CAS has uncovered system characteristics relevant to food safety regulation, which complicate inspection strategy design and should be considered in the guidance for food safety authorities. Furthermore, CAS provided direction for this research. Nevertheless, it's important not to see the CAS view as the definitive answer to the NVWA's question on combining risk-based and random methods in an inspection strategy but as a means to uncover complexities and inform the following research steps.

4.3. Problem of risk perception in multi-actor systems

The CAS theory brought forward the multi-actor context. In fact, the multi-actor characteristics of the system have implications for the risk definition in food safety regulation. Food safety regulation deals with a broad variety of actors. The multi-actor system of food safety regulation leads to complexity in designing an inspection strategy, especially for a risk-based method, because of the different risk perceptions by different actors. The variety in risk perceptions is exhibited in literature, the interviews, and the exploration by Ayaydin (2023), a fellow researcher of the NVWA research team. The last element to be discussed that complicates the design of an inspection strategy is the perception of risk in a multi-actor system.

In the comparative case study by Borraz et al. (2022), the practice of risk-based food inspections by food safety authorities was compared for England, France, Germany, and the Netherlands. The study mentions that risk is often perceived differently and that no consensus exists on risk assessment for enhancing regulatory practices (Borraz et al., 2022). Borraz et al. (2022) concluded that assumptions and institutional context shape how risk is perceived and used by regulating authorities in different countries. The EU requires the inclusion of the risk-based method, but the interpretation and application vary significantly per country (Borraz et al., 2022). Illustrating the impact of risk perception on an inspection strategy, including a risk-based method.

Different perceptions of risk within the same organization came forward in the interviews. Interviewee 1, who worked as a risk assessor, defined risk as a situation that puts human values at stake and where an outcome is uncertain. Interviewee 2 stated that when enforcement requests by consumers or NGOs are received, they always try to execute them because they would risk losing control. The inspection model used by Interviewee 5 is focused on the risk of non-compliance. These three interviewees are part of the same organization but work with different risks in mind. When a risk-based method is included in the inspection strategy, it is important to take into account the type of risk. The risk perception differs depending on the function and department in the organization.

A typology of the different risks encountered during the research project is made by Ayaydin (2023). The typology can be found in Figure 4.1. The risk can be actuarial or perceptual, as represented on the vertical axes. An actuarial risk is defined as the the probability of an unwanted event causing a harmful impact (Ayaydin, 2023). Perceptual risks are perceived risks for the food safety authority (Ayaydin, 2023). On the horizontal axes, the process-orientated and impact-orientated are represented. The risk can be oriented on the inspection process but also on the impact of inspections. When discussing a risk-based method in the inspection strategy for food safety regulation, it becomes crucial to define the specific risk that is to be addressed explicitly. The risk referred to in this research is the process-oriented actuarial risk, which translates to the risk of inspectees not complying with regulations during their production or processing of food. In this research, despite acknowledging the variety of risk perceptions, the demarcation of compliance risk is established to uphold both consistency and feasibility. The recommendation stands to look into the research of Ayaydin (2023) when requiring more elaboration on risk perception.

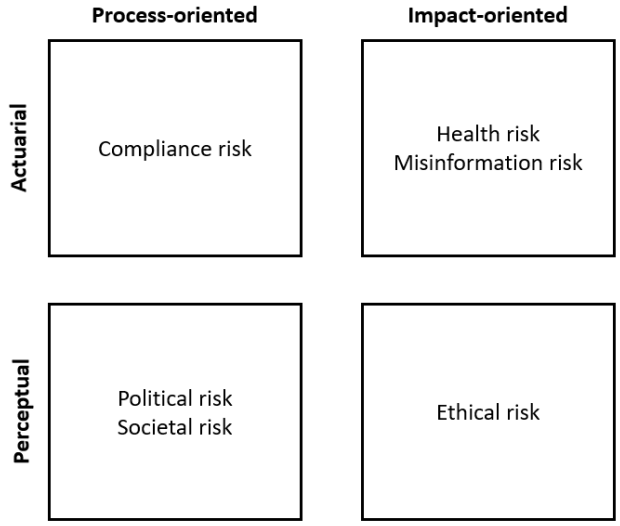

Figure 4.1: Risk typology

This section acknowledges the complicating factor of risk perception within the multi-actor system related to food safety regulation. However, the decision is made not to elaborate on the complexity in the further research steps but to use it as the demarcation of the non-compliance risk. While the potential impact of risk perception on inspection strategies is recognized, this research focuses on the sole risk of non-compliance.

4.4. Compilation complex systems context

In this chapter, the complex systems context of inspection strategy is explored by the literature, the CAS view in relation to food safety regulation and the discussion on risk perception in the multi-actor system.

In the final section of the chapter, a compilation is made to provide an overview of the complex system context of food safety regulation that came forward, impacting the inspection strategy, establishing the implications for the research and setting further direction.

The literature demonstrated the value of a systems approach to food safety regulation as a way to improve regulation practices. The CAS view showed the complex nature of the system of food safety regulation where the design of the inspection strategy is intended to take place. Furthermore, the CAS view exposed the system characteristics to be considered in food safety regulation and, consequently, in inspection strategies. The characteristics adaptive, emergence, goal-seeking and unpredictable exposed significant impacts in complicating inspection strategy design and thus essential to be taken into account in the guidance for food safety authorities to achieve the desired outcome of food safety. Additionally, CAS indicates it is impossible to design one 'best' inspection strategy because of the impactful characteristics. Eventually, CAS provided direction for the research by initially broadening the scope, continuously updating information, and ultimately narrowing the focus through the systems map and the identification of the critical subsystems (see Chapter 5). The discussion of risk perception within the multi-actor system highlighted the complexity of different risks associated with the actors. The discussion, however, ultimately led to the demarcation of compliance risk in this research for feasibility and consistency reasons.

Coming to the end of the problem explication, the inspection strategy, its necessity and its components have been previously defined, and now the complex systems environment of food safety regulation an inspection strategy will be designed within is explored. The complex systems environment explicated the complexities of inspection strategy design further. The system's view, combined with the design science approach, allows to delve deeper into the inspection strategy's design and to establish requirements rooted in the system's characteristics. The inspection strategy and its complex systems context are explicated as the first activity of the design science plan; the next activity is to define the design requirements of the inspection strategy, moving towards providing guidance for the NVWA.

5

Definition inspection strategy requirements

Following the definition of inspection strategy and the exploration of system complexities of food safety regulation as a whole, the next step is to narrow it down to the requirements of an inspection strategy. The systems view is taken along to this next chapter as a logical progression to the prior chapters. The inspection strategy requirements are constructed based on further investigation of the system employing interviews and system mapping. The further system investigation is to expose forces and impacts on the inspection strategy that inform the construction of requirements for an inspection strategy. Consequently, the chapter consists of two main sections: the investigation of the inspection system and the definition of inspection strategy requirements, including the identification, categorization, and prioritization of requirements. The chapter represents the second step of the design science plan (see Figure 2.2) and fuels the design of an inspection strategy through both the rigor and relevance cycle (see Figure 2.1).

5.1. Investigation of inspection system

The investigation of the system is dedicated to uncovering system characteristics that impact the inspection strategy. The system's characteristics to be investigated are the components, challenges, and opportunities. In the first instance, these characteristics are investigated through semi-structured interviews with experts, NVWA employees, and AGES employees (see Appendix A for interview protocol and Appendix B for interview analysis). Building on the interviews, a system map is developed to investigate the impactful structures between the system's components for an inspection strategy. The system-focused interviews and the development of the system map are executed simultaneously. In this section, first, the system characteristics under investigation are appointed. Following this, system boundaries are established, and last, a system map is constructed that highlights critical subsystems impacting inspection strategies. The investigation serves as the base for defining the inspection strategy requirements in the following section.

5.1.1. System characteristics

The following three system characteristics are investigated: components, challenges, and opportunities of inspection strategies in food safety regulation. In total, the interview consists of six predefined questions. Four questions for the components, one for the challenges, and one for the opportunities. Aside from predefined questions, room for associations during the interviews is allowed to uncover additional system characteristics not explicitly addressed by the predefined questions.

Components

The component investigation focuses on the actors, actions, interactions, and variables. Actors are decision-makers with an impact on the inspection strategy. An example of an actor is a risk assessor. A risk assessor plays a role in deciding on the risk focus within an inspection strategy. Actions are the main undertakings of the actors. An action is, for example, allocating a budget for inspections. An

interaction is a relation between two components. In the case of food safety regulation, an interaction takes place between inspectors and inspectees. The variables are influences on the system, such as the logistic possibility to inspect. As illustrated above, both technical (logistics and budget) and organizational (risk assessors, inspector, and inspectees interactions) components are investigated.

Recognizing that an interviewee is not immediately likely to think from a systems perspective, the questions are formulated carefully to uncover system components but remain comprehendible for the interviewee. The following four questions are constructed to uncover the system components. The first question investigates the components impacting the central trade-off for random and risk-based methods, namely how to address both risky areas and new or less familiar areas. The second question touches upon the components in the process of selecting an inspection methodology. The third question focuses on the actors, so the question is who decides on the allocation of inspection resources and the process. The fourth question tries to uncover the external variables that impact the allocation of inspection resources. Together, these four questions aim to uncover a significant part of the different components of the inspection strategy.

Challenges

Since the research aims to uncover what system characteristics complicate the design of the inspection strategy, the interview raises the topic of challenges. Asking the interviewee about their challenges concerning inspection strategies uncovers the potential to uncover various impactful system characteristics. The interview starts with the question: 'What are the largest challenges in the inspection resource allocation and decision-making process?'.

Opportunities

The research outcome consists of guidance for food safety authorities when deciding on a risk-based and random method within a strategy. Guidance for an inspection strategy is to be developed inspired by the opportunities. The opportunities are uncovered by asking the interviewees what could be improved when deciding where, how, and how much to inspect.

5.1.2. System boundaries

Considering that the complete system of all components related to inspection strategies in food safety regulation is impossible to map as a whole, decisions need to be made about what is to be included and excluded in the system map concerning inspection strategies. Therefore, the system's boundaries are defined with the research purpose in mind. Because the commissioner operates on a national level, the global system characteristics and interactions of the system are excluded. The national food safety authorities are central to the systems map, nevertheless, due to the fact that the European Commission has a mission to protect the European citizens' health and ensure safe food (European Commission, 2023). The European influences cannot be disregarded. Variables on a European level are included when they directly influence the national inspection strategies. The European actors, interactions and structures are not elaborated upon to prevent overcomplication.

Furthermore, excessive detail is unfavourable due to the aim of creating insight into the system structures. Several components that came forward from the interviews were purposely left out because of limited influence or over-complication. These components can be found in Appendix C. Examples are NGOs for food safety that make requests to food safety authorities, the perception of consumers on certain producers and processors, and the inner workings of the involved ministries that create policies for the purpose of safe food.

The system to be mapped focuses on the components directly impacting the inspection strategy. The components include, among other things, inspection activities, inspection influences, inspection devices, actors who decide on inspection strategies, and risk assessment. The system map represents a more general map of the structures related to the inspection strategy. No specifications on an organization or sector are included to allow for a generalizable application of the systems map for (European) food safety authorities.

5.1.3. System map

In Chapter 4, the system view was demonstrated to be a direction to pursue, and the system map is the next method employed to narrow down the system view on inspection strategies within food safety regulation. The system map is employed to uncover inspection strategy requirements that are not immediately uncovered from the interviews. The system map creates deeper insights based on the interviews' observations of the system's structures. This application of the system map aligns with the design science approach, as it creates design knowledge on how things are to be arranged.

Before proceeding to elaborate on the development of the system map, an explanation of the system map is provided. A system map visually represents a simplified real-world system (Barbrook-Johnson & Penn, 2022). Since the complete real-world system concerning inspection strategies is incredibly large and complex and thus impossible to map as a whole, purposeful simplifications must be made to uncover requirements for defining an inspection strategy. The necessary simplifications of the system make the systems map an incorrect representation of reality, but when the simplification is purposeful, the map tends to serve as a useful tool (Barbrook-Johnson & Penn, 2022).

The visual overview of the system allows for the examination of system structures. Critical subsystems that inform the development of inspection strategy requirements are uncovered by analysing the system map. First, the development process of the system map is briefly explained. Second, the critical subsystems are spotlighted. Last, the insights uncovered through the system map are aligned and reflected upon.

Development of system map

The system map is developed iteratively based on the investigation through interviews and additional expert feedback. The iterations and their descriptions can be found in Appendix D. The development of the system map does not follow strict guidelines but is more of a trial-and-error approach, continuously improving the content and format. The system map approach is partly inspired by a toolkit of the EU policy lab (EU policy lab, 2023) by focusing on the opportunities, challenges, and actors. The software used to draw the systems map is draw.io (Draw.io, 2023) because of the wide variety of figures representing the system components.

The system map is depicted in Figure 4.1. The legend is placed on the lower left side of Figure 4.1. The system map represents the alignment of the system components in relation to the inspection strategy. The system map illustrates the relations and interactions among components. The placement of the components throughout the system map does not imply any form of hierarchy. The loops within the system are represented through a rounded arrow. Given the extensive number of components in the system map, interpretation at first sight is difficult. The critical subsystems are introduced to discuss the system map and its findings for the inspection strategy design.

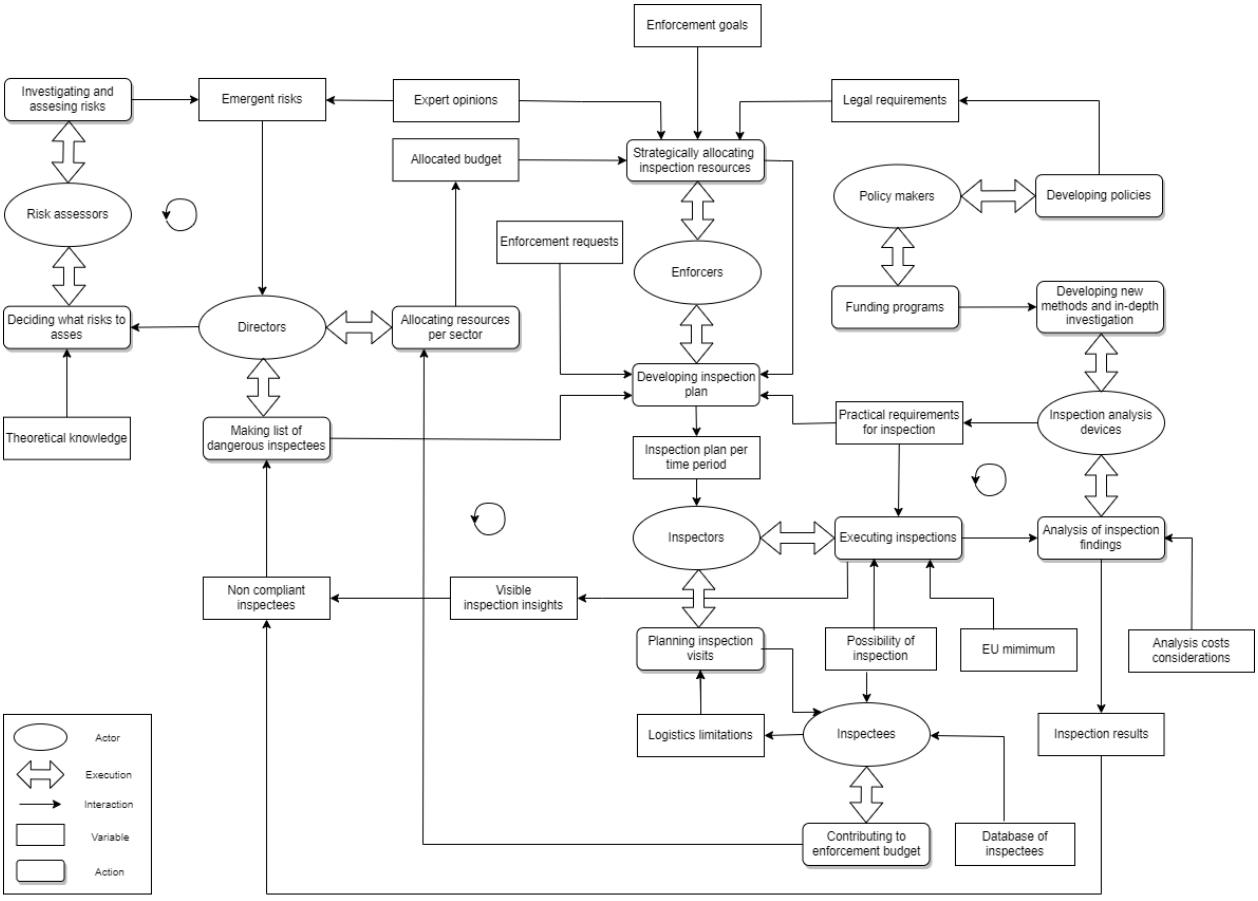

Figure 5.1: System map

Critical subsystems

The system map is elaborated upon in relation to the inspection strategy by spotlighting five critical system structures for inspection strategies. The subsystem is critical when the structure greatly impacts how an inspection strategy will be designed and executed. From the critical subsystems, requirements are constructed for an inspection strategy (see 5.2). Below, the critical subsystems are named and discussed. First, an overview of each subsystem's origin and position is provided, followed by exploring its impact on an inspection strategy.

Device limitations In Figure 5.2, the subsystem of the devices (e.g. laboratories) impacting the inspection strategy is enlarged. A loop between the components related to devices and the execution of inspection demonstrates the reinforcing impact of the components on each other. As shown in Figure 5.1, inspectors execute two actions: planning and executing inspections. Inspection involves checking producers/processors for hygiene standards and regulations, as well as collecting samples and sending them to the laboratory for analysis. Laboratories are essential devices enabling inspection strategy execution in the case of sampling but have limited capacities. Furthermore, as seen in Figure 5.2, the practical requirements for executing inspection have a central role in the subsystem. Interviewee 2 from the NVWA mentioned the need to fulfil practical requirements for the analysis of samples in the laboratory in the sense that analysis is conducted per 24 samples. Consequently, the number of inspections per time period and per inspector is fixed based on the practical requirements. The analysis cost considerations, depicted on the right side of Figure 5.2, are also a limiting factor for designing and executing certain types of inspections. Interviewee 3 stated that the laboratory takes a large part of the budget, and some types of analysis are significantly more expensive than others.

The mentioned device capacity, practical requirements, and cost analysis considerations directly impact the inspection strategy. The variation in analysis costs for different samples influences inspection

strategy design. For instance, when a random inspection method selects a sample with high analysis costs, one might favour selecting multiple samples with a lower cost of analysis. Furthermore, limited laboratory capacity due to high analysis costs may lead to favouring a risk-based method to increase the chances of finding specific substances. On the other hand, if the outcome of the risk-based method is to sample three different kinds of substances, but the laboratory does not have the capacity to do three types of analyses, the inspection strategy has to be adjusted accordingly. The subsystem impacts the inspection strategy through the need for strategic considerations of resources and the possibility of executing an inspection strategy.

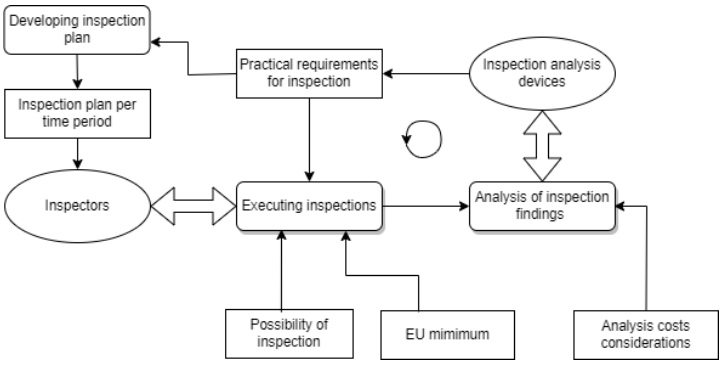

Figure 5.2: Subsystem device limitations

Lack of interaction The complete system map in Figure 5.1 shows the lack of interaction. No direct interactions between the risk assessors and enforcers are demonstrated in the system map. The risk assessors provide the outcomes of their risk assessments to the directors in the form of qualitative advice (Interviewee 1), and the directors can potentially use those outcomes to make adjustments in the allocation of budget per sector. The interaction is indirect since the directors are in between the risk assessors and enforcers. The lack of direct interaction between risk assessors and enforcers is partly because the risk assessors strive to be scientifically based, as objective as possible, and with minimal external influences (Interviewee 1).

For a risk-based method within an inspection strategy, one would expect a close interaction between the risk assessors and enforcers for various reasons. Interviewee 1 stated that the risk assessors would be interested in learning more about the risks in the field and would favour working with enforcers to understand the risks better. Interviewee 1 added that the data retrieved from inspectors, at this moment in time, is not sufficient for their risk assessments because more details are required. Furthermore, in the current system, risk-based methods that the enforcers utilize are not validated by the risk assessors. Because a risk-based method always deals with bias (Interviewee 8), continuous evaluation, validation, and improvement are favourable to limit the potential negative consequences of the bias. The interaction and the exchange of information between risk assessors and enforcers could provide direction to the focus of risk and consequently improve inspection strategies.

Reinforcing bias In Figure 5.3, the subsystem of the directors and inspectors relating to non-compliance is enlarged. As shown in Figure 5.3, the inspection insights are used to create a list of non-compliant inspectees. This list then serves as input for the development of the inspection plan for the inspectors. The non-compliant inspectees are prioritized in the inspection planning because they are more likely to be non-compliant in the future (Interviewee 5). The subsystem thus contains a reinforcing loop through the list of non-compliant inspectees.

The prioritization of non-compliant inspectees represents a risk-based method in itself. Noncompliance can be considered a risk factor in this subsystem. Since noncompliance is the only risk considered and reinforced within the system, the probability exists that, over time, only the non-compliant inspectees are visited. The reinforcing loop could lead to a narrow selection of inspectees and consequently could lead to a potentially unwanted bias. The inspection strategy would only consider a small

part of the to-be-inspected population. According to Interviewee 5, the European Commission emphasized the need to consider more risk factors other than noncompliance to ensure a solid risk-based method. The noncompliance subsystem demonstrated the impact of bias and risk considerations in an inspection strategy.

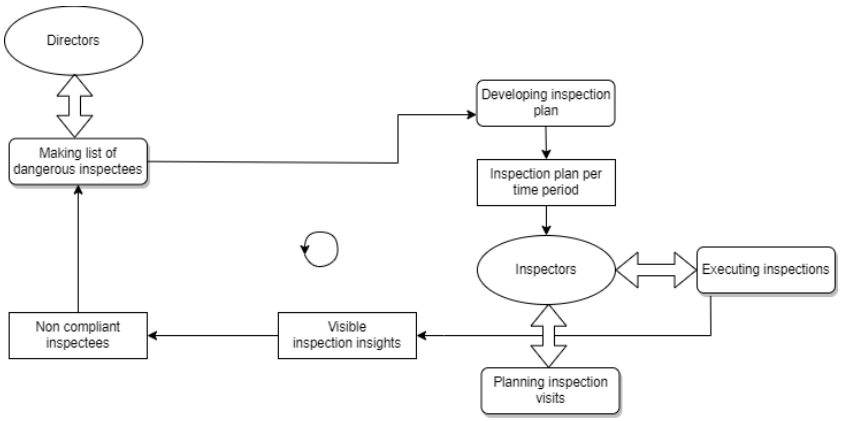

Figure 5.3: Subsystem non compliance

Central role of experts A relatively straightforward observation from the complete system map (Figure 5.1) is the central role of experts in the system. Expert opinions influence both risk assessment and enforcement. For AGES, experts play a central role in defining risk factors that impact the chance of an inspectee being sampled (Interviewee 4). At the NVWA, experts are deployed to make budget allocation decisions for inspections and to start discussions on upcoming risks to retrieve better notifications (Interviewee 3). One of the reasons experts have a central role, named by Interviewee 3, is the limited availability of data to make inspection strategy decisions (Interviewee 3).

The role of experts, especially in the design of inspection strategies, is prominent and can influence the decision whether to deploy a risk-based and/or random method in an inspection strategy. Since the data is not available to substantiate decisions in relation to the inspection strategy, experts have a central role at this point in time. Using the expert knowledge available within the food safety authorities is thus essential to substantiate inspection strategy designs. Ultimately, experts are shown to impact the inspection strategies by defining risks, allocating budget and notifying risks.

Financial dependence Below in Figure 5.4, the financial dependence subsystem is highlighted from the systems map. The figure shows that the inspectees are partly responsible for funding the budget. The directors allocate the budget to enforcers and, further down the line, to the inspectors. This creates a loop. The loop in this subsystem represents the financial dependence of the directors on the inspectees. It is worth noting that the dependence on inspectees for finances depends on the sector, according to Interviewee 5. In the sector of Interviewee 5, financing comes partly from two ministries and partly from the inspectees. The allocation of budget by the directors thus interacts with the type of sector the inspectee is in.

The finances influence the selection process of inspectees, while random and risk-based methods do not select inspectees based on finances but on risk factors or random algorithms. Both a random and risk-based method requires financial independence to select inspectees. Interviewee 5 stated that while their sector is working with a risk model, they are still obligated to receive a certain amount of income from inspectees. The risk model is compromised because the inspections are finance-driven. The subsystem demonstrated the impact on the inspection strategy by dependence on the financial input of inspectees.

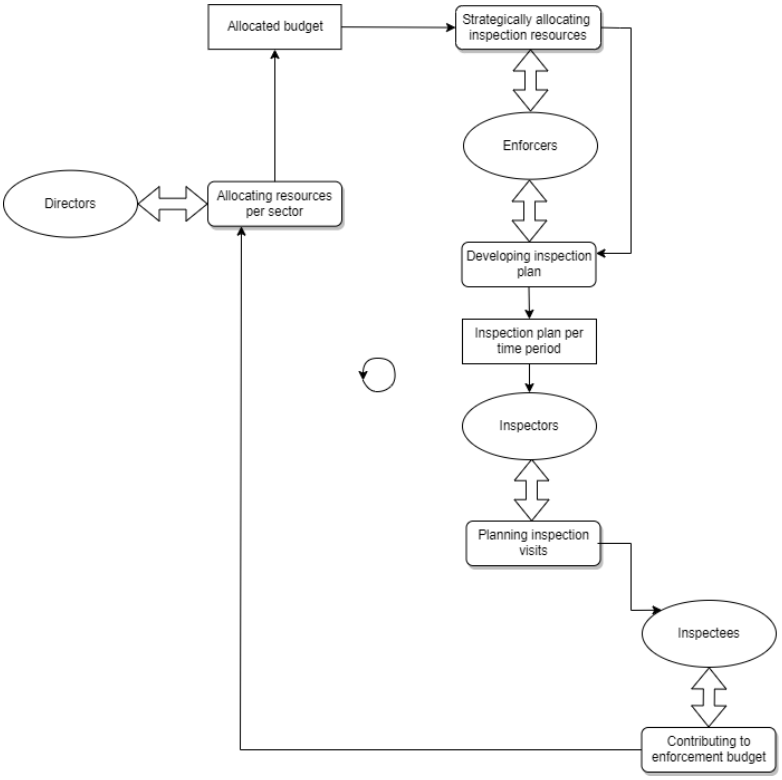

Figure 5.4: Subsystem financial independence

Based on the critical subsystems, system structures that impact the design and the execution of an inspection strategy have been uncovered. Namely, the limitations of devices, the lack of connection between risk assessors and enforcers, the potential development of biases, the large involvement of experts, and the dependence on inspectees for finances. The critical subsystem subsection was the last part of the inspection system investigation; the requirements for an inspection strategy are to be identified based on the insights.

5.2. Inspection strategy requirements

In the previous section, the system map and the elaboration on the critical subsystems provided insights into the inspection strategy requirements. A number of requirements for an inspection strategy can be derived based on the structures of the components, interactions, variables and actors. In addition to the requirements derived from the system map and critical subsystems, requirements for an inspection strategy directly observed from the interviews and implicitly discovered from literature are included. The interview-based requirements emerged directly from discussions with food safety and regulatory authorities in different fields. The literature around inspection strategies and the CAS view also revealed additional requirements. The requirements thus originate from three sources: system map, interviews and literature. The requirements entail both the requirements for the design and the execution of an inspection strategy. The design science approach allows for the iterative process where the requirements can be fueled from all origins at any time in the research process. The requirements' goal is to establish what an inspection strategy needs. First, the requirements are identified based on their origin; second, the requirements are categorized based on their role in the design of an inspection strategy; and third, the requirements are prioritized through the MoSCoW framework.

5.2.1. Identification requirements

This section identifies the requirements for an inspection strategy for food safety authorities. As mentioned before, these requirements originate from three sources: interviews, system map and literature. Per source, the requirements are aligned. To clarify the origins, the specific source, such as a study, interview, or system structure, is named. In Figure 5.5, the origins of the requirements are visualized.

Moreover, per design requirement, the relevance of the requirement for an inspection strategy is described in the text.

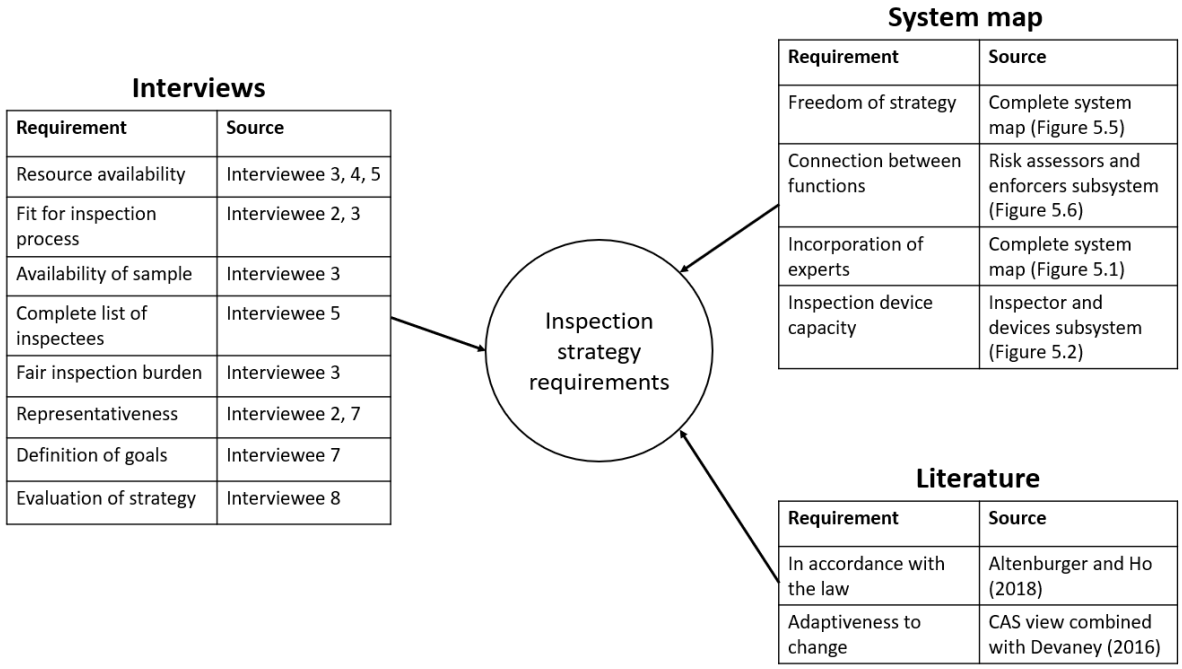

Figure 5.5: Requirements origins

Requirements from interviews

Interviews with food safety and regulatory authorities in other fields were conducted. The interviews not only contributed to the development of the system map but also directly uncovered insights for an inspection strategy that are not based on the structural characteristics of the system map. In the interviews, the discussion on challenges, the trade-off between known risky and unknown areas, method selection, allocation of resources, external influences and opportunities observed directly what an inspection strategy needs. The following eight requirements were derived from the interviews:

- **Resource availability** is a general requirement for food safety authorities to be able to design and execute an inspection strategy. During the interviews, capacity and budget limitations were frequently mentioned in relation to inspection strategy decisions (Interviewee 3, Interviewee 4, Interviewee 5). A certain level of resources needs to be available to design inspection strategies and execute inspections. The exact level was not elaborated upon in the interviews; the necessary level depends on the specific context. In fact, resource availability impacts the potential of methods for inspection strategies. For example, if an authority only has resources available to inspect 0.05 per cent of a population, risk-based might be the only viable way to catch potential food safety hazards. However, when an authority has the capacity to inspect 50 per cent of the population, the food safety authority has 'the luxury' to both catch food safety hazards and monitor developments within the population. A high level of resource availability is especially important for employing a significant number of random methods. Resource availability is a requirement that is challenging to pinpoint to a certain level but certainly cannot be disregarded due to its importance in designing and executing an inspection strategy.
- **Fit for inspection process** is a requirement to consider since inspections in different sectors require different inspection processes. Interviews were conducted with interviewees working in a variety of sectors. This revealed that the inspection strategy heavily depends on what is to be inspected. Interviewee 3 from the microbiology sector demonstrated a notably different inspection process than Interviewee 2 from the chemistry sector. The observation is important to take into consideration because there is no one inspection strategy that fits all sectors. The need exists for an inspection strategy to fit the characteristics of the inspected sector. A requirement for a

strategy is to respect the differences in inspection processes per sector; a risk-based and/or random method should fit these sector-specific characteristics. The requirement on fit for inspection process is to be fulfilled to ensure an inspection strategy that can be executed in practice.

- **Availability of sample** is another essential requirement to be considered in an inspection strategy. Interviewee 2 mentioned that it is a struggle that sometimes certain samples at a certain point in time are not available. A carefully considered inspection strategy can be designed based on risk-based and random methods, but the strategy cannot be executed if the inspector cannot inspect and/or take the sample. For example, fishing practices are to be inspected based on risk analysis, but the boat is on the sea for days, and the inspector cannot reach the boat so no sample can be taken. The sample's availability is a requirement that is to be equally considered for risk-based and random methods to ensure a workable inspection strategy.
- **Complete list of inspectees** is a requirement for the inspection strategy to have an overview of the to-be-inspected population. Interviewee 5 mentioned that the NVWA needs an improvement of a better database of the producers and processors to be inspected. The NVWA is unaware of existing producers and processors in certain occasions and sectors. An overview of the population is required for both a random and a risk-based method to design and employ a strategy that considers the whole population. Similar to resource availability, the requirement is difficult to pinpoint at a certain level. A list with only a few producers/processors missing is expected to be realistic. However, one can expect a list containing only half of the producers/processors of a population to be problematic for the design and execution of an inspection strategy.
- **Fair inspection burden** is another requirement that came forward from the interviews. The inspection burden for producers and processors is to be considered fair, as mentioned by Interviewee 3. An unfair inspection burden entails visiting the same producers/processors too frequently. In the case of a random method, it is rather unlikely that the same producer/processor is visited too frequently. A fair inspection burden is especially required for a risk-based method to avoid disproportionally visiting the same producers and processors based on the risk factors. The requirement of fair inspection burden is particularly to be fulfilled for inspection strategies employing risk-based methods.
- **Representativeness** is a potential requirement that came forward from some interviewees but was disregarded by other interviewees. Interviewee 2 mentioned that the authority aims to create a representative picture but sees it as a challenge because of the small number of samples and visits. Interviewee 7, on the other hand, stated that a representative statement is only necessary when comparing countries but that nobody asks for it and that representative results are not required to continue with future inspections. Representativeness is a requirement for an inspection strategy depending on the goals of the food safety authorities.
- **Definition of goals** is a requirement that came forward in the interviews and is elaborated upon in the work of Ayaydin (2023). Different perceived goals and corresponding risk definitions exist in the multi-actor system of food safety regulation. As revealed during the interviews, food safety authorities' perceptions of the goals and risks differ. Interviewee 7 mentioned the formulation of the goal of inspection as an unmet need for food safety authorities. The authority might work towards an improved inspection strategy when a shared definition of goals and risks exists. The risk is to be clearly defined, especially for a strategy employing a risk-based method. The definition of goals is required to design an inspection strategy that matches the intended goal.
- **Evaluation of the strategy** is a requirement to ensure an inspection strategy accomplishes what it is designed to accomplish in the first place, particularly for a risk-based method within an inspection strategy. Interviewee 8 of the inspection of education stated that they valued evaluation in their strategy. The inspection of education would conduct an evaluation of their risk model to verify whether the found insufficient schools were also categorised accordingly under high risk in the model. The evaluation of an inspection strategy is a requirement to verify whether the strategy in practice matches the design intentions or whether adjustments are necessary to match the intentions.

Requirements from the system map

The systems map provides insight into the system's structures impacting the inspection strategy that cannot be directly observed from the interviews. A number of requirements for an inspection strategy

can be derived through a closer look into the system structures of the components, interactions, variables and actors. The structures upon which the requirements are founded are included as a figure when possible. The following four requirements were derived from the systems map:

- **Freedom of strategy** is an essential requirement to be able to design an inspection strategy employing a risk-based and/or random method in the first place. As shown in the systems map, financial dependence, enforcement requests, and EU standards can lead to little space for a director or enforcer to allocate inspections based on a risk-based or random method. The above-named system characteristics have predefined a significant part of the allocation of inspections. For food safety authorities to be able to define a risk-based or random method, freedom for an inspection strategy is required. Furthermore, the level of freedom to strategize can impact the method selection. Imagine, for instance, if a food safety authority can only decide upon the allocation of one-tenth of the resources for an inspection. A risk-based method might be favourable to be able to efficiently detect a certain number of non-compliances in the small strategic space. However, if a food safety authority can allocate nine-tenths of the resources, the authority can choose to be less efficient and prioritize unknown risks and representativeness with a random method. A certain level of freedom of strategy is required to design an inspection strategy with a risk-based and/or random method. The specific level of freedom of strategy of when the strategic space is sufficient to employ a certain strategy is to be defined by circumstances.

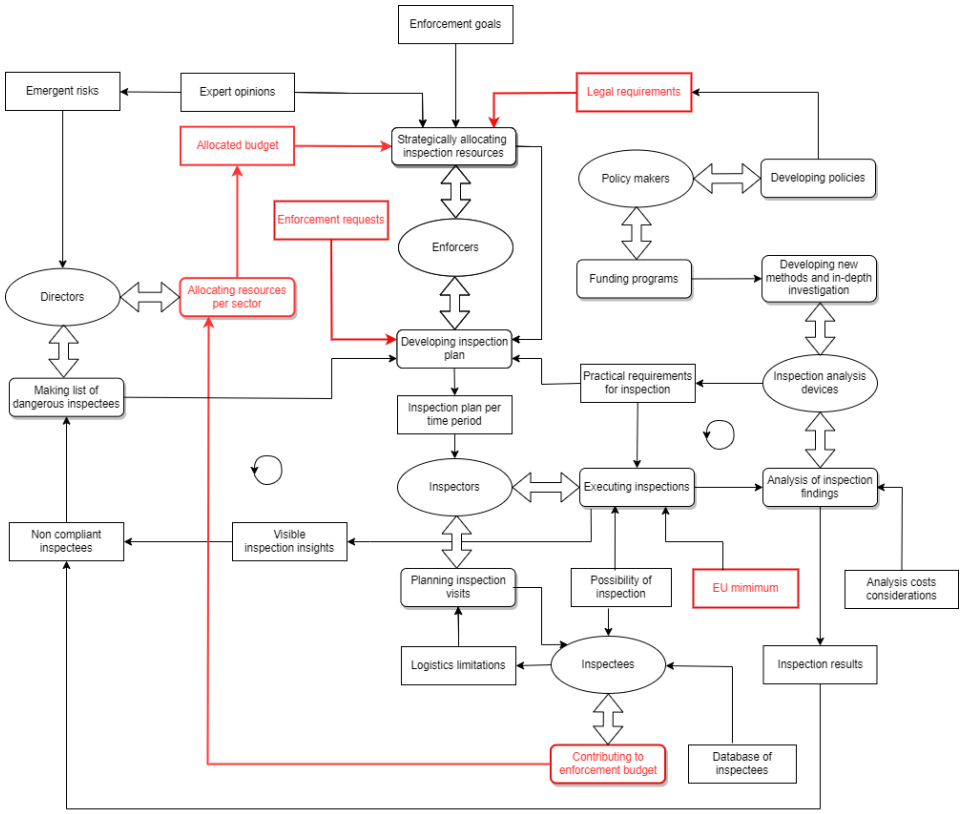

Figure 5.6: Freedom of strategy

- **Connection between functions** is a requirement derived from the organizational structure. The systems map shows no direct connection between the risk assessors and enforcers exists. The continuous validation and improvement of a risk-based method is crucial to keep the method and the risk indicators up-to-date. A risk-based method will always focus more on the past (Interviewee 8). However, a strong connection between functions can potentially reduce the focus on the past through frequently evaluating and updating the risk factors, models, and methods. The figure below shows what is required but missing in the map of the current system. A connection between functions is a requirement for an inspection strategy with a risk-based method.

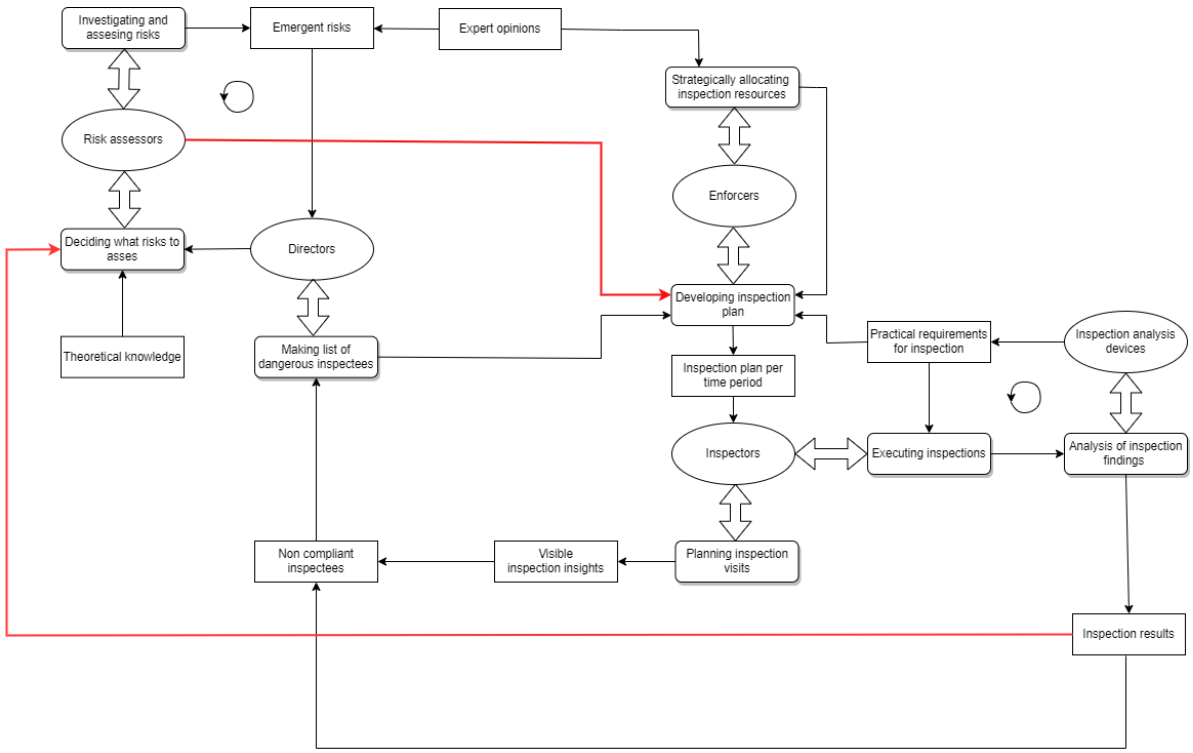

Figure 5.7: Connection between functions

- **Incorporation of experts** is an organizational requirement that was frequently introduced in the interviews, and the system map exposes that experts have a very central role in the system (see Figure 5.1). Especially when selecting an inspection strategy with a risk-based method, careful consideration by experts of risk factors and risk models is necessary to limit bias and prevent tunnel vision. Incorporating experts in the design of an inspection strategy is required because data availability is too limited to make strategic decisions upon (Interviewee 7). Data retrieved from random inspections holds the potential to provide suitable input data for strategic decisions. In an ideal world, both expert incorporation and data from random inspections are utilized to design an inspection strategy. The incorporation of experts is a requirement to be fulfilled to design an inspection strategy that effectively uses the available knowledge in the organization.
- **Inspection device capacity** is a requirement that initially came forward in the interviews but demonstrated to be of large impact in the systems map on the inspection strategy design. The system map shows that the capacity of inspection devices leads to a balancing loop (see Figure 5.2). The capacity of devices, such as the laboratory, impacts the number and type of samples that can be analyzed. Similar to the availability of the sample, this is a constraint for the selection of methods. In the case of the laboratory, if a sample is selected completely random or risk-based, the laboratory needs to have the capacity to analyze that specific type of sample. In the industrial production sector, the focus is on the inspection of hygiene standards so they can select predominately based on the Canadian risk model (Interviewee 5), but for the microbiology sector, a larger dependence on devices such as the laboratory exists; thus making it difficult to select inspections and samples completely based on a risk-based and/or random method (Interviewee 3). The inspection device capacity is a requirement to execute the inspection strategy within logistic possibilities.

Requirements from literature

Literature was employed in multiple phases of the design science process of this research, and literature was employed in the definition of the requirements as well. In fact, the literature uncovered a few requirements for an inspection strategy. The literature on complex adaptive systems theory exposed one requirement, and the literature on inspection strategies exposed another one. The last two requirements were derived from the literature:

- **In accordance with the law** is a requirement that came forward from a literature study. In the study by Altenburger and Ho (2018) on the role of predictive algorithms in regulatory enforcement, the use of predictive analysis in the case of food safety is discussed. Altenburger and Ho (2018) stated that evidence suggests that food-safety inspection scores tend to be worse for ethnic, and specifically Asian, restaurants. Ethnic restaurants being inspected more frequently based on ethnic profiling is against the Dutch law of no discrimination. For the employment of risk-based methods within an inspection strategy, it is essential that the biases are only legitimate and not discriminatory. The Dutch law requires a non-discriminatory inspection strategy. In accordance with the law is thus a requirement to be fulfilled unconditionally.
- **Adaptiveness to change** is a requirement based on applying the complex adaptive systems view to food safety regulation. The application of CAS to food safety regulation is based on literature (see 4.2). As illustrated in the section, food safety regulation deals with many unpredictabilities, changes and/or emergencies. If a food safety hazard arises, e.g. a fast-spreading and new animal disease, immediate action needs to be taken, and the inspection strategy needs to change accordingly. For example, a fast-spreading and new animal disease might take a lot of device availability by analysing the new disease or requiring a specialized team within the organization. Consequently, Devaney (2016) named the need to be adaptive in food safety regulation. Adaptiveness to change of an inspection strategy is thus a requirement within the system of food safety regulation.

The list of the total of fourteen identified requirements is aligned above. The requirements are gathered through the iterative processes of design science. As demonstrated in the list, the design requirements are of different origins, but the requirements are also of different natures. Some requirements are more focused on the design process of an inspection strategy, while others are more focused on the execution of the inspection strategy design. In addition, some requirements have come forward specifically based on a risk-based or a random method within an inspection strategy. The list of requirements is quite extensive. In fact, the large number of requirements further substantiates the complexity of the inspection strategy design. Categorization and prioritization of requirements is the next step to comprehend the nature of different requirements and to distinguish the essential requirements from the favourable ones.

5.2.2. Categorization requirements

Fourteen requirements are identified based on what is needed for an inspection strategy. However, simply aligning these requirements is insufficient in guiding food safety authorities in designing an inspection strategy. Categorization is essential because the goal is to translate the requirements into actionable guidance for food safety authorities. Categorization is a way to make the requirements understandable and workable for food safety authorities. The requirements are categorized based on their role in the design of the inspection strategy. The categorization is executed through an iterative process of grouping and reviewing the requirements. Four categories are constructed:

- **Feasibility** is what is required for a food safety authority to enable the design of an inspection strategy.
- **Accountability** is what is required for a food safety authority to take responsibility in the design of an inspection strategy to ensure a transparent and explanatory design.
- **Applicability** is what is required for food safety authorities to design an inspection strategy that can be executed in its intended environment.
- **Adaptivity** is what is required to design a strategy that adjusts to the changes over time.

The fourteen requirements are listed in the table below with their category. The table does not follow a specific order.

Table 5.1: Categorization requirements

Requirement	Category
Freedom of strategy	Feasibility
Connection between functions	Accountability
Incorporation of experts	Accountability
Fit for inspection process	Applicability
Availability of sample	Applicability
Inspection device capacity	Applicability
Complete list of inspectees	Applicability
Accordance with the law	Accountability
Fair inspection burden	Accountability
Resource availability	Feasibility
Adaptiveness to change	Adaptivity
Representativeness	Accountability
Definition of goals	Applicability
Evaluation of strategy	Accountability

As can be seen from the table, most requirements fall under the accountability and applicability category. Thus, many of the requirements are to be considered to design an inspection strategy in an applicable and accountable manner. Adaptiveness to change is the only requirement falling into the category of adaptivity. The requirement is also the only one directly retrieved from the literature around the complex adaptive systems view. Freedom of strategy and resource availability are the two requirements in the feasibility category, meaning that those are needed to enable the design of an inspection strategy in the first place.

The categories and their requirements focus on the process of the design and execution of the inspection strategy. At the start of the research, the requirements of efficiency and representativeness are named in the central trade-off between risk-based and random methods within an inspection strategy. The requirements from the central trade-off are result-focused, while the previously appointed requirements are process-focused. These requirements are to be considered in the design process of an inspection strategy. Representativeness is both result- and process-focused. Representativeness can be required to retrieve results about the complete inspected population, but representativeness can also be required to build the design of an inspection strategy upon.

Fourteen requirements are allocated to the four categories: feasibility, accountability, applicability and adaptivity. The four categories represent different considerations to be made in the process of designing the inspection strategy. The categorization is the first step in making the requirements more workable and understandable for food safety authorities.

5.2.3. Prioritization requirements

The fourteen requirements for the design of an inspection strategy are categorized in the previous section. However, not all requirements are of the same significance. Furthermore, the best-case scenario would be to fulfil all fourteen requirements in the inspection strategy, but in realistic scenarios, trade-offs are to be made, and not all requirements might be fulfilled. Prioritization of requirements is necessary to retrieve insight into the significance of the fourteen requirements for the design of an inspection strategy.

An applicable technique to prioritize requirements for the design of an inspection strategy is the MoSCoW technique. The MoSCoW technique is one of the easiest techniques for prioritization (Hudaib et al., 2018). The requirements are classified on a nominal scale. The requirements in the same priority group are considered to be around the same priority. The MoSCoW technique prioritizes requirements based on the following four categories:

- M - Must-have
- S - Should-have
- C - Could-have
- W - Won't-have

The must-haves for an inspection strategy are the requirements that are indispensable for an inspection strategy. An inspection strategy cannot be designed and executed without the must-haves. The should-haves for an inspection strategy are the requirements that lead to a better inspection strategy. The could-haves are optional requirements for an inspection strategy that are not essential for a good inspection strategy. The could-haves rather represent an option to consider. The won't-haves are requirements that are not supposed to be included in an inspection strategy.

The list of requirements from the identification through the literature, system map and interviews only consists of the must-have, should-have, and could-have requirements. The requirements are extracted based on what the design of the inspection strategy requires and not what is to be excluded. The wont't-haves of an inspection strategy have not been thoroughly investigated throughout the design science processes and are not to be found in the list of requirements.

The application of the MoSCoW framework provides a basic understanding of the significance of requirements for the inspection strategy. The must-have requirements can also be seen as conditions to be able to design an inspection strategy, while the should-haves can be seen as criteria on which an inspection strategy can perform well. The could-haves represent an option for an inspection strategy. The MoSCoW technique is applied as a simple tool to prioritize based on a short substantiation. The possibility exists to investigate further, discuss and validate the prioritization. However, the research aims to develop practical guidance in a limited time, so the level of detail is currently restricted. In the table, the requirements are aligned together with the allocated priority and the substantiation for the allocated priority.

Table 5.2: Prioritization requirements

Requirement	Priority	Basis priority allocation
Freedom of strategy	Must-have	Enables the design of an inspection strategy
Connection between functions	Should-have	Improves a risk-based method within the strategy
Incorporation of experts	Should-have	Fuels the strategy with expert knowledge
Fit for inspection process	Must-have	Ensures the strategy can be executed in practice
Availability of sample	Must-have	Ensures the strategy can be executed in practice
Inspection device capacity	Must-have	Ensures the strategy can be executed in practice
Overview population	Should-have	Demands that no inspectees are unjust excluded
In accordance with the law	Must-have	Ensures the strategy is legal
Fair inspection burden	Should-have	Allows for a fair inspection strategy
Resource availability	Must-have	Enables the design of an inspection strategy
Adaptivenessness to change	Should-have	Establishes a strategy that is up-to-date
Representativeness	Could-have	Depends on the goals and tasks of the authorities
Definition of goals	Should-have	Clarifies the authority's goals within the strategy
Evaluation of strategy	Should-have	Ensures the execution matches the intention

Moving forward, the categories and priorities of the requirements are combined and displayed in the table on the next page. Resource availability and freedom of strategy are the requirements that fall into the feasibility category and, consequently, are must-have requirements. The accountability requirements are exclusively must-haves when the requirements are demanded by law. Representativeness is the only could-have because the interviewees mentioned the requirement as an aspect that can be both included and excluded. The priority of the applicability category, however, might be less straightforward. For example, in the case of sample availability, a strategy could be designed and then

not executed because no sample is available. In theory, it is possible to design a strategy and not execute it. However, in practice, the design of a strategy that cannot be executed is hard to imagine for a governmental organization such as a food safety authority. The availability of the sample is thus considered a must-have. The same reasoning is used for the fit for inspection process and inspection device capacity. On the other hand, the complete list of inspectees is an applicability requirement that is considered a should-have. Executing an inspection strategy, for example, on 80 per cent of the population would be unfavourable but can still be considered applicable to a certain extent.

Table 5.3: Prioritization and categorization requirements

Requirement	Category	Priority
Freedom of strategy	Feasibility	Must-have
Connection between functions	Accountability	Should-have
Incorporation of experts	Accountability	Should-have
Fit for inspection process	Applicability	Must-have
Availability of sample	Applicability	Must-have
Inspection device capacity	Applicability	Must-have
Complete list of inspectees	Applicability	Should-have
Accordance with the law	Accountability	Must-have
Fair inspection burden	Accountability	Should-have
Resource availability	Feasibility	Must-have
Adaptiveness to change	Adaptivity	Should-have
Representativeness	Accountability	Could-have
Definition of goals	Applicability	Should-have
Evaluation of strategy	Accountability	Should-have

The requirements are prioritised based on the MoSCoW technique, and the requirements are listed under the must-haves, should-haves and could-haves. The prioritization of requirements represents their significance for an inspection strategy. The prioritization is the second step in making the requirements more workable and understandable for food safety authorities.

5.2.4. Requirements framework

A framework is designed to bring together the prioritization and categorization of the requirements visually. The framework creates a visual overview of the requirements and their category and priority. The inner circle represents the must-haves, and the outer circle represents the should-haves. The must-haves can be seen as conditions for an inspection strategy, and the should-haves as criteria. The size of the area covered by a category does not aim to represent a weight of importance.

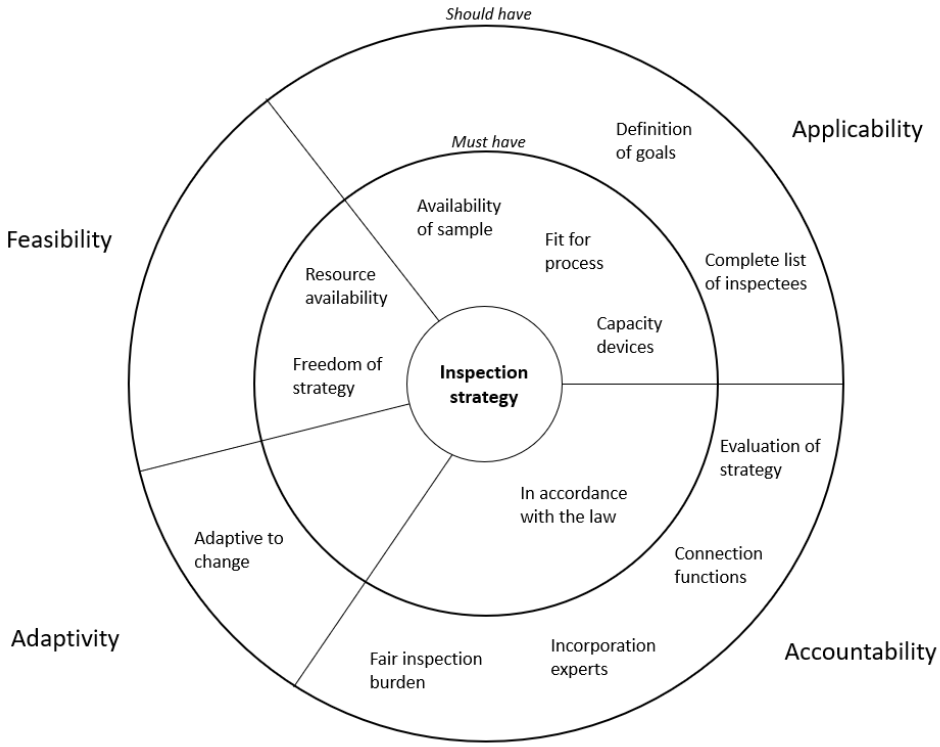

Figure 5.8: Requirements framework

In Chapter 4, the complexities of designing inspection strategies came forward, and the framework is to respect the complexities. The framework respects the complexity of inspection strategies by providing guidance without imposing rigid standards. Rigid standards deny the context dependence and the continuous changes in food safety regulation impacting inspection strategies. For instance, the level of freedom of strategy required is not set to a certain standard because the level of freedom of strategy depends on the specific context and time. The framework allows food safety authorities to set their own standards within the defined requirements. The framework is to be seen as a manner for food safety authorities to consider the requirements, their prioritization, and category when designing their inspection strategies.

Furthermore, the system characteristics that especially challenge food safety regulation of adaptive, emergence, goal-seeking and unpredictable come back in the inspection strategy requirements. The characteristic of adaptive within the system is directly addressed through the inspection strategy's requirement to be adaptive to change. Food safety authorities address the goal-seeking characteristic by the requirement of goal definition for their inspection strategies. When it comes to dealing with the emergence and unpredictability characteristics, the evaluation requirement is introduced to ensure that unexpected and emerging changes are integrated into the inspection strategy through ongoing evaluation and improvements. The complex systems characteristics of food safety regulation are translated into the inspection strategy requirements.

By the end of this chapter, fourteen requirements of an inspection strategy are identified, categorized, and prioritized. This results in the requirements framework that brings everything together. The requirements framework provides an overview for food safety authorities designing an inspection strategy. At first sight, a food safety authority can see what must and what should be included in an inspection strategy. Furthermore, when applied, the framework provides insights into the potential trade-offs since fulfilling all fourteen requirements is not, by definition, realistic. The framework visualizes what to take into account when designing an inspection strategy. In the next chapter, the framework is utilized to discuss the directions for an inspection strategy and the value of the framework for food safety authorities is demonstrated.

6

Guidance for inspection strategy design

In this chapter, building on the previous chapters, the guidance for the design of an inspection strategy is constructed as the last step of the research plan. The guidance is twofold: the evaluation of inspection strategy directions that have come forward in the research through the requirements framework and questions for food safety authorities to ask themselves before, during and after the design of an inspection strategy. Altogether, guidance on the trade-offs and considerations to be minded when designing an inspection strategy for food safety authorities is constructed. The guidance is validated through another interview with Interviewee 2.

6.1. Inspection strategy design directions

During the research, various inspection strategies employing risk-based and/or random methods were encountered that can be viewed as a design direction for an inspection strategy. The directions are placed on a scale from completely random to completely risk-based. In Figure 6.1, the directions of an inspection strategy are aligned. The scale shows the diversity of inspection strategies utilizing risk-based and random methods. The scale does not represent all possible combinations of risk-based and random methods but includes those encountered during this research.

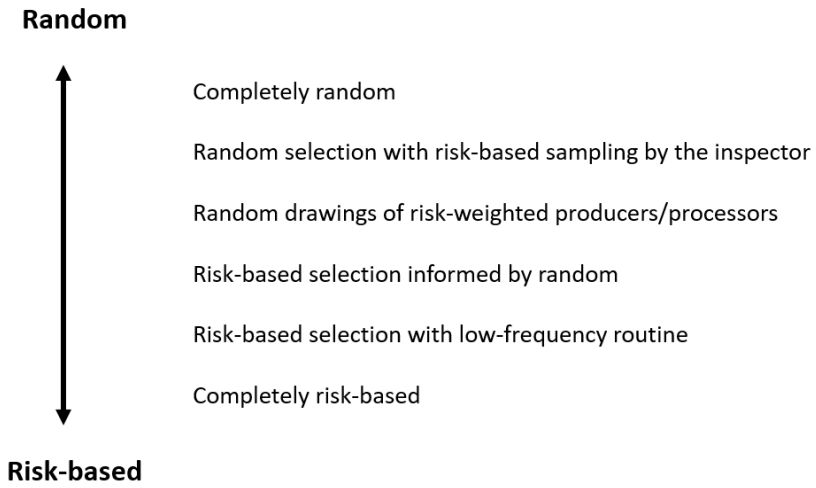

Figure 6.1: Scale of inspection strategies

The directions are evaluated per category based on the requirements relevant to the direction of the strategy. The evaluation is based on both interviews and literature. After the evaluation, trade-offs are identified for inspection strategy directions. Through the evaluation of categories and the discussion on the trade-offs per strategy direction, insight for food safety authorities is created on the considerations to be made when designing an inspection strategy.

The strategy directions on the scale are evaluated based on their current implementation in context, except for the completely random and risk-based strategy directions. Those strategies have only been encountered in the research through literature. The completely random and risk-based strategies are included to provide the frame of the extremes. However, some categories are challenging to evaluate for the strategies retrieved from the literature since the knowledge is limited due to a lack of current implementation.

A visualization of the requirement framework for that particular direction is incorporated per strategy direction. The visualization represents which categories of requirements perform well and which ones perform poorly. The visualization is based on qualitative data, so the visual serves as an indication rather than a quantitative comparison tool.

6.1.1. Completely random

A completely random inspection strategy entails selecting every producer/processor for inspection based on a random drawing and in the case of sampling, selecting a sample based on a random drawing. The strategy has not been shown to be practised extensively by encountered food safety authorities within this research. However, the strategy direction can be employed in areas where the European Union does not require a risk-based strategy.

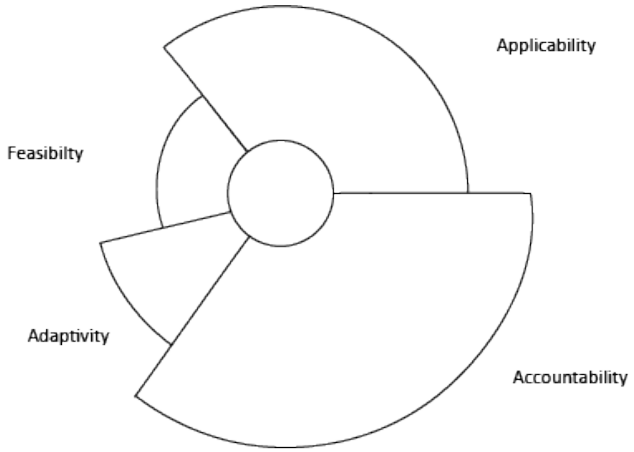

Figure 6.2: Completely random

- **Feasibility** does not come without challenges for a completely random strategy. The resource availability requirement is the first challenge discussed. Presi et al. (2008) stated regarding sampling slaughtered calves that resources are saved by going from random sampling to risk-based sampling. Random sampling is thus the unfavourable choice considering resources. Furthermore, Blickenstorfer et al. (2011) noted, in a study on using scenario tree modelling for targeted herd sampling to substantiate freedom from disease, that random sampling does not take into account the uneven distribution of risks in diseases within herds and consequently detects diseases with a lower probability than risk-based sampling. In order to tackle a substantial number of risks present in the population, a considerable allocation of resources is required when employing random sampling. Especially when inspecting within a sector with a low occurrence of hazards, a high number of random inspections need to be executed to prevent food safety hazards. Considering freedom of strategy, Blickenstorfer et al. (2011) demonstrated to set a baseline for a number of random samples to retrieve the benefits of a random method, including representativeness. A

certain level of freedom of strategy is required to similarly ensure the benefits of random methods. In the end, resource availability has shown to be the largest challenge for the feasibility of a completely random strategy.

- **Accountability** within a completely random strategy is well-represented. Blickenstorfer et al. (2011) stated that in conventional approaches to document freedom of disease, producers/processors are selected randomly from a database, and that sampling randomly ensures the representativeness of a population. In random sampling, bias is inherently constrained because the representativeness reflects the entire population. The lack of bias lowers the chance of discrimination and not being in accordance with the law. The should-haves within the category, like the incorporation of experts, evaluation of strategy connection between functions, and fair inspection burden, are favourable for a risk-based strategy but are not directly relevant for a completely random one. The fulfilment of accountability requirements is easily achieved in this strategy.
- **Applicability** is slightly challenged as well. For example, imagine one would select producers/processors of the complete inspected population of the Netherlands randomly. An inspector might have to visit locations of producers/processors that are very far apart or have to execute different types of inspection processes in one day. According to Interviewee 2, convenience and efficiency are to be considered in inspection planning. A random strategy still deals with the must-have requirements fit for the inspection process, capacity of devices, and availability of samples to ensure convenience and efficiency. Definition of goals is to be included in the strategy. For instance, a random strategy is more applicable when the goal is to map the sector versus to catch non-compliance. The complete list of inspectees is another should-have requirement that increases the applicability of this strategy when fulfilled. Ultimately, a completely random inspection strategy must be conveniently and efficiently executed within the logistic possibilities of a complete sector and with the goals in mind.
- **Adaptivity** in a random strategy demands some attention. Interviewee 2 mentioned the struggle to maintain an up-to-date list of producers/processors because there is no connection with the Chamber of Commerce that informs the NVWA of new producers/processors. A random strategy does not deal with having to update risk factors like a risk-based strategy. Adaptivity solely needs to be represented in a random strategy by including new producers and processors in the list that is randomly drawn from.

The feasibility category especially challenges a random strategy, mainly through the resource availability requirement. A completely random strategy is inefficient resource-wise. On the other hand, accountability is a well-represented category because the strategy leads to representativeness and limited bias. Applicability and adaptivity require some consideration but are not the main obstacles within this strategy direction. The main trade-off to be made by food safety authorities within this direction is between feasibility and accountability.

6.1.2. Random selection with risk-based sampling by the inspector

The strategy of random selection with the risk-based sampling of the inspector came forward in an interview in relation to inspecting animals (Interviewee 2). The inspection strategy represents producers/processors being selected randomly for the inspection visits plan, but when the inspector executes the visit, he/she takes samples based on perceived risks. Within the animal sector, a perceived risk can be a sick-looking animal when sampling for pathogens, for example (Interviewee 2).

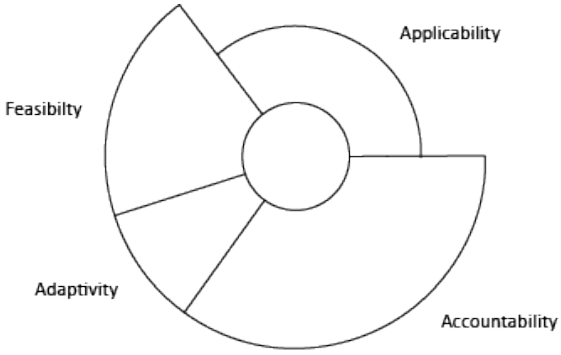

Figure 6.3: Random with risk-based sampling by the inspector

- **Feasibility** is increased from a completely random strategy. Interviewee 2 stated that they select producers and processors randomly to a large extent. At least no risk factors are involved in the selection. The aim is to visit most producers/processors while considering the last inspection visit in the selection process (Interviewee 2). A substantial amount of resources is required to include most producers/processors in the selection. On the contrary, relatively few samples are taken, thus lowering the required resource availability. For sampling veterinary medicinal products, Interviewee 2 said: 'We take 25,000 samples a year, but for example, we slaughter 17 million pigs and 15 million fuel cows'. Similar to completely random, a baseline of a random selection of producers/processors is to be allocated to be able to have the benefits of randomness, So a certain level of freedom of strategy is favourable. The feasibility is increased from completely random by taking a limited number of samples that are chosen based on risks.
- **Accountability** requires attention within this strategy. No bias is present in the selection, but bias is present in the risk-based sampling by the inspector. Risk-based strategies always deal with bias (Interviewee 8). The bias of the inspector when looking for risks could possibly be based on discrimination, while no discrimination is a must-have requirement. A potential discriminatory bias could be addressed by evaluating the bias and reflecting on its justifiability. An example of discriminatory bias in the case of sampling animals is an inspector being more alert in an ethnic slaughterhouse. Furthermore, the inspector is required to be an expert in identifying risks during the producer/processor visit properly. The requirement for the inclusion of risk assessors in risk analysis did not appear to be currently fulfilled in the strategy but holds the potential to take the form of risk assessors and inspectors meeting up frequently to exchange knowledge. The inspection burden's fairness is less challenging since the producers and processors are selected randomly. The accountability category encounters challenges in meeting all requirements; some of these requirements hold the opportunity to be improved. Nevertheless, the strategy still represents accountability relatively well because of the random selection of producers and processors.
- **Applicability** might be an obstacle to this strategy. For the animal sector, the strategy is fit for the inspection process but could potentially be challenged by the capacity of the devices and the availability of the sample. Inspectors have targets for certain samples to use the laboratory efficiently, and the availability of the sample is a difficult requirement to fulfil for smaller producers and processors (Interviewee 2). Interviewee 2 gave a hypothetical example to illustrate the difficulties: if an inspector needs to take 20 samples of horse meat a year, but there are only 1000 horses slaughtered a year, it is possible that an inspector visits the slaughterhouse and needs to wait hours before a horse is slaughtered and can take a sample. Next to that, applicability is challenged by not having a complete list of inspectees (Interviewee 2). Moreover, challenges exist in relation to the strategy's applicability to other sectors. Not all sectors that are inspected have visible risks. The risk's visibility influences the strategy's fitness for the inspection process. The goal definition appeared to be implicitly twofold by Interviewee 2: ensuring antibiotics are used to prevent antibiotic resistance, which falls under the goal of catching non-compliance and monitoring increased painkiller use in animals for the goal of animal welfare. When evaluating the applicability category, the availability of samples and the capacity of devices demonstrate to be minded within this strategy. Furthermore, the strategy does not easily translate to other sectors due to its specificity in terms of fit for process, which limits its applicability across different sectors.

- **Adaptivity** also plays a role within this direction. The risk perception of inspectors is to be adaptive to continuous changes within the food safety regulation system. Risk analysis tends to be focused on the past (Interviewee 8). The inspector must be informed if a new risk arises, such as an emerging pathogen. The risk perception of an inspector is to be adaptive to change by updating knowledge and keeping the inspectors well-informed. Adaptivity is significant for the risk perception central to the strategy.

The feasibility, accountability and adaptivity categories challenge the strategy to a limited extent. Resource availability needs to be relatively significant to ensure feasibility. Bias needs to be dealt with properly to ensure accountability and risk factors must be prospective to support accountability. Applicability, however, is the largest challenge since the laboratory plays a large role in the strategy, and the strategy direction cannot be easily employed in different sectors. Nonetheless, the random selection of producers/processors increases accountability, and the limited number of samples increases the feasibility. This strategy direction does not impose one large trade-off like the completely random direction but rather demonstrates considerations to be made.

6.1.3. Random drawings of risk-weighted producers/processors

AGES is currently practising the direction of random drawings of risk-weighted producers/processors. The strategy is stated by Interviewee 4 to be executed in the following way. AGES has a list of farms in the national farm registry. First, the sample size is calculated, and then the sample size is proportionally allocated to the federal states. Hereafter, sampling probabilities are calculated for each producer/processor based on risks. Last, random samples are drawn from that list based on the sample probabilities. The chance of being drawn is thus increased for the higher-risk producers/processors. In the case of AGES, the samples to be taken are selected by them, but the federal states execute the inspections (Interviewee 7). The inspectors of the federal states receive an annual sampling plan provided by AGES (Interviewee 7).

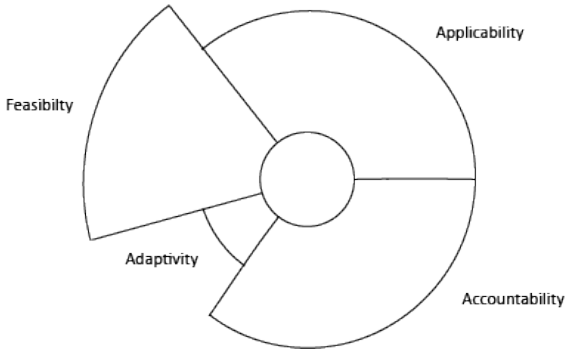

Figure 6.4: Random drawings of risk-weighted producers/processors

- **Feasibility** increases moving towards risk-based on the scale till this point. The amount of resources required for an inspection strategy is relatively flexible for this strategy. The resources depend on the number of drawings that are decided upon. Interviewee 4 mentioned dealing with limited resource availability, demonstrating the possibility of executing this strategy with this constraint. Since the strategy is risk-based, fewer resources are required to catch non-compliance compared to random strategies. Freedom of strategy is required for this strategy as well. Nevertheless, it's not necessary to obtain a specific number of samples and a specific number of producers/processors in order to achieve representativeness, as this outcome is not feasible to start with. The feasibility of this strategy is rather high because of the possibility of executing the strategy with little resources and little freedom of strategy.
- **Accountability** in this inspection strategy direction is particularly important in the definition of risk factors that determine the sampling probabilities. Interviewee 4 viewed risk-based as the way to go but doubted whether the risk factors were defined correctly. The correct definition of risk factors relates to all requirements in the category of accountability. The risk factors are required to be non-discriminatory. This can be accomplished by expert-defined risk factors, the inclusion

of risk assessors, and evaluation of the factors and their fairness. Obtaining representativeness for increasing accountability is difficult with this strategy because all samples are weighted by risks. The accountability category requires attention in this strategy, and all the must-have and should-have requirements must be carefully considered. In conclusion, ensuring accountability in this inspection strategy proves to be challenging due to the fact that all samples are risk-weighted.

- **Applicability** requires logistical factors to be considered similar to previous strategies. Specific in this case, applicability might be challenging because of the organizational split between the planning and the execution of the inspection. Interviewee 7 stated they had difficulties retrieving up-to-date information about the producers and processors (size, processes, etc.). The lack of this information limits the fit for process of the designed sampling plan. Considering the availability to sample, if the inspector cannot do the inspection, they must command it so AGES knows the inspection was not executed (Interviewee 7). The information on whether the inspection was executed is taken along to the next planning. Furthermore, Interviewee 7 mentioned that the definition of goals was still challenging. The interviewees did not consider the capacity of devices and retrieving a complete list of inspectees as a challenge, so it is assumed that these requirements won't form a significant obstacle to the strategy. Ultimately, the applicability category holds potential for improvement but is not in a critically unfavourable state.
- **Adaptivity** in this direction is low because of the current way the strategy is executed; a sampling plan is created annually (Interviewee 7). Adaption can take place over the years and not over weeks or months. In addition, adaptivity is required in relation to the risk factors. Risk factors might change over time and are to be changed over time in this case. The strategy does hold the potential to be made more adaptable through more frequent planning and evaluation. The adaptivity is represented poorly in this strategy but can certainly be improved.

The strategy has high feasibility but low adaptivity. The adaptivity could be improved through more evaluation. Accountability would benefit from this as well. Frequent evaluation, however, would take from the feasibility. The central trade-off here is feasibility versus adaptivity and accountability. Applicability is not considered in the trade-off since the applicability does not take from other categories. The organizational split causes the current state of applicability and cannot be easily adjusted.

6.1.4. Risk-based selection informed by random

The inspection of education added a significant number of random inspections to their previous completely risk-based inspections. The amount of random was defined based on the confidence interval of the entire population to be able to make statements of the entire population (Interviewee 8). The inspection of education authority deals with a variety of sectors. For instance, primary education, secondary education, newcomer education, and special needs education (Interviewee 8). The amount of needed random inspections differs per sector. Smaller sectors, such as special needs education, need relatively more random inspections to be able to make statements about the whole inspected population (Interviewee 8).

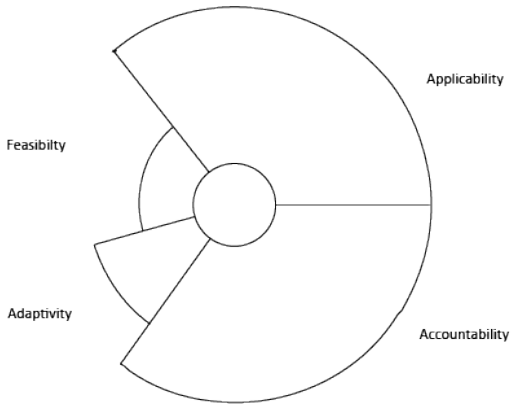

Figure 6.5: Risk-based selection informed by random

- **Feasibility** is poorly represented in this direction. Significant availability of resources is required to execute random inspections on top of risk-based inspections. In fact, the inspection of education stated to have received a substantial budget in the last years (Interviewee 8). Similar to most of the previous strategies, freedom of strategy would be favourable for the insights and benefits from the random inspections. The requirement of resource availability in this strategy predominantly challenges the feasibility category.
- **Accountability** is well-presented in the strategy of the inspection of education. First, the requirement of accordance with the law to not discriminate is fulfilled. Some risk factors showed coherence with the risk models but were left out of the model to prevent discrimination (Interviewee 8). This also demonstrates the fulfilment of the evaluation requirement. Furthermore, Interviewee 8 stated to evaluate whether the allocated high-risk schools were indeed non-compliant. In addition, the data from the random inspections is employed to develop the risk factors for the risk-based part of the inspection, leading to a fair inspection burden and a connection between risk assessment and enforcement. Incorporation of experts is less prominent as a requirement because the data from random inspections is accurately used to support strategic decisions. The majority of accountability requirements have been demonstrated to be fulfilled in strategy.
- **Applicability** is required for the different sectors. As mentioned before, the size of the education sector determines the number of random inspection that is necessary for the goal of the inspection of education (Interviewee 8). Thus, the strategy at the moment is made to be fit for the inspection process. Capacity of devices and availability of sample have not been shown to play a significant role in the field of education. Furthermore, considering a complete list of inspectees, it is quite improbable that a school's existence would remain unknown. The definition of goals did not emerge as a challenge from the interviews. Applicability is predominantly determined by the fit for inspection process, which is well-represented in this strategy.
- **Adaptivity** is twofold within this direction. First, the risk selection is to be adaptive, which can be done through the previously mentioned evaluations. Second, the inspection strategy is also required to be adaptive to available resources. Interviewee 8 mentioned having received a lot of budget in recent years and that the strategy might have to change in case of budget cuts from the ministry. The representation of adaptivity is increased by the frequent evaluation but decreased by the lack of flexibility in the budget required to design and execute this strategy.

The feasibility of this strategy is highly dependent on the available resources since the budget needs to be large. The large budget, however, allows for the fulfilment of applicability and accountability requirements. The central trade-off here is applicability and accountability versus feasibility.

6.1.5. Risk-based selection with low-frequency routine

Risk-based with low-frequency routine is an inspection strategy direction of the department of industrial production within the NVWA. The risk-based selection is made through the Canadian risk model (Government of Canada, Canadian Food Inspection Agency, 2022). Interviewee 5 stated that low-frequency visits are required to make sure producers/processors are visited at least once in a while. Interviewee 5 emphasized the importance of keeping in contact with low-risk producers and processors but that it is not necessary to visit them every year. In addition, Interviewee 5 stated that often risks are not exactly known, and the low-frequency routine visits can lead to inspectors identifying previously unknown risks. The low-frequency visits are not fully random because they are chosen based on the passed time since the last visit, but they still hold the potential to contribute to the overview of the sector.

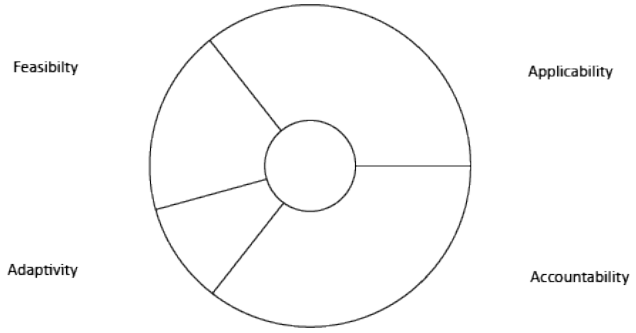

Figure 6.6: Risk-based selection with low-frequency routine

- **Feasibility** is problematic in relation to the freedom of strategy because Interviewee 5 named that the employed risk model is restricting. In fact, Interviewee 5 stated to not always be free to choose where to do inspections because of requests. Furthermore, the department depends on inspectees for the budget, so the freedom of strategy is limited in selecting producers/processors because the department is obliged to retrieve a certain amount of money. Considering resource availability, since the largest part is risk-based, the efficiency is relatively high, which is favourable for the feasibility. The feasibility category is well-represented for resource availability but falls short regarding freedom of strategy.
- **Accountability** is important for a predominantly risk-based strategy. Many requirements are to be fulfilled to ensure an accountable risk-based strategy. The model is in accordance with the law when the risk factors are non-discriminatory. The Canadian risk model incorporates different types of risks as input: inherent risk factors, mitigation risk factors, and non-compliance factors (Government of Canada, Canadian Food Inspection Agency, 2022). Expert knowledge is used to define these factors. The model thus prevents the potentially unwanted reinforcing loop of only non-compliant producers/processors and contributes to a fair inspection burden. However, Interviewee 5 stated that the model is still to be evaluated to check if the model is effective. The model has been in use for just a year. The evaluation aims to retrieve an understanding of the sector, and the model leads to inspecting in the right place. Interviewee 5 expressed hope for more capacity in the future to do this. The requirement of connection between functions has not been shown to be fulfilled. While some requirements have been fulfilled in the accountability category, others remain unfulfilled, yet all of them are to be considered in the strategy.
- **Applicability** posed some challenges but didn't significantly hinder the strategy as appeared from Interviewee 5 of the industrial production sector. The Canadian risk model risk can be customized to the specifics of an inspected population by adjusting the risk factors, and consequently, the risk model could be applied to different sectors (Interviewee 5). Nonetheless, within the sector of industrial production, no samples are taken (Interviewee 5). So, the strategy does not deal with constraints considering the availability of the sample or device capacity, like the microbiology sector. The complete list of inspectees is a bit of a challenge, primarily because producers and processors are required to self-register, and there is no direct link with the Chamber of Commerce. Interviewee 5 stated that they have a definition of goals, namely catching non-compliance. It is still being studied how much the inspections on demand and/or notifications in the sector challenge the risk model, impacting the fit for the inspection process (Interviewee 5). The complete list challenges the applicability but is not to be seen as a major obstacle in this strategy.
- **Adaptivity** can take the form of the model being updated over time through the defined risk factors. From the discussion with Interviewee 5 on the current strategy, it did not appear to happen frequently. However, the model does hold the opportunity to be adaptive. In the current execution of the strategy, the adaptivity is estimated to be rather average.

The extra capacity required for evaluation to increase accountability would require a higher resource availability and, thus, lower the feasibility. All categories are generally represented within the strategy direction but only to a certain extent. The categories are in balance, yet all categories leave room for improvement.

6.1.6. Completely risk based

A completely risk-based strategy represents all producers/processors and samples being selected based on some risk consideration. The encountered inspection strategies appeared to have some inclusion of risk but were not completely risk-based. Accordingly, this strategy is hypothetical, similar to completely random.

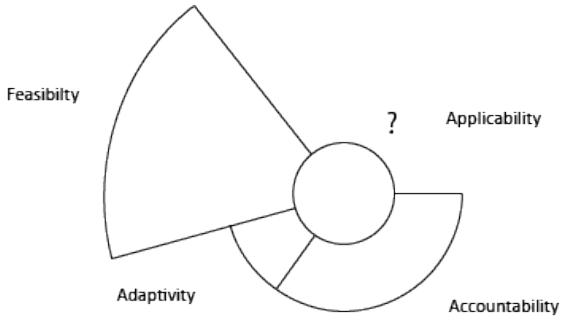

Figure 6.7: Completely risk-based

- **Feasibility** appears to be high. According to van Asselt et al. (2021) in a study providing an overview of risk-based methods, risk-based methods lead to high efficiency with limited resources. Few resources can find a substantial number of non-compliances and potential hazards with a risk-based strategy. Consequently, the requirement of resource availability is relatively easily fulfilled. The high efficiency, in this case, is achieved to catch non-compliance. If the goal would be mapping sectors, the strategy is the opposite of efficient (see Figure 3.1). Unlike random strategy directions, a risk-based strategy does not require a specific baseline for freedom of strategy. Overall, a risk-based strategy appears to be highly feasible.
- **Accountability** is an obstacle to this strategy. Requirements need to be fulfilled to ensure an accountable risk-based strategy. van Asselt et al. (2021) stated that risk-based methods must be executed as objectively as possible and documented carefully to provide transparency in the prioritization based on risks of producers and processors. As Interviewee 8 mentioned, risk-based strategies are always in retrospect and deal with bias consequently. For a completely risk-based strategy, the must-have requirement of accordance with the law logically has to be fulfilled, but the should-haves are also highly important to be minded. Limited knowledge exists on the current implementation of a completely risk-based strategy and its representation of requirements, but literature and interviewees indicate the importance of fulfilling all requirements. Challenges to ensure an accountable strategy are probable to be present for a completely risk-based strategy because all requirements in the accountability category are to be considered carefully.
- **Applicability** is undetermined for this strategy. No literature was found in this category about a risk-based method. Since the strategy is hypothetical and not implemented in a certain environment, the applicability of the strategy direction can not be evaluated at this moment.
- **Adaptivity** of a completely risk-based strategy is difficult because the authority is unaware of the population outside the defined high-risk population. Including a random method is required to consider the complete population (Blickenstorfer et al., 2011). Adapting to emerging risks is challenging if the complete population is not actively monitored. Adaptivity is comparatively underrepresented in a risk-based strategy.

In a completely risk-based strategy, the main trade-off between feasibility and accountability is similar to a completely random strategy. However, for a risk-based strategy, the feasibility is high and the accountability low, and for a completely random strategy, it is the other way around. The applicability of a risk-based strategy is to be further investigated before that can be determined.

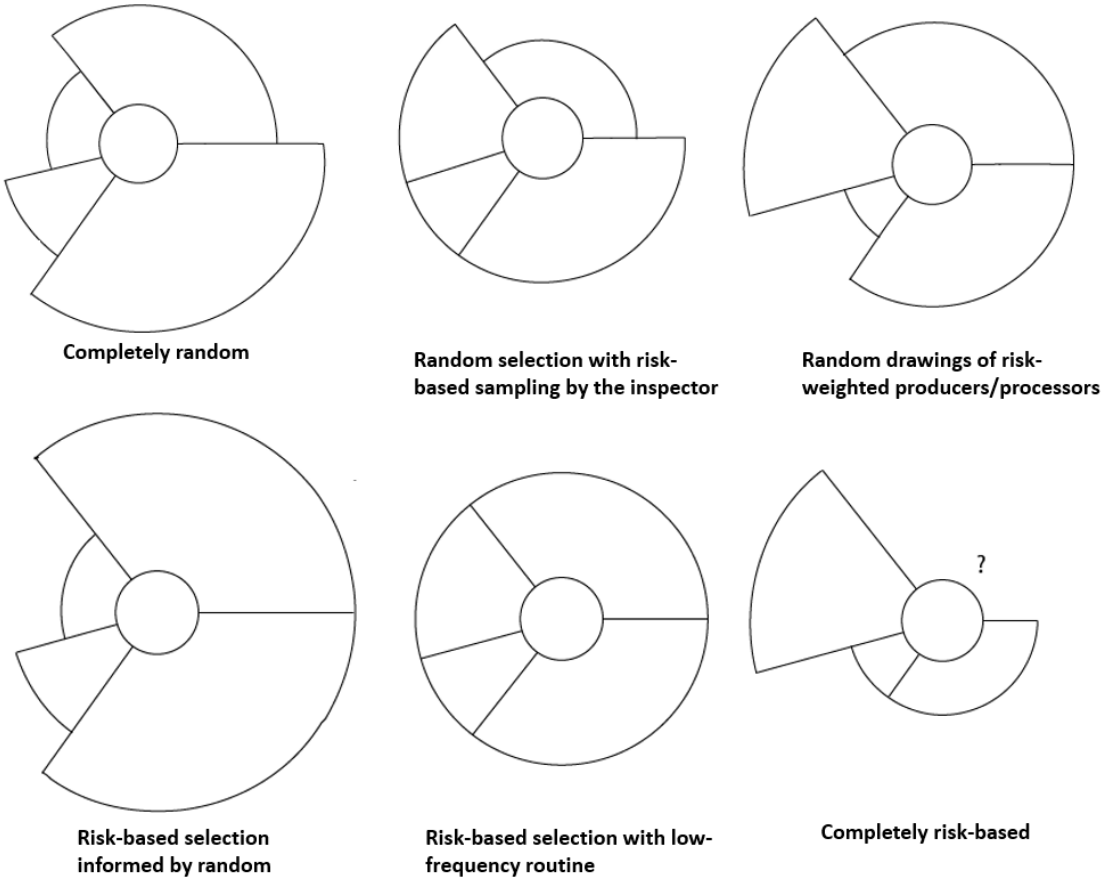

Figure 6.8: Overview strategy directions

To summarize, all the strategy directions represented in Figure 6.1 have been evaluated in the categories of requirements. The results of the evaluation are aligned in Figure 6.8. Per strategy direction, the representation of categories of requirements and the potential trade-offs are now defined. The section guides in two ways for food safety authorities. First, the evaluated directions can serve as guidance in choosing one of the inspection strategies. Second, the evaluated directions serve as guidance in uncovering the considerations and trade-offs to be made in an inspection strategy.

6.2. Inspection strategy questions flow

Based on the previous chapters and the previous guidance sections, questions can be constructed for food safety authorities to ask themselves. The questions flow is chosen as a format to increase practicality and implementability for food safety authorities. The questions aim to make food safety authorities think about what an inspection strategy requires. Questions are formulated that are to be asked at the start of designing an inspection strategy, during the design of an inspection strategy, and after the design of an inspection strategy. For each question, the corresponding requirements are explicitly mentioned.

Before questions The questions before are to examine whether it is possible to employ a strategy with a risk-based and/or random method. The questions are based on the requirements from the feasibility category.

- *Is there freedom to strategize?*
  The first question is based on the requirement of freedom of strategy for an inspection strategy. A sector deals with enforcement requests, financial dependence or EU standards that impact the freedom of strategy. Before designing an inspection strategy, knowing what strategic space is available to design within is essential.

- *What resources are available?*
  This question is based on the requirement of resource availability. The available resources impact the possible strategies to design and execute. For example, random inspection is more resource-intensive than risk-based inspection when the goal is catching non-compliance. Beforehand, the available resources are to be established to understand the possibilities for inspection strategies.

During questions During the design of an inspection strategy, questions are to be asked to verify whether the strategy can be executed in practice. The questions are retrieved from both accountability and adaptability requirements.

- *What do we consider the inspection goal?*
  The inspection goal is the should-have requirement of applicability. One could execute an inspection strategy without a goal in mind. However, when the goals are defined, the design of an inspection strategy can be tailored to that goal to ensure an intentional strategy.
- *What laws need to be taken into consideration?*
  The question is based on the must-have requirement of accountability, namely, accordance with the law. A strategy must always be in accordance with the law to be executed, so importance rests in examining which laws are to be considered in the design of an inspection strategy.
- *How can we make the most out of the knowledge we have and/or can obtain?*
  The question represents two should-have accountability requirements: the connection with risk assessors and the incorporation of expert knowledge. Data availability can potentially also be added as a requirement in the future. Incorporating the available knowledge in the organization reflects taking accountability to make the most informed decision.
- *What methods are possible within the sector-specific inspection processes?*
  The question reflects the adaptability category by the fit for inspection requirement. The question aims to make the food safety authority think about what method matches the context-specifics.
- *What could hinder the execution of the intended strategy, and how can that be addressed?*
  The question covers the applicability requirements of availability of sample and capacity of devices. The question reflects whether the inspection strategy, including the selected methods, can be executed.

After questions The questions after the design of an inspection strategy are purposed to guide in evaluating the design combining risk-based and random methods. The evaluation, in turn, can provide insights into areas of improvement. The questions come from the accountability, applicability and adaptivity categories.

- *In what way can the strategy be evaluated?*
  The question is based on the evaluation requirement to contribute to accountability. The question aims to remind food safety authorities about the need to evaluate. Evaluation is important to employ a strategy that has the wanted impact in a context with the continuously evolving system characteristics of emergence and unpredictability.
- *Is the bias within the strategy fair?*
  The question touches upon both the requirement accordance with law and fair inspection burden of the accountability category. The question encourages food safety authorities to think about whether the bias is fair and/or legitimate. This could reduce and prevent undesired discrimination.
- *Is the strategy still up-to-date?*
  This question is based on the adaptiveness to change requirement. Since food safety regulation is subject to change, the inspection strategy must change accordingly. A food safety authority that frequently asks themselves whether the strategy is up-to-date and improves the strategy accordingly will lead to a strategy that is adaptive to change.
- *Does the strategy serve the goal?*
  The question is based on both the applicability category by the requirement definition of goals and the accountability category by the requirement evaluation of strategy. The question aims to verify whether the strategy in practice aligns with the intended strategy.

A total of eleven questions are constructed with the purpose of providing another type of guidance for food safety authorities to design an inspection strategy. The questions are to be implemented by food safety authorities before, during, and after the design of an inspection strategy. The last form of guidance is provided with the questions, adding to the evaluation of strategy directions. The guidance is only still to be validated.

6.3. Validation of design guidance

Validity in qualitative research cannot be proven through a straightforward test (Pyett, 2003). Nevertheless, that does not imply that it lacks relevance or cannot be put into practice. Validity in predominantly qualitative research, like this one, can take the form of reflection on the research by asking questions (Pyett, 2003). In qualitative research, the perspective of the researcher impacts the interpretation of the research. As stated by Pyett (2003) postmodern qualitative researchers should acknowledge that there are multiple realities. For validation, the perspective of Interviewee 2 of the NVWA is introduced to bring in another reality.

The validity aims to establish whether the research is useful for the commissioner, the NVWA. The validity is examined through the reflection on three elements with Interviewee 2. First, the degree of understanding by the interviewee of the research findings. Second, the degree to which the guidance applies to the real world. Third, the extent to which the guidance is considered helpful. The results of the research, including the list of requirements, the requirement framework, strategy directions, and the question flow, are presented to Interviewee 2, and the following questions are asked:

- Is it understood?
- Is it applicable?
- Is it helpful?

This section on validity focuses on external validity, whether the research aligns with the real world. The internal validity, whether the research process and methodologies are correct, is not discussed in this section. So, only a part of the validity is addressed. It's crucial to note that validity is never an absolute state but rather an extent of something.

6.3.1. List of requirements

During the presentation of the requirements of an inspection strategy, the interviewee expressed that the requirements are understandable and clearly formulated. Furthermore, she stated that the large number of requirements affirmed the complexity of the design of the inspection strategy, which is often missed by the outside world. The requirements thus showed to confirm with the practice.

Two comments for improvement were provided based on the list of requirements. First, another requirement is to be added; 'timing'. The interviewee expressed that the momentum is to be included in an inspection strategy. In an inspection strategy, it is to be considered what is the right time for a certain action. Second, the requirements would still have to be complemented with good management. Even if all requirements are fulfilled, the inspection goals might still not be met because of a lack of management.

Moreover, Interviewee 2 expressed that the requirements would be useful to share within the NVWA because the requirements demonstrate the design of an inspection strategy is more complex than is often initially thought of. In fact, the requirements can provide insight into, for example, why a department is behind on planning and can help appoint the bottlenecks (Interviewee 2).

6.3.2. Framework of requirements

While showing the requirements framework, the interviewee stated that she thought the categories were logical, that she would have done the prioritization similarly, and that the framework makes a good representation. Interviewee 2 affirmed the prioritization of the requirements fit-for-process, availability of samples, and capacity of devices in the must-have category because she views the fulfilment of those requirements as the base to ensure the government funding is not wasted.

The only improvement the interviewee named was to equally distribute the categories into four in the circle of the visualization. The unequal distribution insinuates that the categories' accountability and applicability weigh heavier than feasibility and adaptivity.

6.3.3. Strategy directions

The strategy directions directly sparked the interviewee to wonder what could be done with it. Interviewee 2 stated that the strategy directions are very insightful for two reasons. First, the strategy directions demonstrate that there are many possible strategic choices considering risk-based and random inspection, while it is often thought there are not so many choices. Second, the strategy can help find problematic elements of a strategy, what to mind in a strategy, and how to choose a strategy.

6.3.4. Questions flow

The questions hit the mark for the interviewee because she expressed that most project leaders do not ask themselves these questions; they rather copy-paste the strategy of last year and do not tend to think about the possibilities they have. Interviewee 2 thought that having these questions at the start of a project would be very favourable for thinking about certain elements. She added that she considered it informational to see all the questions aligned and complete.

One question that particularly sparked her interest was the one to ask afterwards touching upon evaluation. She said that many employees within the organization struggle to include evaluation in a strategy after implementation. Not because the employees are not capable but because of the limited amount of time. In fact, she considered it to be more time-efficient to include evaluation to limit overlooking certain things and to consequently prevent small scandals from happening.

6.3.5. General reflection

Overall, the interviewee stated that employees tend to be tempted to work very content-focused while having a broader look can be very beneficial, which can be achieved through these previously provided results. The requirements, framework, directions, and questions are very useful for the NVWA by providing a different and out-of-the-box view. She stated that she thought the research would make employees think, 'Why am I doing what I am doing?'. She appreciated that the research does not lead to a ready-to-use strategy but rather a way to ask the right questions to make the right decisions.

The last comment that was expressed was to check these results, and especially the question flow with other food safety authorities, for example, the Belgium one. She said that she recognized the results clearly for the NVWA but wondered whether it would also apply to other food safety authorities. Ultimately, this validation illustrates the large extent of applicability and usefulness of the guidance for the NVWA but does not provide knowledge on whether it could be generalizable for food safety authorities throughout the European Union.

7

Discussion

The research focusing on inspection strategies for food safety regulation has been qualitative and explorative. Much of the terrain was uncharted at the start of the research, having to address the question of the NVWA for which there was no clear research path. A design science approach, combined with a systems view, was chosen to navigate the unknowns and uncover the research path step by step. The approach allowed for learning-by-doing. While this research approach led to profound socially and academically relevant findings, it was not a straightforward research process. The research process was dynamic, fueled iteratively from multiple origins and explored a broad topic, leading to limitations and untapped potential for future research. A foundation has been laid by establishing definitions, exploring complexities and developing guidance regarding inspection strategies, leading to a good starting point for future research. However, this field still has unexplored knowledge waiting to be further uncovered and refined.

The findings, limitations and recommendations of the research are discussed in this chapter. The findings include the definition of an inspection strategy, the requirements for an inspection strategy and guidance for food safety authorities to design an inspection strategy. On top of that, the performance of the research approach for the retrieval of the findings regarding the question of the NVWA is discussed. The findings are discussed first by societal relevance. Societal relevance entails the contribution to tackling problems the society faces. Second, the academic relevance is discussed, which touches upon the knowledge gap in the academic field that is filled by the research. Furthermore, the limitations of the research are addressed to ensure transparency and identify gaps within the research. Building on the limitations, the recommendations for future research are brought forward.

7.1. Societal relevance

Since the research aims to guide food safety authorities in designing an inspection strategy, the research holds the potential to improve the inspection strategies among the authorities. The improved inspection strategies enhance food safety in society. Furthermore, the consideration of the feasibility and applicability requirements within the inspection strategy leads to efficient use of the resources, allowing for more regulation and, thus, safer food with fewer resources. Additionally, by guiding the food safety authorities in the design of an accountable inspection strategy through the accountability requirements, the discrimination of producers and processors can be limited. Altogether, the research adds to society through safer food and less discrimination.

The validation indicated that the findings are directly relevant to the NVWA. When the NVWA employs the guidance, the state of food safety and discrimination can be improved in the Netherlands. Moreover, the research can be relevant for food safety authorities across the European Union since all member states are required to include a risk-based strategy for ensuring food safety. The research provides valuable insights into complexities and requirements for food safety authorities struggling with the design of an inspection strategy, particularly those incorporating random and risk-based methods.

The relevance for food safety authorities is established by contributing to safer food and less discrimination. However, the research also holds the potential to be relevant for regulatory authorities in different fields. The inspection of education dealt with similar considerations in the design of an inspection strategy as the food safety authorities. Understanding the system complexity of an inspection strategy, the process of identification of inspection strategy requirements and the way guidance can be developed can serve as inspiration for regulatory authorities in different fields.

7.2. Academic relevance

The research is relevant to the academic field in two manners. First, the chapter 'What is an inspection strategy?' determined the need for a broader view than method selection in the academic literature regarding inspection for food safety regulation. The literature tended to focus on one method within one context. For example, the study of Ferri et al. (2023) where a risk-based method is evaluated for the context of meat safety. Especially risk-based methods are discussed frequently, but the combination of a random and risk-based method in its context is first explored in this research. The academic field benefits from the expansion of method selection to inspection strategy to include considerations intrinsic to the method and the operationalization in its context. The construct of the inspection strategy, which represents the broader view, is formulated and clarified to create a common language throughout the academic field.

Second, the research creates knowledge on the application of the systems view in the field of regulatory governance. van der Heijden (2022) stated that this knowledge was missing in the academic field but is rather valuable to start understanding how systems thinking can be utilized as an approach to regulatory governance. For instance, Corbett (2015) discussed the potential of a systems view for the problem of poverty. However, system thinking was applied inadvertently in the case of the complex problem of poverty, and Corbett (2015) discussed it afterwards. The approach to tackling poverty did not appear to initially start from a deliberate intention to employ a systems view. A scarcity of examples where the application of systems thinking was initiated from the start, and its impact on regulation was evaluated.

This research substantiates the potential of the systems view to uncover requirements for regulatory governance and other approaches, including risk-based and random inspections. In Chapter 5, requirements for an inspection strategy were identified based on the systems map that would not have been uncovered through the interviews and literature review. The systems view provides insight into what interventions can lead to more successful regulation. For example, creating a connection between risk assessors and enforcers (see Figure 5.7). Or, the systems view exposed challenges for inspection strategies. For example, the reinforcing loop in relation to inspecting decide capacity (see Figure 5.2). Furthermore, the system's characteristics of the CAS view also fueled the inspection strategy requirements, such as the adaptiveness to change requirement. The research demonstrates the added value of the application of the systems views as an approach for regulation, thus contributing to the academic field.

7.3. Limitations

A couple of limitations are important to be mentioned for the purpose of transparency and future research recommendations. First, regarding the literature review, the academic field showed to use of large variations of terms concerning inspection strategies. For example, risk-based inspection is also referred to as targeted inspection. Furthermore, inspection can be referred to as enforcement, surveillance or monitoring. These are only two examples. The possibility exists that terms relating to the design of an inspection strategy remain undiscovered. Literature regarding inspection strategies could possibly be overlooked by these undiscovered terms.

Another limitation of the research relates to the system view. The systems view, even though aiming to create a complete understanding, cannot get around the reductionist tools (van der Heijden, 2022). In this research, the systems view of the whole food safety regulation was narrowed down to a systems map on inspection strategy. The process of narrowing down leads to the exclusion of certain variables,

interactions and actors. Moreover, the systems view might be difficult to be employed by food safety authorities themselves. For the required revision of the inspection strategy to remain adaptive to the continuous change of the system around food safety regulation, the food safety authority is to utilize the system's view themselves. However, utilizing a systems view might be challenging because it is a time-intensive and challenging undertaking.

Out of the five-step design science plan by Johannesson and Perjons (2014) only the first two steps were executed. The inspection strategy lacks the demonstration of the design in a real-world context. The design is to be made and implemented by food safety authorities themselves. Because of the time limits within this research, it was not possible to design multiple ready-to-use strategies and implement them within a specific department of food safety authorities. The implementation could perhaps uncover new requirements for the design. When food safety authorities have implemented the guidance, the guidance is to be evaluated and potentially adjusted.

The last limitations to be discussed are those regarding the validity. First, the internal validity is discussed and then the external validity. The internal validation examines whether the research design, conduct and analysis were executed properly and without bias (Andrade, 2018). The internal validity is limited by certain elements of the research. The design science approach is dependent on the researcher's perspective and logical reasoning. The repetition of this research's design science process by another researcher is likely to lead to somewhat different results. Besides, the categorization and the prioritization with the MoSCoW technique of the requirements is in its current execution also defined by the researcher's logical reasoning. The external validation examines whether the research findings are generalizable (Andrade, 2018). The study showed to be generalizable for the NVWA. The generalizability for the NVWA is derived from the fact that the majority of interviewees were of the NVWA. More interviewees from food safety authorities across the European Union are to be included to make generalizable statements on the validity of the research for all EU food safety authorities.

7.4. Recommendations

Recommendations are constructed to tackle the previously mentioned limitations, provide directions for improvement and propose future research. First, the categorization and prioritization of the requirements, which are now based on logical reasoning, should be improved by including a participatory method. A participatory method can entail a number of employees of food safety authorities gathered to discuss and evaluate where the requirements fit in. The inclusion of a participatory method would decrease the influence of the perspective of the researcher and increase the internal validity of the research.

Second, the inspection strategy is to be designed, implemented and evaluated by food safety authorities firstly to establish the impact and secondly to uncover potential shortcomings. This could lead to improvement of the guidance for the design of an inspection strategy based on the encountered shortcomings in the real world. The food safety authorities can only implement the inspection strategy themselves because of their in-house knowledge of the organizational specifics per department and technical specifics per sector. The demonstration of the design, implementation and additional evaluation holds the opportunity to increase the implementability of the guidance for food safety authorities. Future research is to be executed to measure the impact of the guidance and provide recommendations for improvement of the guidance. The main research can be: "How can the implementation and evaluation of inspection strategy design guidance reveal valuable insights to improve inspection strategies?". The results of such research can be twofold: quantitative measures on the impact of the guidance to improve inspection strategies and, second, the potential adjustments for the guidance on inspection strategy design.

Third, food safety authorities must validate the guidance for designing an inspection strategy throughout the European Union and regulatory authorities across fields. Interviewee 2 recommended validating the guidance with the Belgium food safety authority. The Belgium food safety authority is considered a good starting point because the authority is expected to have some differences from the NVWA, although not to a great extent. The validation of the guidance with more food safety authorities will further

disclose the level of generalizability of the guidance. Future research is to be executed with the following research question: ”Is the inspection strategy guidance applicable to food safety authorities across Europe?”. A multi-case study could potentially be an interesting format to answer this question.

Last, the application of systems thinking in regulation demonstrated value in this research. Yet, a multitude of studies on the practical application of systems thinking would enhance understanding of its implications. The multitude of studies would further uncover limitations and opportunities for systems thinking for regulation. As an illustration, research could explore systems thinking as a tool for risk assessors to identify risks by the dynamics of the food safety interactions. Food safety regulation is a large field, and future research will determine the value of systems thinking in various parts of the field. This research is the first application of systems thinking touching upon one part of food safety regulation.

8

Conclusion

The last element of the research is the conclusion. In the conclusion, a concise answer to the subquestions and main research question is provided to finalize the research with a clear understanding of the findings. The questions and their answers are aligned below.

SQ1: What is an inspection strategy and why is it necessary?

Based on literature and interviews, an inspection strategy is defined as the selection and combination of methods based on inherent considerations and operationalization based on contextual considerations. The construct of inspection strategy is placed between method selection and food safety regulation. It is necessary because the discussion on method selection is too limited and food safety regulation too extensive. Components such as resource availability, actors, goals and organizational structure must be considered by food safety authorities. Consequently, the broader construct of inspection strategy is necessary to answer the question of the NVWA on how to combine risk-based and random methods.

SQ2: Why is the design of an inspection strategy complex based on its context?

A systems view was adopted to explore the contextual complexities of inspection strategy design. The system view exposed that food safety regulation must continuously adapt to unpredictable and emerging food hazards and safety risks. Furthermore, the characteristics of adaptive, emergence, goal-seeking and unpredictable in food safety regulation significantly impacted inspection strategy design. The complex systems environment makes the design of a 'best' inspection strategy impossible. The systems view demonstrated that the design of an inspection strategy combining a risk-based and random method is a rather complex undertaking.

SQ3: What are the requirements for an inspection strategy?

The design science approach and the systems view fueled the construction of requirements of an inspection strategy from various origins. In fact, fourteen requirements originated from the literature, interviews and the systems map. The fourteen requirements fall into the categories of feasibility, adaptability, accountability and adaptivity and are prioritized accordingly. The variety of origins, different natures and the large number of requirements align with the previously demonstrated complexity. In fact, the complex systems characteristics of food safety regulation are translated into the inspection strategy requirements. The requirements and their category and prioritization are visualized in a framework. The framework provides an overview of what to take into account when designing an inspection strategy and, when applied, provides insight into potential trade-offs for food safety authorities.

SQ4: What guidance can be developed for food safety authorities designing an inspection strategy?

Building upon the systems context and the established requirements, guidance is developed through discussing the scale of existing strategy directions with risk-based and/or random methods based on the framework and a questions flow for food safety authorities to ask themselves for inspection strategy design. These formats are chosen considering that the inspection strategy is to be designed and implemented by the food safety authority themselves. The strategy directions discussion guides authorities in choosing an inspection strategy by exposing trade-offs of the requirements per strategy. The questions flow guides authorities by demonstrating what questions to ask before, during and after the design of the strategy. Together, food safety authorities are provided with the guidance to design a strategy best fitting the context and goals.

SQ5: Is the guidance applicable to the problem of the food safety authority?

The guidance is validated by another interview later in the research process. Through the interview was confirmed that the guidance is generally applicable to the NVWA, the Dutch food safety authority. The research indicates the potential applicability of the guidance for safety authorities across the European Union. However, the applicability of the guidance outside the Netherlands is yet to be confirmed.

MQ: How can guidance be developed for food safety authorities aiming to design an inspection strategy that combines risk-based and random methods based on the process of understanding the complex context?

The research started with the question of the NVWA on how to combine risk-based and random methods for inspection. A void in knowledge existed to answer this question. The design science approach combined with the systems view laid out the path to create an understanding of the complex context, leading to knowledge on how to guide food safety authorities with this question. The design science approach started with exploration but narrowed down to practical guidance. The systems view provided insight into the complexities of the system that are to be considered in the inspection strategy design. Ultimately, through the design science process fueled by the systems insights, two-fold guidance is developed. First, the scale of inspection strategies from risk-based to random was evaluated based on the requirements framework, guiding food safety authorities by providing insight into the trade-offs. Second, questions are developed to guide food safety authorities before, during and after the design of an inspection strategy. Eventually, the guidance is to be implemented by food safety authorities to reap the research results.

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A

Interview protocol

Interviews are conducted for two research purposes. First to investigate the food safety inspection environment to serve as input for the systems map and second to compare inspection systems across sectors. The selection of interviewees is made based on propositions by the NVWA, AGES and experts from the Delft University of Technology. If approved by the interviewee through verbal consent the interviews are audio recorded and transcribed. For confidential reasons, the interviewees remain anonymous. The interview questions can be found below, however, the interviews will take a semi-structured approach meaning that potential additional questions depending on the answers can be asked to serve the research purpose. A part of the interviews is executed in collaboration with a fellow researcher, Ayaydin (2023). The questions focus on uncovering system components, challenges and opportunities.

A.1. Interview questions

1. What are the largest challenges in the inspection resource allocation and decision-making process?
2. How do you both address known risky areas and explore new or less familiar areas?
3. What is the current process for selecting an inspection methodology, such as random or risk-based methods?
4. Who decides on the allocation of inspections and the areas to be inspected, and what are the complexities of this decision-making process?
5. What are external influences that impact the allocation of inspection resources beyond the organization's control?
6. In your opinion, what changes or improvements could be made when deciding where, how, and how much to inspect

A.2. Interview register

	Organization	**Function**	**Type**	**Date**
1	NVWA	Risk assessor Chemistry	Online	03/04/2023
2	NVWA	Enforcer Chemistry	Online	10/05/2023
3	NVWA	Enforcer Microbiology	In person	12/05/2023
4	AGES	Statistician	Online	17/05/2023
5	NVWA	Enforcer Industrial Production	Online	30/05/2023
6	NVWA	Enforcer Microbiology	Online	31/05/2023
7	AGES	Statistician	Online	01/06/2023
8	Education Inspection	Data scientist	Online	12/06/2023
9	TU Delft	Harbour inspections researcher	Online	22/06/2023

B

Interview analysis

Multiple semi-structured interviews have taken place of about one hour. Analysis of the interview transcripts is needed to provide input for the system map. A methodological approach to interview analysis is essential to increase transparency and decrease bias (Kalu & Bwalya, 2017). The method chosen is the Six Step Thematic Analysis Process by Braun and Clarke (2006). The method is a widely-used for analysis of qualitative data such as interviews. Furthermore, the method is flexible and ensures assumptions are made explicit.

B.1. Six step thematic analysis

1. **Familiarization of data**: Automatically generated interview transcripts were read over and improved based on the recordings.
2. **Generation of codes**: Relevant quotes were selected reformulated.
3. **Generating themes**: Based on the systems perspective themes were developed to fuel as input for the systems map.
4. **Reviewing themes**: Themes were removed and added. 'external influences' was removed as a theme and 'dilemmas' was added as a theme.
5. **Defining themes**: Reflection was done on the themes but since all themes appeared to be relevant as input for for the system map no differences in significance have shown.
6. **Writing up findings**: Findings within the themes were translated and visualized into the systems map.

C

Excluded components

- **NGOs for food safety**: Interviewee 2 mentioned that they would receive a large number of enforcement requests from NGOs for food safety. The enforcement requests are included as a variable. However, the NGO itself is excluded as an actor to prevent overcomplication of the systems map.
- **Consumers perception**: Interviewee 7 mentioned that consumer perception can sometimes be an external influence. Interviewee 2 mentioned that a risk-based strategy might give the consumer the idea that the food is very unsafe because of the high number of findings. Consumer behaviour and perception can impact the inspection strategy. Nonetheless, a large expansion of the systems map would be required to include consumer interactions for an expected limited impact. To prevent overcomplication, consumer perception is chosen to be excluded.
- **Ministries**: Interviewee 2 mentioned the Ministry of Agriculture considering the budget allocation and Interviewee 2 mentioned the Ministry of Health as a policymaker. The budget allocation and policymakers are included in the map but the specific ministries are excluded to ensure generalizability.
- **Specific risk factors and/or models**: In the interviews often specific risk models and factors were named that are not included in the systems map for generalizability.
- **Laboratory specifics**: Laboratory specifications that come up in the discussion with interviewees are not included. The laboratories fall under the broader term inspection analysis devices to allow for generalizability for sectors where other types of devices are used.

D

Iterations system map

Iteration 1: System map developed after the first interview with only the risk assessment perspective.

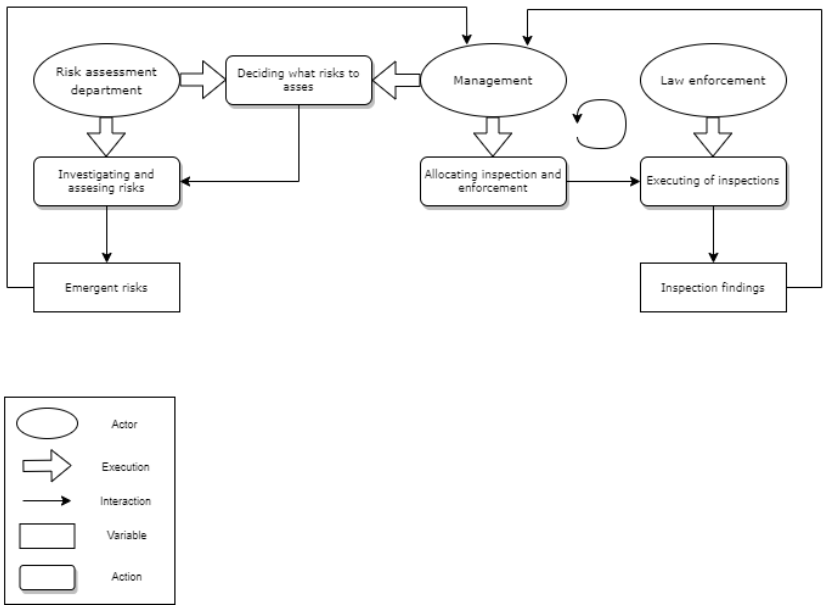

Figure D.1: System map 09/05

Iteration 2: Elaboration on the inspection subsystem through more knowledge.

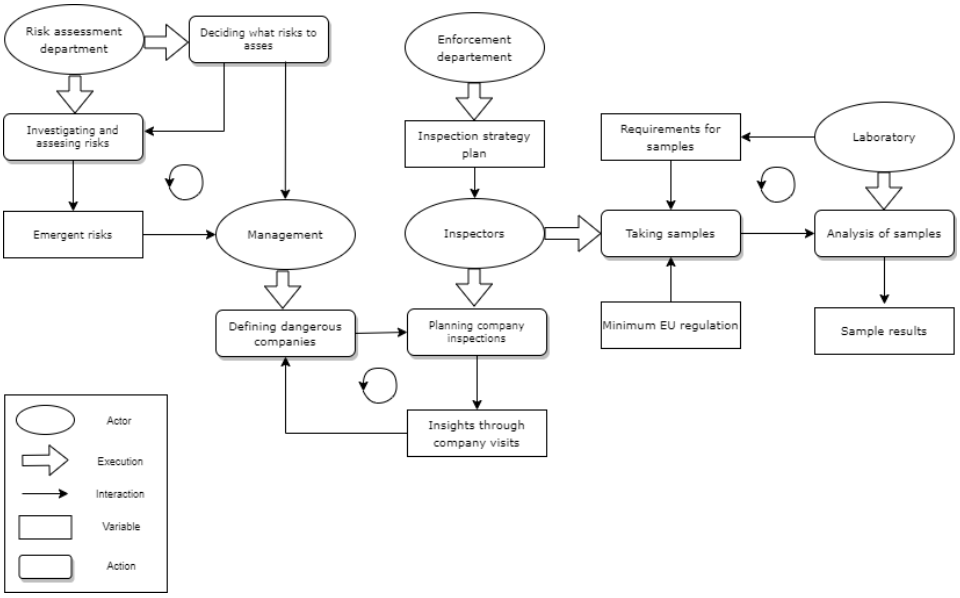

Figure D.2: System map 19/05

Iteration 3: Experts have become central.

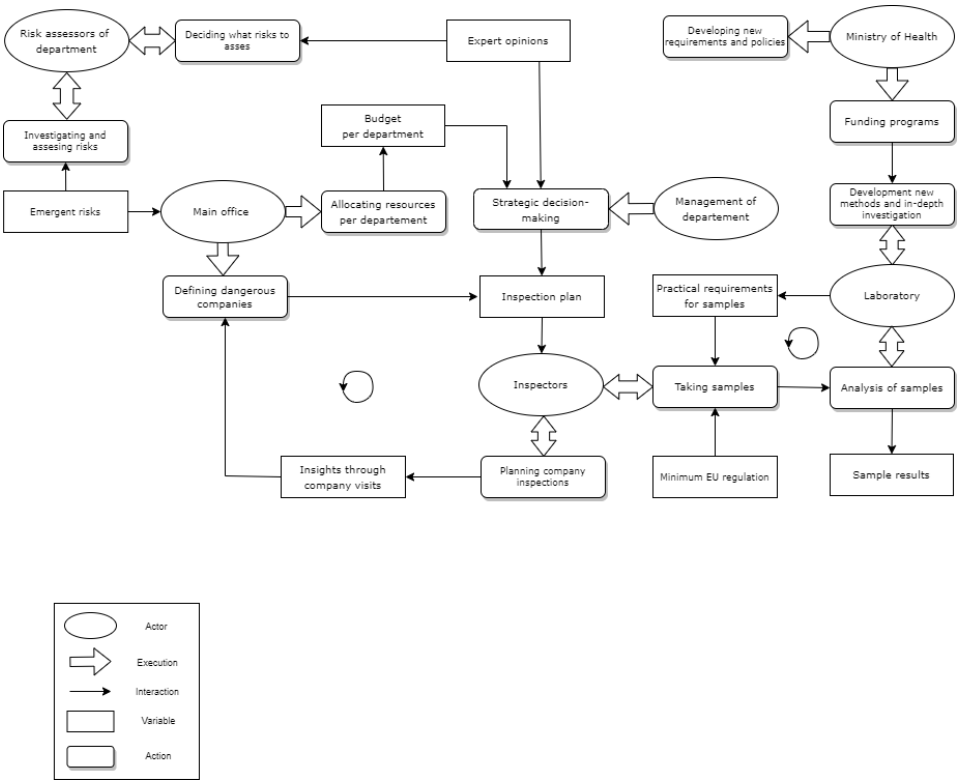

Figure D.3: System map 23/05

Iteration 4: Re-organization to create a clear visualization and naming functions instead of departments to make it more generalizable.

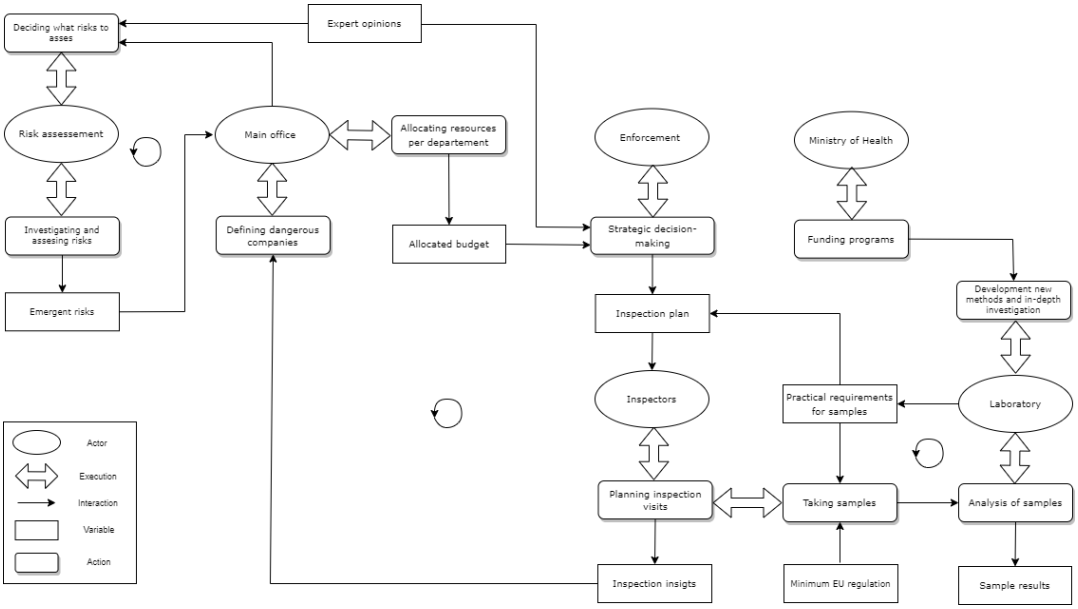

Figure D.4: System map 24/05

Iteration 5: Inclusion inspectees and its financial and practical influences and the additional influencing variables to strategic decision-making.

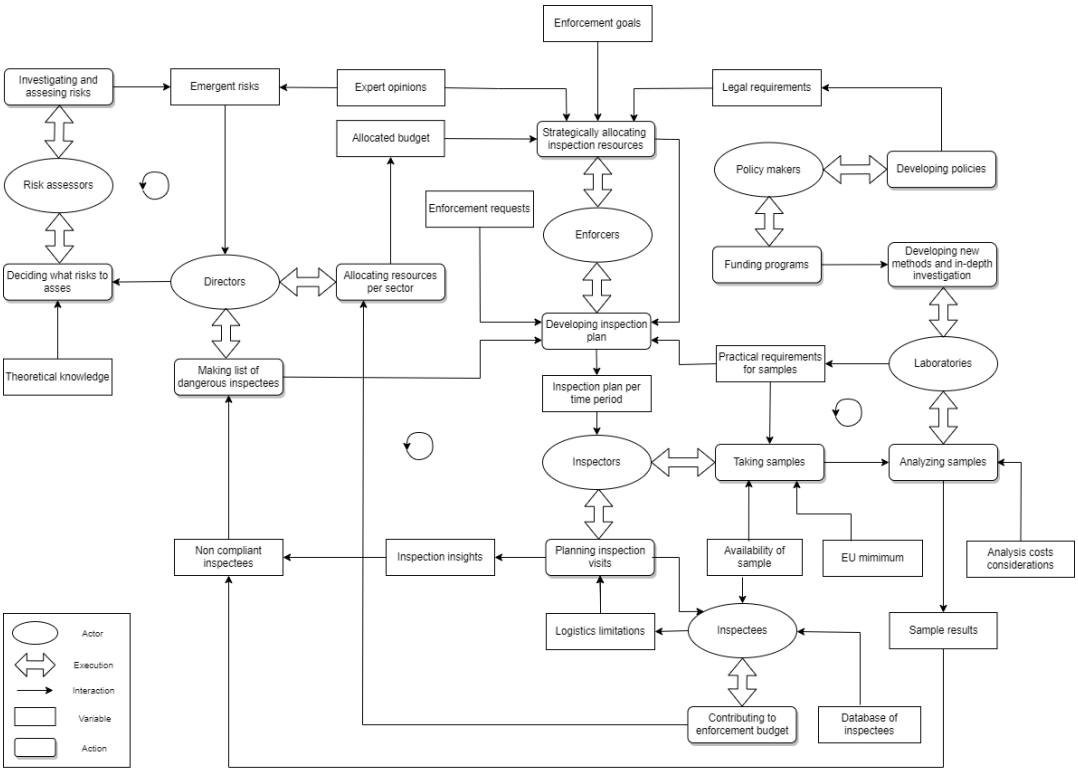

Figure D.5: System map 05/06

Iteration 6: Change from laboratories to devices to become more inclusive and representative of the whole inspection sector.

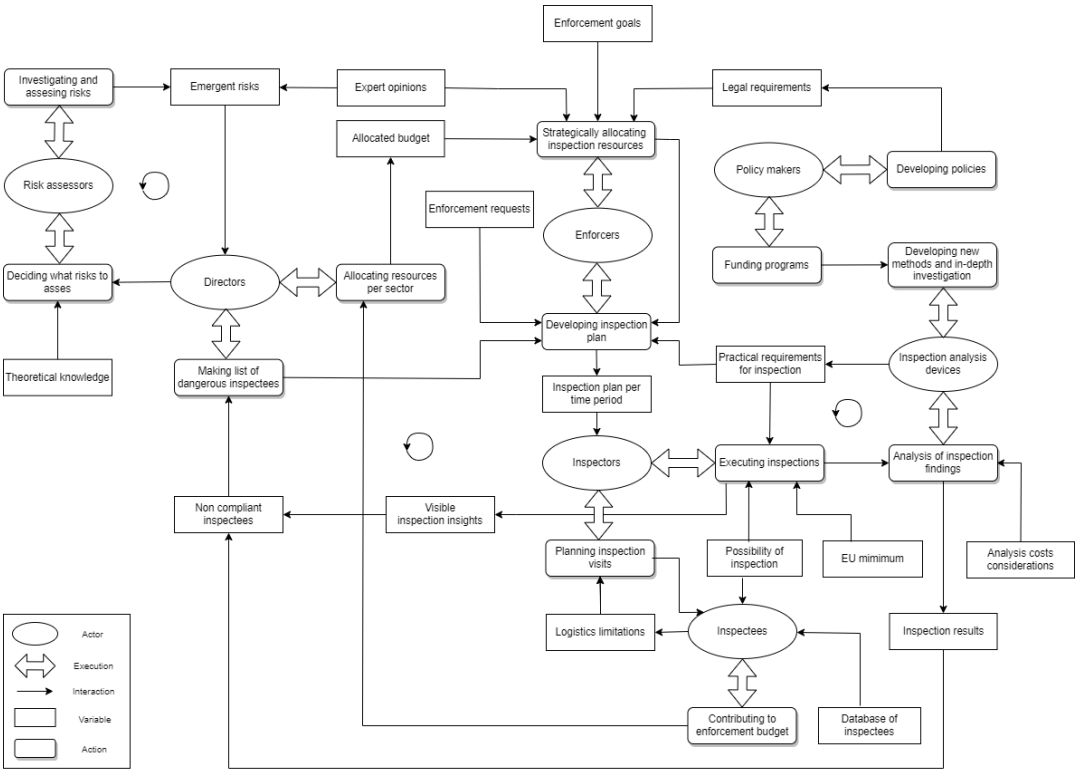

Figure D.6: System map 14/07