Towards an Assessment Framework for Inspection Strategies:

Combining Risk-Based and Random Approaches in Food Safety Inspections

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Suzan Nur Ayaydın

Student number: 4612116

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Graduation committee

Chairperson	: Dr., H.G., van der Voort, Organization & Governance
First Supervisor	: Dr., H.G., van der Voort, Organization & Governance
Second Supervisor	: Prof.dr.ir., P.H.A.J.M., van Gelder, Safety and Security Science

Delft University of Technology

THESIS

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Suzan Nur Ayaydın
Student Number: 4612116

Graduation Committee

Chairperson & First Supervisor: Haiko van der Voort
Second Supervisor: Pieter van Gelder

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Executive Summary

Food safety inspections play an important role in the safety of consumers of food products. Even though food safety regulations have disciplinary power over food-related businesses, inspections are needed to ensure that regulations are followed for the well-being of consumers. Traditionally inspections did not have a goal of targeting higher risks. However, since 2004 EU regulations require all EU Member State inspectorates to follow a risk-based approach within their inspection plan. This is an effective way of inspecting and gives high results in catching violations. However, to be able to know what is happening in the overall industry representative results are needed, and performing inspections based on risks does not provide representativeness. Random inspections if performed in a representative way can provide this. Inspectorates are looking for ways to combine random and risk-based inspections to get representativeness from risk-based approaches. To do this the inspection strategy might need to consist of a combination of random and risk-based approaches. The reason for this is to avoid bias that may result from performing risk-based inspections.

The main research question of this thesis therefore is:

How can inspectorates adapt their inspection strategies to mitigate bias that results from risk-based inspections?

Furthermore, when talking about risk-based inspections, a further evaluation of risk is necessary. To analyze this situation this thesis goes deeper into why inspections are done and the trade-off between risk-based and representative approaches by exploring the concepts of risk and bias.

Purposes of Inspections

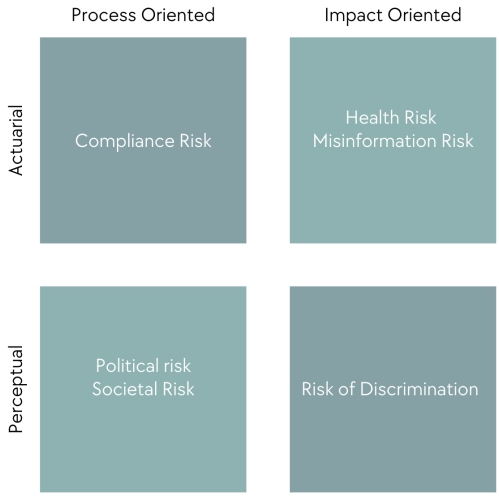
First, reasons why inspections are performed are explored. The purposes for inspecting are key when inspection strategies will be developed. The process depends highly on the purpose. Four main purposes are identified which are

- Imposing Higher Values
- Encouraging Compliance
- Mapping Sectors
- Catching Violations

The first two purposes relate to the higher goals of inspections and need to be kept in mind when planning and executing inspections. The last two serve inspection strategies. Mapping sectors relates to random inspections and catching violations relates to risk-based inspections. These two purposes relate to each other within the question of looking for representative results from risk-based inspections. This is why it is possible to find combination strategies that serve those purposes.

Conceptions of Risk and Bias

The inspection process and risk-based approaches are intertwined with the concepts of risk and bias. These concepts are ambiguous and less tangible. Defining risk is the foundation of risk-based inspections. However, risk is affected by different perceptions and definitions in different contexts which makes the concept of risk difficult to define, and leads to fuzziness. A conception of risk in the form of a typology is developed to get a better understanding of risk and what risks are important in terms of risk-based food inspections.



Risk assessments are frequently associated with bias. This can be due to the fact that the human factor is involved in certain parts of the process. Furthermore, taking a risk-based focus will lead to biased results and biased information because the information collected belongs to a higher-risk population. Therefore, the assumption that risk-based inspection leads to biased results can be made. Bias is also a fuzzy concept, and is difficult to visualize. A conceptualization of bias that facilitates the analysis of how to mitigate this bias is developed as well.

- **Base layer:** Is it fair to use data from other organizations to decide on data about another organization?
- **Middle layer:** Is the data used about organizations biased? Does it include all related factors sufficiently?
- **Top layer:** Is the model used to assess the riskiness of organizations biased?

Analysis of Methods

Even though a perfect selection algorithm is difficult to achieve because of these complex and fuzzy concepts that lie in the background there are certain methods that can support the decision-making process. The search aims to find methods that help to combine risk-based and random approaches to find the optimum balance, however, as the literature lacks this combination, other methods that support risk-based decision-making are analyzed. The analysis of methods and the conceptualization of the concept of risk and bias lead to the development of criteria that are important for the choice of method. Various methods exist that can facilitate the inspection decision process. Those methods can help to prioritize risks or can make estimates to find risks. However, because of the bias in risk assessment and the imbalance of inspection data, we searched for what methods can be used to get representativeness from inspections. Furthermore, these methods can not be applied blindly to the decision process, they need to be evaluated based on certain criteria. However, because of the abstract concepts included in the process, it is difficult to develop and assess these criteria. Although, practical criteria have been identified and the methods are assessed based on data requirements, and implementability and transparency criteria. Considerations about the concepts of risk and bias are applied as considerations for the inspection plan.

Implications for Inspection Plans

Finally, based on previous chapters, assessment criteria to judge and evaluate these methods to help the decision of selecting the tool to use are provided. Based on these criteria and the conceptualizations of risk and bias, it is concluded that there is no one method that can be the true method for all inspection strategies. There are various considerations to be done among which identification of the purpose, consideration of the assessment criteria for the methods and multi-actor perceptions of risk. Since a selection will always be there for inspections when there are time, resource, and monetary constraints, it is not possible to inspect everything that is happening in the food industry. Therefore, where there is selection an unbiased approach is nearly impossible however there are ways of mitigating bias as much as possible which can be done by going for combination methods to increase representativeness in order to reduce the bias of missing important information and the risk of discrimination. Furthermore, bias that comes from risk assessment process can be mitigated by considering the layers of bias.

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Lastly, I would like to thank all interviewees for their valuable contributions and insights for the development of this thesis. I would like to thank the interviewees from the inspection agencies for their time to answer our questions. Furthermore, I extend my thanks to the professors of TU Delft and Wageningen University & Research that we have consulted for inspiration in shaping this project.

Thank you.

Suzan Nur Ayaydın
Delft, August 2023

List of Abbreviations

ABM	Agent Based Modeling
AGES	Austrian Agency for Health and Food Safety
AHP	Analytical Hierarchy Process
BN	Bayesian Network
EU	European Union
FBO	Food Business Operator
ML	Machine Learning
NN	Neural Network
NVWA	Dutch Food and Consumer Product Safety Authority
STM	Scenario Tree Model

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1 Introduction

Do inspectorates want to plan their inspections completely randomly? Or do they want to catch the most violations with a risk-based approach? Risk-based inspections have recently gained popularity, especially after 2004 when an EU regulation required inspectorates to carry out a portion of their inspections based on appropriate risks. But then what about lower risks, are they completely ignored or is there a need for representative outcomes?

Food safety is regulated by laws and regulations. The adherence to these laws and regulations is supervised by means of inspections in order to ensure consumer rights. Even though the goal of producers and vendors is to serve their customers well, it might happen that violations of regulations occur. These could be involuntary due to a lack of information about regulations or mistakes such as health hazards that are overlooked. However, voluntary violations take place as well, as some companies might try to gain profit by ignoring the regulations. Either way, the consumer needs reassurance that products are safe to consume. This is where regulatory inspections come in. These inspections are done by inspection authorities to ensure the safety of consumers. One of these authorities in the Netherlands is the Dutch Food and Consumer Product Safety Authority (NVWA) which is responsible to ensure the safety of food products and non-food products for consumers.

It is nearly impossible to inspect every organization because of constraints such as time, cost, and resources. This is why most of the time a selection needs to be done on which places will be inspected. This selection was traditionally done randomly but since around 20 years inspection plans have started to gain a risk-based approach. Selection in risk-based inspections is based on information about risks, such as previous inspection results, or intrinsic factors such as the size of the organization. Adopting a risk-based approach is motivated by an increase in efficiency, referring to the capacity to identify a higher frequency of violations. However, the focus is limited by known risks. The emphasis on higher risks entails the neglect of certain areas, therefore, risk-based inspections can be prone to bias because the obtained results will only reflect the high-risk areas. Random inspections, in theory, do not carry this bias and might be useful in exposing blind spots of the inspection process however, they disregard risk altogether. An ideal situation would be to keep the efficiency gain from risk-based inspections and get representative results. Therefore, it might be useful to find a combination of the two. Of course, a combination might not be applicable to all situations and there might be certain situations where complete random or complete risk-based approaches are preferred. In order to comprehend this, the reasons for performing risk-based and random inspections need to be understood.

Risk-based inspections include a concept of risk that is quite difficult to define by itself. It is important to understand what risk stands for within this frame and how risk-based approaches regard risk. Risk considerations and perceptions can differ per situation or even per person. Therefore it is necessary to get an understanding of risk as there is no one definition or perception of what is considered as risk. Another challenge when it comes to risk-based approaches is the assumption that risk-based approaches and especially risk assessment are prone to bias. Focusing on certain risks while ignoring others can lead to biased conclusions. Furthermore, using the results from a risk-based inspection process for the next round of inspections has the risk of missing information. Hence, bias presents itself as a concept that is hard to define. Where does bias come from and how can it be prevented? These two concepts, risk, and bias, are concepts of equivocal nature and present themselves as the cornerstone of risk-based inspection strategies.

1.1 Research Problem and Research Question

Within the question of whether to choose risk-based or random approaches or if a combination of those is better, another question arises: How can one choose between those approaches? If the choice is a combination, how can the combination be decided on? Then if there are methods that can help the decision of this combination, how can these methods be assessed? The equivocal nature of risk and bias needs to be studied in order to address this difficulty. The research problem is that there is a need for an understanding of important considerations for inspection plans. The goal of this project is to explore assessment criteria for inspection strategies or methods by conceptualizing risk and bias. By analyzing different methods and the conceptualizations criteria that the NVWA and other inspecting agencies could use when making decisions regarding inspections can be built. This research is therefore inspired by the question asked by the NVWA and accordingly a research question can be defined as follows:

How can inspectorates adapt their inspection strategies to mitigate bias that results from risk-based inspections?

1.2 Research Question and Sub-questions

Research Question: *How can inspectorates adapt their inspection strategies to mitigate bias that results from risk-based inspections?*

To support the main research question, sub-questions are developed as followed.

RQ1: Why is there a need to combine risk-based and random inspections?

RQ2: How is risk perceived within food safety inspections?

RQ3: What kinds of biases are seen in risk-based inspections and what causes these biases?

RQ4: How can representativeness be improved with risk-based inspections?

RQ5: What are important considerations to develop inspection plans and assess inspection methods?

1.3 Academic Relevance

The thesis makes valuable contributions to both practical and academic domains. On the practical side, it addresses NVWA's question of identifying methods from the literature that combine risk-based and random inspections. The practical worry brought out by the NVWA is about their struggle to make decisions on when and how to do risk-based or random inspections. This also brings forward the question of what are the limitations of risk-based inspections. The initial idea for this thesis comes from the practical concern of the food inspection authority (NVWA), however, academic concerns allowed this problem to be investigated at the master thesis level. On the academic side, this thesis delves into the conception of risk and bias and explores criteria to assess the various methods to achieve an effective combination strategy. Various publications mention how risk-based approaches are efficient in performance, reduce costs of inspection and allow for better resource allocation. In several articles about risk-based inspections, the fact that only focusing on risk can lead to bias and that representativeness is necessary is mentioned as well. Few of those do propose combinations of risk-based with representative approaches. Furthermore, publications on conceptions of risk and bias are available, however, an investigation of these concepts is not adequately explored within food safety inspections. The aim of this thesis is to explore the knowledge gap on the complexity of risk-based inspections by conceptualizing risk, and examining the impact of bias in the context of decision-support methods to combine inspection strategies.

1.4 Thesis Outline

The structure of this thesis report is as follows: First, the research approach is presented after which the theoretical background of the problem is presented after which the objectives of doing inspections are investigated. This is followed by a conception of risk that investigates multi-actor perceptions of risk. Subsequently, the concept of bias is investigated in layers of bias that affect risk analysis along with ways to mitigate this bias. Furthermore, methods that are associated with inspections in the literature are explored which permits certain criteria to be developed to assess these methods as well. The investigation of the concepts of risk and bias leads to the considerations that are important for the development of the inspection plan. Finally, limitations, generalizations, and future implications are discussed after which the research questions are concluded.

2 Research Methodology

This chapter covers the methodology taken towards answering the main research question. First, the objective of the research as well as the research methods that are used to achieve the objective of this thesis are elaborated on. Furthermore, sub-questions are developed which are supportive of the process of answering the main question. The research methodology and design are presented as well.

2.1 Research Objective

An initial investigation of the literature on the topic of how to combine random and risk-based inspections yielded no sufficient examples of methods that can be used for this objective. It was realized that claiming a certain ratio to combine these two inspection strategies is not possible and that these strategies depend on a lot of variables. The exploration of how risk-based and representative inspections can be combined is aimed to be supported with an investigation of methods that support this decision. This research aims to develop an assessment framework for evaluating such methods. In order to evaluate these methods, assessment criteria are needed that measure the methods appropriately. Since the reason to combine random and risk-based approaches is to reduce the assumed bias of risk-based inspections, there is a need to understand what bias is in risk-based inspections. Furthermore, to understand this, what risk means needs to be investigated. Therefore, the goal of the research is to find out how risk and bias affect the choice of inspection strategies, by investigating random and risk-based inspections and how these can be combined in order to leverage their advantages.

2.2 Research Approach

The research uses a combination of research methods. First, a literature review is conducted in order to investigate the research questions, in order to discover what kind of research has been done on food safety regulatory inspections, and to reveal what needs to be further investigated. Because theory might not always reflect practice, the literature review is supported by expert interviews from inspectorates to discover how the concepts of risk and bias are seen in practice and what methods are currently being used in inspection strategies. The reason for using a mix of two research methods is to support and enrich the insights gained from both of these methods. As such the literature provides theoretical insights into the research problem and interviews are carried out to explore the practicalities of the inspection process.

Since risk and bias are abstract concepts an empirical study is not suitable, therefore the research is performed on a conceptual analysis base. The search for combining representative and risk-based approaches requires a better understanding of the concepts of risk and bias. These qualitative methods are used to develop the conceptual research of risk and bias, and these methods also permit the exploration of methods used for inspections.

2.3 Research Question and Sub-questions

In order to answer the research question, 5 sub-questions elaborating on different areas that the main question encompasses are defined.

Research Question: *How can criteria be defined for the search of methods that include risk and aim to mitigate bias?*

RQ1: Why is there a need to combine risk-based and random inspections?

In order to understand why there is a need to combine risk-based and random inspections, their limitations and advantages need to be explored. Publications in the literature are investigated to explore the areas where risk-based inspections are applied and the reasons for doing so. Furthermore, interviewees are also asked about their take on risk-based and random inspections and to see if they recognize any practical limitations or advantages the approaches provide. Moreover, the purposes of inspections are investigated to understand why inspections are done with the aim of better understanding the distinction between risk-based and random inspections.

RQ2: How is risk perceived within food safety inspections?

Risk is often described as something that includes danger. However, this can only be described by the affected stakeholders. It is important when doing risk-based inspections to evaluate what risks should be included and how these should be described. What kinds of risks are considered for risk-based inspections in food safety inspections? How are risks seen for different areas of inspection? This question aims to uncover what types of risk are taken into account in publications that develop inspection methods and what types of risk affect the inspection process in practice by addressing this topic in interviews.

RQ3: What kinds of biases are seen in risk-based inspections and what causes these biases?

When inspections are done risk-based, the results are also risk-based which can lead to a biased assessment of the overall situation of food safety. Furthermore, risk analysis is commonly said to be biased because of the human factor involved in risk assessment processes, which could cause the results obtained from risk-based inspections to be biased as well. It is necessary to understand what the reasons for this bias are and how to avoid or counteract it.

RQ4: How can representativeness be improved with risk-based inspections?

The ways to combine random and risk-based inspections are explored by investigating possible methods to do this combination. Besides the lack of representativeness, risk analyses are often mentioned with caution to bias. In order to investigate this publications about bias will be analyzed on how to mitigate bias. Furthermore, interviewees will be asked about their awareness of bias in risk-based inspections.

RQ5: What are important considerations to develop inspection plans and assess inspection methods?

Assessing methods is actually the difficult part of this research. The reason is that there are no universal common criteria. Methods can be used for different purposes and different areas and each one has different requirements. Therefore, this research will analyze what kind of characteristics are required from methods in food safety inspections and it is aimed to build assessment criteria. Furthermore, how this assessment fits in the inspection plan development will be investigated along with important considerations that should be taken into account when developing these inspection plans.

2.4 Research Approach

The research is constructed in two parts. First conceptions of the goals of inspection and deeper evaluation of the abstract concepts of risk and bias are performed. This part of the research consists of conceptualizing the learnings of the research methods. By combining theory from literature and practical information from interviews it is aimed to better understand relevant concepts of this research.

The second part of the research is an exploration of methods available for inspections. This part mainly consists of a literature review of existing methods. Furthermore, what methods are used in practice are explored through interviews. In order to build the assessment framework and make an analysis of methods to be used for a combination of risk-based and random inspections, a comprehensive understanding of risk and bias is needed. To summarize this approach, an overview is provided in Figure 1.

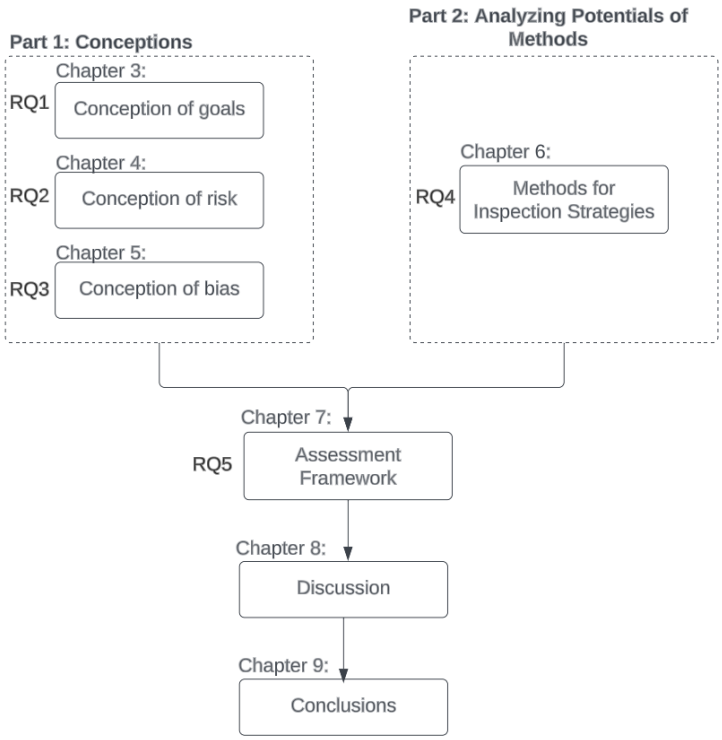

Figure 1: Research Desing

2.5 Research Methods

The conceptual research makes use of qualitative data which will be used in the conceptual analysis of risk and bias to develop the assessment framework. Most of the data is collected from publications about food safety inspections in the literature and these theoretical data are supported with interviews from practice.

2.5.1 Literature Review

This literature review is constructed in 3 parts. The first part consists of a to gain an understanding of food safety inspections, why inspections are done, what kind of strategies are taken when doing inspections, reasons why random or risk-based approaches are preferred, and under which conditions one is preferred over the other. The second part is about risk and bias. Here the goal was to find out what bias and risk mean, how risk-based approaches are applied, and their advantages and disadvantages which brings the question of bias of risk-based approaches. The third part is done to distinguish models that are available in this domain, what kind of methods there are to do prioritization, if there are any models that are capable of combining inspection strategies, what kind of models are capable of respecting the complexity of the concepts of risk and bias. The methodology of this literature review is as follows:

- Scientific publications were identified with the use of the databases Web of Science, Scopus, and Google Scholar. When relevant articles were found from the database search, a snowballing approach was also taken to analyze the references used. The focus of the search was on articles written in English.
- The search results were initially screened for title, keywords, and abstract. However, when the title already revealed that the paper was not relevant the abstract was skimmed in case it was relevant but most of the time they were not. Relevant and possibly relevant articles were selected and stored on a Mendeley database. Possibly relevant articles were further examined based on their introduction and conclusion, the ones that were concluded to be relevant were added to the Mendeley database. Relevant articles were then fully read and a categorization was made.
- Publications about methods were also added to an Excel sheet in order to note down the used method, the purpose, and if applicable a risk definition.

Keywords that have been used during the search process are as followed:

For the 1st part: "food safety", "inspection", "monitoring", "supervision", "regulatory supervision"

For the 2nd part: "risk", "risk-based inspections", "bias", "bias in risk assessment"

For the 3rd part: "food safety monitoring methods", "food safety monitoring models", "decision making", "risk random", "modeling decisions", "inspections", "risk", "food"

2.5.2 Interviews

In order to be able to say something about how inspection authorities can mitigate bias that comes from risk-based inspections, it is needed to gain an understanding of what the inspection strategies of inspectorates look like and what the limitations of the methods used are. For this reason, interviews are performed as a supplementary source of information added to the literature review.

The research project makes use of interviews as a method of gaining knowledge from the industry and from academic experts. In order to develop the conception of risk in the context of inspections the research makes use of interviews and qualitative data. The research project makes use of interviews as a method of gaining knowledge from the industry and from academic experts for different reasons.

Professional Expert Interviews

It is important to see the perspective of the industry which can be done by interviewing people closely related to inspections, especially in the food industry. The interviews with the NVWA and AGES (Austrian Agency for Health and Food Safety) will have an exploratory objective, as it is valuable to find out how risk is perceived in various sectors and what their current risk assessment looks like. These interviews will not be restricted to only the food industry but will also include experts from other industries such as education so that a broader view of how risk is perceived in different industries can be obtained.

Academical Expert Interviews

Academic experts are consulted to uncover the possible methods that can be used for this research project. Experts that are interviewed are professors from the TU Delft and the Research University of Wageningen. These consultations aim to get knowledge from experts on how to tackle the representativeness problem of risk-based inspections, and what kind of methods can be used.

2.5.3 Interview Plan

The professional expert interviews have been planned as semi-structured interviews. A set of questions is prepared, however, the interviews will not strictly depend on the set of questions and the direction of the interview will depend on the flow of the conversation. The reason for this is that this way while still pertaining to a guideline of questions, the freedom allows for open-ended data which reflects the interviewee's thoughts better. This is important because perceptions of risk are explored.

Interviewees that work in inspectorate authorities were asked what the main challenges of the selection and resource allocation process were, how they address bias in their current processes, and what risks they consider for risk-based inspections. The interview plan can be found in Appendix A. The results of the interviews are synthesized in Appendix C.

3 Background and Purposes of Inspections

Food safety is governed by laws and regulations to enforce safety standards on food products. Ensuring that food products adhere to those standards is important for consumer health. While organizations dealing with food products are required to comply with food safety laws and regulations, their mere existence does not necessarily guarantee compliance. Violations can happen for reasons such as cutting costs. Therefore, supervision of these laws and regulations is necessary.

This chapter presents key definitions of the background of the research problem. Terminology definitions are given on terms such as inspection, enforcement, and food safety. Furthermore, inspections within food safety are elaborated on to emphasize why food safety inspections are necessary. Random and risk-based inspections are elaborated on with an emphasis on why risk-based inspections have gained popularity and their limitations. Furthermore, in order to understand what inspection strategies need, the purposes of inspections are analyzed and a conception is presented as well. This supports the possibility of combining risk-based and random inspections.

3.1 Inspections & Enforcement

Inspection involves closely examining an object or an entity to evaluate its quality. Higher authorities conduct inspections to supervise organizations and ensure the quality of the products or services provided by these organizations. These inspections are performed by either the governmental agencies themselves or by other organizations that conduct the inspections for them (Blanc, 2012). Supervision, control, and monitoring are some of the other terms used for inspections. These inspections are mandatory controls issued by the regulatory state, to see whether or not organizations comply with the rules. These controls are done by visiting the inspectees, which are generally private organizations that carry out their business. Enforcement is another term used by inspectorates. This term, however, includes inspections as well as the actions done after an inspection (Blanc, 2012). For instance, when non-compliance is detected re-inspections might be needed or even further measures such as the closing of the business might be needed.

3.2 Food Safety

Food safety entails that food products should not cause any harm to their consumers. This is not only related to the end product but accounts for all stages of the production, processing, and distribution of food products (Boeck, Jacxsens, Bollaerts, & Vlerick, 2015). Food business operators (FBOs) are accountable for food safety by complying with food safety regulations and labeling laws (BEUC, 2019). EU regulations about food safety are known to be strict (Boeck et al., 2015). These regulations only work when they are executed, which is where controls and inspections come into play. The safety of products is important for the health of the consumer. Even though these laws exist, to make sure FBOs are in fact complying with the regulations under EU regulations, the EU Member States are required to perform controls on FBOs. Even though food handles are required to inspect the quality of their products, regulatory food safety checks are needed to ensure food safety and reassure consumers. Especially recent food scandals, such as selling meat products containing horse meat when the label indicated beef, have caused the importance of food safety to gain importance (BEUC, 2019).

FBOs carry the responsibility of providing safe products and causing no harm to their consumers. However, even though the importance of food safety has gained more and more importance in the last years, food hazards still happen. To supervise these companies and to ensure food safety regulations are complied with, inspection agencies or inspectorates are in place. Governmental inspectorates act as the bridge between regulatory bodies and companies (Jacobs & Cordova, 2005). These inspectorates carry out quality inspections. In the case of food safety, these are called food safety monitoring or surveillance. Food safety inspections that aim to ensure that companies such as food producers, retailers, and farms comply with the regulations and follow the procedures accurately by examining food products for safety hazards is called food safety monitoring (X. Wang, Bouzembrak, Lansink, & van der Fels-Klerx, 2022).

The NVWA is responsible for the safety of consumers of food and non-food products in the Netherlands. To address this responsibility, the NVWA conducts inspections on various food and non-food products, production facilities, and venues that sell these products such as supermarkets and restaurants, which are called FBOs (NVWA, 2023). The NVWA operates in many different areas that concern consumer health. The main areas are food safety and product safety where the NVWA strives to ensure the safety of consumer products by making sure that producers, importers, traders, and sellers comply with safety regulations. NVWA further works on

tobacco and alcohol discouragement by ensuring that sellers comply with regulations regarding age restrictions and advertisements of these products. Additionally, NVWA is responsible for inspecting plant health, animal welfare, nature and environment, and animal health to ensure that animals are treated in good conditions, control plant, and animal disease outbreaks, and preserve nature and the environment (NVWA, 2023).

As can be seen, food safety entails the responsibility of inspecting a large variety of food products. Each of these food products has different complexities such as containing different products, different storage requirements, different perishability, possibilities of bacteria or diseases, and different consumption rates. Along with various hazards that can be present in each of the products ranging from microbiological, chemical, and physical hazards. All these aspects add up to make up a highly complex food safety issue.

3.3 Inspection Plan and Strategies

According to discussions with the NVWA, mainly 2 types of supervision are performed: “inspections” where the authority supervises an organization, and “sampling” where the authority inspects the products of an organization. These two terms are intertwined which is why the term inspections in this thesis refers to both terms.

Conducting inspections is not an easy task, in fact, there are many factors and constraints to take into account. Firstly, there are certain constraints that prevent inspectorates to visit all FBOs such as time and monetary resources. Because of these constraints, a selection has to be done, and the decision of which inspectees to visit becomes important (Guzmán, Riffo, Telha, & Vyve, 2022). The decisions on what will be inspected and how the inspections will be done are defined in a food safety monitoring plan (X. Wang et al., 2022), this includes which risks, and which products will be screened and sampled. This can be referred to as the inspection plan and encompasses the process of selecting which sector to inspect and the selection of FBOs to visit.

Inspectorates develop their inspection plans based on their purposes and constraints. The inspection plan encompasses the selection of the purpose and the selection of inspection strategies and this can differ per sector even per food product or per the investigated hazard. Inspection strategies are related to the decision of a random, risk-based, or combination approach and different strategies of how this combination can be taken are explored by Heerkens (2023forthcoming). This selection can be done randomly, however, there are also risk-based approaches where the selection is focused on higher risks in an attempt to increase inspection efficiency.

3.3.1 Random Inspections

Inspections are called random when there is no selection procedure or targeting involved. The term "random inspection" is also related to the inspections being performed unannounced, but in this research, the term refers to the random selection of FBOs to be visited. The selection is done randomly for instance when there is no information about the industry to be inspected (Blickenstorfer et al., 2011). The objective of doing random inspections is to get a representative picture of the industry. Some studies show that random selection or random sampling can be assumed to deliver non-biased results (Blickenstorfer et al., 2011), which therefore can provide a transparent overview of the unit of analysis. However, for the results to be unbiased the sample needs to be completely random (Blickenstorfer et al., 2011). Sometimes this is not the case when selection is made by convenience. For instance, when some places are inspected based on their proximity, the obtained results will not represent the whole population. However, random sampling does not take into account the uneven distribution of disease risk (Blickenstorfer et al., 2011). Moreover, in terms of animal-derived food inspections, Presi et al. (2008) mentions that inspecting randomly can result in few detections of unwanted residues and is resource-consuming relative to its results.

These reasons and a requirement from EU regulations led to an increase in the use of risk-based inspections.

3.3.2 Risk-based Inspections

As previously stated, constant supervision and inspection of all companies is not possible. Therefore, inspectorates aim to allocate resources as efficiently as possible. Risk-based inspections are a way to achieve this. A way to do this allocation is by targeting higher risks. In publications where risk-based inspections are investigated, efficiency relates to reducing health hazards and catching infringements (Cameron, 2012; Cannon, 2009; Presi et al., 2008). The reason for doing risk-based inspections is to get the highest possible benefit-to-cost ratio in terms of catching as many infringements as possible with the least cost (Presi et al., 2008). A study on animals in Switzerland shows that risk-based sampling is more efficient than random sampling (Presi et al.,

2008). According to Farrell, Gebre, Hudspeth, and Sellgren (2013) risk-based approaches are useful to make the best out of scarce resources such as time and money. Risk-based approaches also help to reduce the waste of resources by inspecting where inspecting is not needed. This is the case when the goal of inspecting is to catch unwanted situations as much as possible to avoid hazards. Therefore, it is claimed that risk-based approaches increase efficiency and improve the allocation of resources. Furthermore, in terms of food regulations, the 2004 Food Hygiene Package requires EU Member States to use a risk-based approach in the prioritization of inspections (Borraz et al., 2022). Therefore, besides efficiency reasons, the requirement by a higher authority is the main reason why risk-based approaches have gained importance.

Doing risk-based inspections requires risk analysis to be done. This can be based on the riskiness of the organizations themselves or based on the possible hazards that can occur with the product. Cannon (2009) discusses some requirements that are needed to do risk-based inspections which are
- Differences in the level of risk
- Detection of risk
- Knowledge of risk factors
- Categorisation based on risk(profiling)
- Possibility to inspect

It can be seen that in order to do risk-based inspections, information about risks and how these can be detected are necessary. All the interviewees that were asked what the reason for doing risk-based inspections was mainly responded as a requirement from the EU regulations. Therefore, this requirement seems to be the main motivation although, efficiency became an important factor as well. According to these interviews, risk-based inspections are based on data from previous years such as whether or not the organization was compliant last year, or if a violation had been found.

Cameron (2012) also states that the reason why risk-based sampling is more efficient is that *"one is more likely to find something if one looks where it is most likely to be"*. However, if one only searches for things one expects to find, unknown areas will be left even more unknown and a generalistic view of the industry will be lost. Furthermore, determining where inspecting is not needed is easier said than done.

Although some interviewees found it highly reasonable to inspect what has resulted in efficient results, some mentioned that taking a completely risk-based approach ignores what happens at the organizations that are not being inspected. Furthermore, while obtaining results with a high number of violations means that those violations are caught. At the same time, this makes it look like there is a high percentage of violations within the industry and can cause safety concerns (Interviewee #7) whereas these violations might be a small percentage of the whole population. Therefore, this means that focusing on risk-based prioritisations defies the objective of obtaining a representative picture.

To sum up, risk-based inspections have advantages compared to random regarding efficiency and better allocation of resources but lack representativeness which can lead to biased inferences.

3.4 Reasons to Combine Risk-based and Random Inspections

The mission of inspection authorities is to make sure consumers are receiving safe products. Considering food safety, it is important that consumers know how safe the food products are. As mentioned many times, it is very costly and time-consuming to inspect all food-related organizations and all food products. Therefore, it is crucial to be able to get a good picture of what the industry looks like. By saying a good picture, it is meant to have a general overview of the industry. This is done by getting samples that represent the whole population by representative inspections. Risk-based inspections are done so that as many violations as possible can be caught. However, these miss the target of looking at the whole picture. First of all, only doing risk-based inspections mean that places that are considered not risky are overlooked. Based on the differences in these two methods and the search of the NVWA to get representativeness while also keeping risk-based inspections, a need for a combination or a mix of these two comes forward. How this combination can be done is another tricky question. Although there is not much published about methods to combine risk-based and random inspections, Martin, Cameron, and Greiner (2007) realizes that there is a necessity to combine random and non-random approaches both approaches have their advantages and disadvantages. Furthermore, Blickenstorfer et al. (2011) recognize the value of representativeness gained with randomizing samples and the increased information gain with targeted sampling and therefore propose a combination of the two methods to make use of the advantages of both strategies.

There are many reasons why risk-based inspections are preferred, especially in terms of increasing the number

of infringements caught. Then what is representativeness and why is it important? According to Martin et al. (2007) a perfectly representative surveillance system does not involve any sort of targeting. The authors claim that approaches that are less representative do not cover the population and may lead to biased results. Therefore, it is important to take representativeness into account in the design of the inspection plan. During a symposium with the NVWA, the reasons why they aim for representativeness were presented. First of all, without a representative picture of the market, sector, or industry, it is difficult to distinguish trends in the obtained results. Holistic inferences are not possible without representativeness. Even for risk-based approaches, it is needed to know what is being searched for, and getting a general view of the industry helps with understanding the risks that appear. Another important reason to get an overview is to see whether or not the inspections have an impact on the outcome, for instance, do violations decrease thanks to inspections or do they stay at the same level? Furthermore, the NVWA mentions that in terms of the selected places to visit, making sure of representativeness can have a preventive effect as well. Knowing that they could be inspected might lead the FBOs to be more reluctant to violate regulations. Another advantage of representativeness is the ability to compare systems and results with different countries (Interviewee #7). If the obtained results come from high-risk areas then comparisons have no meaning because of the lack of representation of the whole country.

3.5 Purposes of Inspecting

Now that random and risk-based inspections are investigated, it is also worth exploring what actually are the reasons for inspecting in general and what are the reasons for the distinction between random and risk-based inspections. Why are inspections performed? What are the drivers behind the decision of inspection strategies? Within the distinction between random and risk-based inspections, there is a very recognizable difference in gaining representativeness versus catching high-risk violations. What if the purpose is to catch violations while also aiming for representativeness? How does the purpose of inspections relate to the inspection strategy?

Food safety authorities have several purposes to perform inspections on FBOs or companies. The main objective is to ensure public welfare by making sure food products are safe to consume and ensuring truthful communication with consumers. This main objective is supported by sub-goals. One of these goals is to make sure regulations are adhered to and thereby catch violations through regulatory control. Even if inspections are not frequent, their existence alone is a driver for organizations to follow regulations (Blanc, 2012). By doing so authorities aim to ensure the quality of the products or services provided by these organizations (Guzmán et al., 2022). Another reason why governments inspect besides catching violations is to get an understanding of the overall view of a market or sector. Getting an overall picture is about seeing for instance which food products are consumed most, which safety issues arise in which areas or which products, and so on. This means that by doing inspections the authority can understand what trends there are in consumption or how safe a certain industry is. A broader objective is that inspections are a means to introduce or incentivize higher values such as public welfare, animal welfare or sustainability. For instance, by performing the inspections on animal welfare, the importance of this is communicated as well, public welfare however is the main value that encompasses these purposes. Moreover, inspections are also a motivation factor for FBOs to comply with regulations. To sum up, 4 reasons can be distinguished:

- **Imposing Higher Values:** Showing the importance of public values.
- **Encouraging Compliance:** Giving the message that non-compliance can be discovered and fined.
- **Mapping:** Obtaining an overview of a market, sector, or the food industry.
- **Catching Violations:** The detection of non-compliance with regulations.

These objectives are not independent from one another, in fact, they are closely associated with and even depend on each other. A hierarchy and the relation between these objectives can be identified. First of all, catching violations depends on certain conditions such as the availability of information on these violations. In order to catch infringements there is a need to know where the infringements are, what kind of infringements happen, or to know how safe/unsafe a sector is which can be achieved with a clear overview of the sector. Thereby mapping sectors both helps authorities to be aware of what is happening in the sector and also helps to find where to look in order to detect violations. Mapping is a broader purpose than catching violations. These two purposes together serve the purposes of stimulating compliance, which ultimately serves the imposing of higher values. The highest objective here is the aim to impose values that improve people's lives and the ability to live in a society.

Such values are important to stimulate well-being as a society and a way to achieve this is by encouraging

compliance. By motivating companies to comply with regulations, the incentive and understanding of these values are imposed. Furthermore, fines that can be given as a result of an inspection also encourage compliance. Hereby the hierarchical relation amongst these objectives is illustrated in Figure 2.

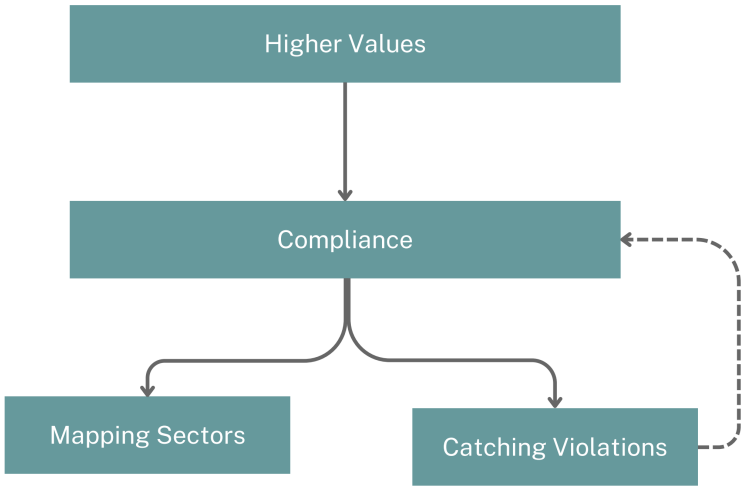

Figure 2: Purpose Hierarchy

What this conceptualization of purposes shows is that inspectorates need to keep in mind what the higher objectives of inspecting are especially while developing the inspection strategy this needs to be taken into account. More specifically, during the development of inspection strategies, the objectives must be clearly defined. As interviewee #7 mentioned, the most challenging part of the allocation process is to define the objective and to come up with a concrete formulation of the goal. The inspection strategy will depend on whether the goal is to find something that is being looked for or if it is just to get samples (Interview #7). Hereby, it can be understood that if the goal is finding something the strategy is risk-based, and if the goal is getting an overview the strategy aims for representative results. Especially the lower 2 goals seem to be more distinctive from each other. To get an overview of the sector it is important to get a representative picture to be able to understand what is happening in the sector altogether. However, to catch violations efficiency is important, in the sense of catching as many violations as possible, whereby it is more practical to look where the risks are higher. Although, when focusing on high risks, the results will lack representativeness. The relation between these two traits seems like a trade-off, however, these goals together serve the broader purposes, hereby this hierarchy of purposes shows that these purposes can work together and feed each other. Therefore, there is a need for an inspection strategy that serves these purposes together. In order to serve these purposes, the inspection strategy should respect the traits that relate to these purposes. These 4 purposes are broad ones and although they highly relate to the food safety inspections, specific purposes need to be defined per inspection plan/strategy. Thereby, the method to help the decision needs to be flexible to respect the differing purposes. And this also relates to being the first step of developing inspection strategies.

3.6 Conclusions

The purposes of inspections affect the decisions of the inspection strategy. However, the higher purposes need to be kept in mind by inspectorates at all times. The inspection plan also requires more specific objectives such as proving freedom from a disease or inspecting compliance with antibiotic regulations for animal products. These are not included in this thesis as the research has a generalistic view of food safety inspections.

If the purpose is to map a sector, a random approach will be taken and if the purpose is to catch an unwanted event the approach will be risk-based. However, as inspectorates are also searching for combination methods mapping and catching violation purposes can also be taken together.

4 The Concept of Risk

"Risk is a way of representing events so they might be made governable in particular ways, with particular techniques, and for particular goals" (Dean, 1998).

As can be seen from this quotation, risk is a manner of perceiving certain events, and what risk is, depends on what it is associated with. Since how things are perceived can change from one person to the other, the definition of risk can depend on certain situations and perceptions as well. Something that is seen as risky in one situation might not be risky in the other.

It may be assumed that the variation in the definition of risk do not impact inspections, however, Helsloot, Scholtens, and Haen (2020) shows otherwise. In their article about the implementation of risk-based inspections, the authors examine the evolution of such inspections and investigate their application in two inspectorates in the Netherlands. Upon this investigation, the authors explore reasons why risk-based approaches have not been successful in the Netherlands. The main reason identified is the difficulty in reaching a consensus on what risk means. This has been a topic of several publications for many years and yet there is no agreement on a universal definition of risk. This thesis does not claim to solve this problem, nor to provide a universal definition. Rather, the objective of this chapter is to present a conception for understanding risk in the context of food safety inspections, which can serve as a foundation to formulate effective inspection strategies.

This chapter develops a conception of risk by analyzing publications about food safety and risk-based inspection methods on how risk is perceived. Furthermore, a typology is developed in order to shed light on what types of risk are seen and to see what kinds of risk affect the decisions on the allocation of resources for inspections.

4.1 Complexity of Risk

What Helsloot et al. (2020) points out by saying that there is no consensus on a definition of risk, is because risk is a complex concept. A multitude of factors need to be taken into account to address risk. Stern and Fineberg (1996) also agrees that risk is complex that is important to analyze in order to prevent possible hazards. This complexity, according to Stern and Fineberg (1996) comes mainly from the shortage of analysis tools, uncertainty, and misconception of risk. Since the time this book was written, many risk-analysis tools have been developed, therefore this research does not focus on this part. However, uncertainty and misconception are still important to the complexity of risk. Risk includes uncertainty, and the misconception is also related to the variance of defining and describing risk in different domains.

Inspections are a means to impose regulations. Haines (2017) explains how there are three types of risks that affect regulation which are actuarial, socio-cultural, and political risks. Actuarial risks are ones that comply with the scientific definition of the probability of an unwanted event causing a harmful impact. Haines (2017) explains that this type of risk does not reflect the political and social impacts that can affect regulation sufficiently. Stern and Fineberg (1996) mention that seeing risk characterization as a synopsis of a technical analysis to take a decision is misleading and may fail. According to the authors, risk characterization requires complex judgment which can be identified by analyzing all stakeholders of the process such as experts as well as the people affected by the risk. Therefore, it is valuable to understand the complexity of risk and conceptualize it in the context of inspections in order to gain an understanding of how this affects the inspection plan.

4.2 Risk within Food Safety

The OECD definition of Food Safety is *"a reasonable certainty that no harm will result from intended uses under the anticipated conditions of consumption"* Barlow et al. (2015). By the term "reasonable certainty" it can be said that 100% safety is not feasible and there will always be accepted risks. However, the goal of risk-based approaches is to minimize these risks as much as possible in order to reach this reasonable certainty. How the acceptance level of risks is seen, depends on the context and interested parties (Barlow et al., 2015).

Food products may become contaminated with various types of safety hazards, including biological hazards (e.g., bacteria, viruses, and para-sites), chemical hazards (e.g., heavy metals, pesticides, and mycotoxins), or physical hazards (e.g., metal fragments and pieces of glass) X. Wang et al. (2022). The presence of these hazards has the potential to impact the safety of products, potentially leading to adverse consequences for both human and animal well-being. To illustrate the variety of risks in food safety a summary of risks that are considered in the literature review about the methods can be found in Table 1. As can be seen from the variety of considered risks it is difficult to reach a one true definition or consideration of risk.

Table 1: Risks from various publications

Source	Considered Risks
(Al Qubaisi et al., 2016)	Residues of antimicrobials
(Blickenstorfer et al., 2011)	Occurrence of diseases in animals
(Chermiti, 2019)	Non-compliant import declarations
(Boeck et al., 2015)	Low food safety culture/climate
(Geng, Zhao, Tao, & Han, 2017)	Pesticides
(Greda, 2009)	Risk of heavy metal pollution, Risk of chemical contaminant pollution, Risk of pathogenic bacteria pollution
(Pielaat, Chardon, Wijnands, & Evers, 2018)	Diseases
(van Asselt, Osinga, & Bremmers, 2016)	Microbiological public health risk associated with retail food products
(Van Asselt, Hoffmans, Van Den Hil, & Van Der Fels-Klerx, 2021)	Compliance behavior
(Van Der Fels-Klerx et al., 2018)	Risks related to the safety of food products, identification of hazards and food groups
(X. Wang et al., 2022)	biological, chemical and physical hazards
(X. Wang, Bouzembrak, Oude Lansink, & van der Fels-Klerx, 2023)	Food safety hazards: hazards that cause food to be dangerous for consumer health

In food safety, some risks that are analyzed are; presence of diseases (Blickenstorfer et al., 2011; Marchi & Page, 2014; Martin et al., 2007), presence of antimicrobial residues (Alban, Rugbjerg, Petersen, & Nielsen, 2016), heavy metal, chemical or bacteria pollution (Geng et al., 2017), public health risk (Pielaat et al., 2018; X. Wang et al., 2022) and compliance behavior (Van Asselt et al., 2021). X. Wang et al. (2022) identifies 3 types of hazards for food safety which are biological, chemical and physical hazards. Presences of bacteria, viruses or parasites are considered biological hazards, pesticides or heavy metals are considered chemical hazards and the presence of physical things in food products such as glass are considered physical hazards.

4.3 Identification of Definitions and Perceptions of Risk

The reviewed articles that contained a definition of risk are summarized in Table 2. As can be seen, those publications relate to the actuarial risk and define risk as a function of the likelihood of a hazard in food products and the severity of the consequences of this hazard on health (Van Asselt et al., 2021; van Asselt, Sterrenburg, Noordam, & Fels-Klerx, 2012; Van Der Fels-Klerx et al., 2018). Similarly, in plant risk management, risk is seen as the likelihood of component failure and the impact this may cause (De Carlo, Borgia, & Tucci, 2011). Theoretically, this measurement is the most common way to express risk. However, this may not always be so feasible and simple to calculate in practice. It can be especially difficult to quantify impact or predict probabilities when these are unknown, and require many assumptions. In the context of food safety van Asselt et al. (2012) define risk as the combination of the likelihood that food products are contaminated, consumption rates, and the health effects of the event. In many cases, risk is defined as the product of likelihood and consequence or:

$$Risk = Probability*Impact$$

or more formally:

$$R = \sum \left(P_{f_i} \cdot C_i \right)$$

where P is the probability of failure and C is the consequence of the failure Bai and Jin (2016).

As Haines (2017) explains, this is a way to express actuarial risks. This expression seems straightforward, but

is complex as well because the estimation of probabilities is based on assumptions and because quantifying the consequences is difficult as well. However, with the use of historical data about events and valuing consequences, this is the most common way of expressing risk. Even this definition can be interpreted differently in different contexts. These differences in defining risk are seen in risk-based inspection plans too. According to Cameron (2012) risk, depends on the objective of inspecting. For instance, if the objective is proving freedom from disease, Cameron (2012) defines risk is the probability that a population is infected, however, when the purpose is to detect a disease before it is spread, the authors say that risk is that the population might get infected. This means that what is considered a risk depends on the perception of risk. Therefore, it is crucial to define what the objectives are according to which the risks and risk factors can be determined. The reason why Cameron (2012) claims that risk-based sampling should be based on likelihood only, in the case of proving disease freedom is because they claim that the best way to find something is to look where it is most likely to be found. Since disease freedom needs to be proved, any disease wants to be caught or prevented regardless of the impact. On the other hand, Farrell et al. (2013) claims that it is important to measure both the probability and consequence of events and use the product to estimate an expected value of risk.

Table 2: Risk Definitions from various publications

Source	**Risk Definition**
(Boeck, Jacxsens, Vanoverberghe, & Vlerick, 2019)	*"Risk of a component is a combination of the probability of failure with the implication of its consequences"*
(De Carlo et al., 2011)	Risk score on the basis of information regarding the supplier guarantees, country of origin, commodity processing and vulnerability to cross-contamination
(van Asselt et al., 2012)	Function of the likelihood of a health effect and its severity which is caused by the presence of a hazard in a food product
(Van Der Fels-Klerx et al., 2018)	*The General Food Law (Regulation EC/178/2002, art. 3.9) defines risk as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard"*
(L. Wang, 2018)	The analysis and prioritization of the combined probability of food contamination, consumer exposure and the size of the anticipated public health impact of specific chemical, microbiological and/or nutritional hazards related to food.

The perception of risk can even change among inspectorates of different countries of the EU even though they are all bound to the EU regulations. Borraz et al. (2022) explore why risk is perceived in different ways in 4 different countries namely, Netherlands, France, UK, and Germany. Those different countries yet in some ways are similar because they fall under EU Member States and are bound to EU regulations. As EU regulations require inspections to have a risk-based aspect, how the prioritization should be done is not explicitly stated. The authors first present 6 hypotheses from the literature and further analyze the 4 countries in order to compare them to test the hypotheses. Even with the EU-based requirement of a risk-based approach to food inspections, it is seen that there is no explicit guideline on how this should be done. Borraz et al. (2022) bring forward that even 4 similar countries assess and calculate risk in different and even opposing ways. This further supports the complexity of risk, differences in perception and the importance of a conception in this context.

Interviews also show differences in perception of risk across various domains and the involvedness in the inspection process in practice. According to Interviewee #1, inspectors see risk as whether or not the law is complied with, whereas risk assessors see it as a function of probability and impact, regardless of whether or not it is stated in the law. Furthermore, Interviewee #2 defines risk as "a situation or event when something of human value, including humans themselves has been put at stake and where the outcome is uncertain." Here the main stakeholder is people as the risk is considered as having an effect on people. However, the department of animal welfare will focus on risks regarding the well-being of animals. An example here is that pain medication admitted to animals is not a risk for human health, but is important for animal welfare. Although

the use of antibiotics on animals can lead to resistance in the consumer and is considered a risk for humans as well (Interviewee #3). In the area of freedom from disease risk is a measure of the probability of a disease or (Interviewee #5). However, Interviewee #4 and Interviewee #8 see risk with a higher focus on consequences. Furthermore, Interviewee #6 and Interviewee #7 regard risk based on non-compliance of the FBOs.

Table 3: Interview Results about Risk

Interviewee Number	Risk Measuring / Risk Model	Risk Perception
1	Probability of occurrence within animals * impact on animal welfare	risk in enforcement: is the law complied with? risk in the risk assessment department: broader (as opportunity and effect) regardless of whether or not it is stated in the law. Whether factors will affect animals well-being
2	-	Risk is a situation or event when something of human value, including human themselves has been put at stake and where the outcome is uncertain.
3	Decision based on the occurrence of substance in the in the past if it is found a lot it should be high. They have no system for it	There are differences in the definition of risk, pain medication is not a concern for the food safety of humans but for animal welfare, it is
4	Not only probabilities or consequences but whether a factor is an indicator of many other factors is important	Consequence based Cost of illness, disease burden
5	Risk factor identification by expert opinions or common sense. Regression model of risk factors and probabilities (in one particular project) Risk factors are included in sampling probability allocated per farm (e.g. High risk, higher probability of being selected)	Prioritization is probability-based and not regarding consequence except for zoonotic diseases(if humans can contract them)
6	Risk categorization adapted from a South Australian model	Non-compliance
7	A risk ranking of the risk strata of the categories is discussed by experts.	Non compliance
8	Risk assessment based on legislation and experts	Consequence based

4.4 Typology of Risk

Haines (2017) conceptualized risk in 3 parts. The first one is actuarial risk. This consists of risks that are seen as harmful to people, animals, or the environment. These risks can be operationalized into a function that consists of the possibility of the event occurring and its consequences. Calculating or estimating these risks has a scientific basis, even though most of the time the values of the impact and the probabilities might be done with assumptions. Haines (2017) argues that actuarial risks are less effective in the development of regulations. This also relates most common way of assessing risk is the more scientific way of breaking it down to a function of likelihood and impact. This was also seen in Table 2 where the risk definition in publications on risk-based inspections was identified. However, risk that affects the inspection process does not only consist of the risks mentioned in the previous section. As Haines (2017) also mentions socio-cultural and political risks are not very well represented in this manner. Sociocultural risks are the ones that affect social and collective well-being. Furthermore, since regulations are closely related to politics, the third risk is political risk which refers to risk that affects the legitimacy of the political system (Haines, 2017).

Along with the conception provided by Haines (2017) for risk within regulations, in the food safety field, there are also various factors that affect risk and therefore also different types of risk exist.

Health Risk: One of the first risks that comes to mind is health risk. It is crucial that food products don't cause any health-related harm to their consumers. Therefore, cautious considerations are done while assessing

the safety of food products. Health risk includes many factors in itself. Some hazards that may cause negative health effects in food products can be biological hazards such as pathogens or bacteria that cause disease, chemical hazards such as pesticides even physical hazards such as foreign objects in food products (X. Wang et al., 2022).

Misinformation Risk: Furthermore, besides the unwanted health hazards that can be found in food products, also miscommunication with the consumer is a risk. Whether it can be a wrong list of ingredients of the product that can lead to allergic reactions, hiding what is actually inside the product such as the fraudulent incident of selling horse meat as beef or promoting products in a way that misleads the consumer to thinking, for instance, promoting health benefits when it is not true is giving misinformation and misleading the consumer.

Compliance Risk: Within food safety, and animal health issues there are certain regulations organizations need to adhere to. Compliance risk refers to the risk that organizations act in a manner that violates those regulations. (van Asselt et al., 2016) These violations could be avoiding hygiene regulations, or administering certain drugs or hormones to animals.

Political Risk: Political risk refers to the fact that inspectorates might need to change their inspection plan because of a change in regulation or request from higher authorities which will get a high priority.

Societal Risk: It is also possible to discuss societal risk which reflects the fact that some events might take priority as they may cause political concerns within society. Such an event may be unfair treatment to animals being seen. In such a case, when the inspection authority is notified, these events might take priority over other events.

Risk of Discrimination: If inspectors often visit the same companies, this can cause worry of unfairness for the companies. Especially with risk-based inspection, it is the case that high risks are focused on rather than low risks (Black & Baldwin, 2012) and this may cause concern of discrimination and representativeness.

These 6 types are identified in general terms as the risks that have an impact on the development of inspection plans. As well as the 3 way conception of Haines (2017) explains the connection between risk and regulation, here a typology is presented of these 5 risks which are categorized as actuarial and perceptual risks. Actuarial risks are the ones that are included in the risk-based selection and are more visible, and perceptual risks are perceived risks for the inspection agency and are less visible and difficult to predict. Perceptual risks affect the inspection strategy besides the analysis of the companies. Inspectorates do not want to be seen as discriminating, therefore, they want to avoid the risk of visiting the same place too often. Furthermore, external requests that need to be taken into account with high priority refer to the political risks.

Furthermore, some risks affect the process of inspecting or the inspection process whereas others can cause impacts. Process-oriented risks refer to the risk happening during the process of handling food products or inspections and impact-oriented ones come forward after the process.

Hereby a typology is possible and presented in Figure 3.

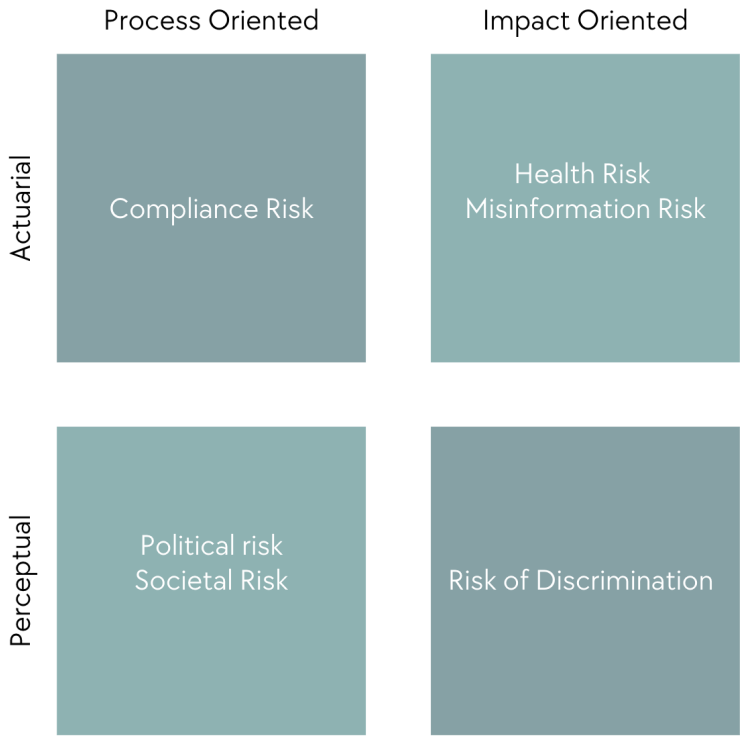

Figure 3: Typology of Risk

To elaborate on the typology, there are 4 classes of risk which are:

- Process-oriented actuarial risks: The risk of compliance is related to the inspectees complying with regulations during their production, processing, or handling processes.
- Impact-oriented actuarial risks: The risk of health hazards and miscommunicating the information of the product is related to the impact that is caused by these risks. These risks are more visible than perceptual risks since probability estimates can be done based on historical data.
- Process-oriented perceptual risks: Political and societal risks affect the inspection process and most of the time are not foreseeable.
- Impact-oriented perceptual risks: Risk of discrimination of the selection the FBOs to visit can lead to fairness concerns after visits to the same place happen.

4.5 Multi-Actor Perceptions of Risk

Inspections are a tool that involves a multi-actor setting. Therefore, these actors have different understandings of risk as well. The perception of risk not only changes in the way risk is assessed by inspectorates, but the inspection authorities also need to take into account what risks affect other parties.

Firstly, the inspectorates are the organizations that conduct the inspections. These actors have a certain budget and sometimes instructions from the government to perform the inspections. Firstly, because inspectorates need to select where to do the inspections they have a risk of discrimination. Moreover, besides these risks, the inspectorate is also subject to certain risks. While performing inspections the inspectorate should behave and select in a fair way. Visiting the same companies can cause bias and can be seen as unfair from the company's perspective. They also check if regulations are complied with. Therefore, they are affected by political risk. Furthermore, the inspectorate aims to ascertain of food safety on a large scale and missing important outbreaks, besides safety implications can result in political and societal pressure. Moreover, since the inspectorate operates on a certain budget, the goal is to avoid wrong or unnecessary inspections as much as possible that could end up with violations to go uncaught. Interviewee #1 further mentioned that a risk for the inspectorate is that events that are notified to the inspectorate can happen such as someone seeing animals treated badly. Inspectorates want to avoid this as much as possible since this impacts the credibility of the inspection authority.

The second actor is defined as the inspectees, which in food safety are FBOs that are subject to inspections by the inspectorate. Those actors have a risk of violating the regulations and risk getting caught. Moreover, violating the regulations also affects their risk of losing their reputation. From the inspected company's perspective, they can be intentionally or unintentionally non-compliant with regulations (Van Asselt et al., 2021). The authors discuss that food safety is affected by the behavior of the organization as well as the safety of the products itself depending on compliance behavior. They further identify some aspects that affect non-compliance behavior which are food safety culture and climate.

Finally, the main reason for doing inspections is the public welfare, which, brings out the last actor which is the people. Health risk, and misinformation risk are the ones that this actor gets affected by. The most recognized risk within food safety is health hazards against consumers. In terms of consumers, there is also a risk of misinformation especially when it comes to the packaging of products. An example is, if a product is claimed to be high in fiber but in reality, the product does not contain a high rate of fibers, this is misleading the consumer (NVWA, 2023). This risk can also overlap with health risks in the sense that important allergen information is missing from the label. This causes misinformation to the consumer and on top of that can be threatening to the safety of allergic people. Furthermore, inspectorates also take into account the well-being of animals especially because of animal cruelty concerns within society. The risks are whether or not animals are kept in a safe environment and treated in a good way.

From all the variety of definitions and perceptions of risk and the multi-actor component, it can be concluded that risk can not be defined in a universal way. When working with risk, the actors need to be identified and a definition needs to be developed accordingly with careful considerations.

4.6 Conclusions

Food safety monitoring is a complex job because of the diverse industries and products that are inspected. Risk-based approaches require different types of risk to be accounted for which makes them even more complex. This conception of risk is built to represent the complexity behind the concept of risk and shows that risk is a multifaceted concept. Further, it shows that not only actuarial risks affect the inspection and regulation process. Political risks also come into play.

Inspectorates face risk of discrimination in risk-based approaches if they need to inspect the same places again (excluding re-inspections). However, if that place was non-compliant before and the risk factors such as the size of the company, and the prevalence of products is high, it is more likely to find something there again. This is a trade-off between efficiency and fairness. Furthermore, not prioritizing notifications on fraudulent behavior is a trade-off between following the inspection plan and societal risk where the inspectorate might be judged for allowing the fraud to happen. These trade-offs are why risk is such a fuzzy concept and including this fuzziness makes it difficult to be able to claim to accurately measure risk. Furthermore, the perception of risk is not constant, the perception may change after something has happened. Organizations usually have a risk appetite or risk tolerance which is a level of acceptance however this can also change once an adverse event has happened. The different perceptions of risk and several trade-offs represent the fuzziness of risk. Furthermore, since risk perceptions are also dynamic this makes the concept of risk even fuzzier. It is important that the inspection plan respects this fuzziness and variances in perceptions since what risk is, also affects how the combination of random and risk-based inspections can be performed.

5 The Concept of Bias

If risk-based inspections are efficient in catching infringements and making food safer, then why is there a search for something else? What is the reason risk-based inspection results are not representative? Firstly, focusing on higher risks can cause an unwanted bias toward the high-risk areas and no enforcement on the other areas could cause for things to arise there. Moreover, risk analysis itself is assumed to be prone to bias.

In this chapter, an investigation into this assumption of risk-based approaches being biased is presented. What types of bias are seen within risk-based inspections and the underlying causes of bias are discussed.

5.1 Layers of Bias in Risk-Based Inspections

Eckhouse, Lum, Conti-Cook, and Ciccolini (2019) introduces the conceptualization of bias within 3 hierarchical layers. The article is about risk assessment within the criminal justice system but the conceptualization of bias is made in general terms which makes it applicable to different domains as well. The authors explain that human judgment can affect criminal justice decisions and mention that data-driven models are more and more finding their place as a solution to human bias. The authors investigate algorithmic fairness in 3 layers which are presented as the top, second, and base layers. The top layer is about the fairness of the assessment models, the second layer is about data being biased and the base layer is about conceptual issues within the models (Eckhouse et al., 2019). These layers are hierarchical which means that without fairness in the foundational layers, improving bias in the further layers is irrelevant (Eckhouse et al., 2019).

It is possible to distinguish similar layers for risk-based inspections. The questions that need to be asked when relating the layers of bias to inspections are proposed as follows:

- **Base layer:** Is it fair to use data from other organizations to decide on data about another organization?
- **Middle layer:** Is the data used about organizations biased? Does it include all related factors sufficiently?
- **Top layer:** Is the model used to assess the riskiness of organizations biased?

5.2 Base Layer of Bias

Is it fair to use data from other organizations to decide on data about another organization?

About the base layer, Data used by inspectorates should encompass all FBOs with the help of a database where information about the FBOs is stored, especially for intrinsic data about the organizations such as size, location, and number of years they in business. Information about compliance and previous inspection results are related to those FBOs as well but these data are not collected in a univocal manner. Furthermore, according to Interviewee #3 they try to inspect all places that are feasible to reach within a certain period of time but some places might not be reachable or there might be nothing to sample during the visit. However, contrary to the criminal justice system where judgments are made to sentence people, in risk-based selection for inspections using data related to other FBOs leads to an inspection of their processes, which is something all FBOs should expect will happen one day and only the outcome of the inspection can lead to a sentence or fine. Therefore, making selections based on non-compliance data of other organizations is not seen as a concern. However, what needs to be taken into account on this level is that because the data about certain FBOs show high risk, coming back to the same FBOs will lead to thoughts of unfairness. Which needs to be avoided.

5.3 Middle Layer of Bias

Is the data used about organizations biased? Does it include all related factors sufficiently?

The middle layer is an important layer. In order to make just decisions, it is important that all related factors are sufficiently represented in the risk assessment process. Bias in data can be systematic errors or imbalances in data. As mentioned by Martin et al. (2007) and Willeberg, Nielsen, and Salman (2012) that targeting is a way to deliberately introduce bias, and therefore, risk-based approaches by definition carry bias. In the context of risk-based food safety inspections, this bias can be the fact that by focusing on high risks, there is a chance of missing information from the lower-risk areas. Furthermore, inspections deliver input for future inspections and risk-based inspections will deliver the results based on risk which will be biased and not representative. Unbalanced data or bias in data is mainly caused by lacking representative sampling. Therefore, risk-based inspections since they focus on risks are assumed to lead to unbalanced results in data. The data obtained from inspections are however important to be used in the next round of inspections. Therefore, it is necessary that

the inspection data is either collected in a representative way or that representative estimations can be made from this data. Willeberg et al. (2012) discuss that with risk-based inspections the outcome is deliberately biased because the goal is to get higher efficiency. We discuss that risk assessment involves bias but what is actually underneath this? Why does it happen? According to Martin et al. (2007), lack of coverage and representativeness will generally cause biased samples. Bias comes from the fact that risk-based, possibly risky places are targeted. Therefore, targeting is the main source of bias in the middle layer. However, is there a way to aim for efficiency and reduce the possible introduced biases? This is discussed in Chapter 6.

5.4 Top Layer of Bias

Is the model used to assess the riskiness of organizations biased?

Risk analysis includes the human factor in decision-making and the use of expert opinions, however, this can make the risk-analysis model vulnerable to biases. Clarke (1988) argues that risk analyses are social products and are prone to different types of bias.

5.4.1 Types of Biases in the Top Layer

Farrell et al. (2013) mention in their risk-assessment model that sometimes risks can be underestimated because humans have biases. To improve the risk assessment it is important to mitigate these cognitive biases. Besides these, Hunziker (2021) discuss that risk managers deal with motivational and group biases as well. Asbury and Jacobs (2014) mention as key biases seen within the risk-assessment process as; hindsight bias, anchoring bias, availability bias, and representation bias. The types of bias most encountered in the literature are availability bias, anchoring, hindsight bias, confirmation bias, ambiguity effect, and representation bias. These are defined as:

- Availability bias: Making judgments based on how easily similar examples come to the fact that events that happen less often tend to be forgotten and underestimated (Baybutt, 2018). Thereby this relates to the fact that events that happen less often tend to be forgotten and underestimated.
- Anchoring: The effect of the first encounter has on the following evaluations.
- Hindsight bias: The tendency to view past events with a different predictability than it was thought (Baybutt, 2018). Hindsight Bias is also known as the "know it all-along" bias which means that people tend to claim they already knew a certain event was going to happen only after it happens. Farrell et al. (2013) defines it as the bias where greater value is attached to past events and less to non-happened ones.
- Confirmation bias: The tendency to look for something that is assumed to be found, to confirm what they were searching for.
- Ambiguity effect: The tendency to prefer known areas rather than uncertainties.
- Representation bias: Making judgments based on how familiar a situation is to another event.

These types are because of the human factor that is needed within the risk assessment process. This can especially be caused by the need to use expert judgments. Martin et al. (2007) refer to expert opinions as a "necessary evil" in this process. It can be prone to bias but because of data availability about probabilities of risk, some judgments have to be based on expert opinions. Here it is important to find ways to counteract these cognitive biases.

5.5 Bias in Practice

Is bias in risk-based approaches recognized in practice?

What Interviewee #3 recognized as bias in the risk-based inspection strategy is the lack of information about the unvisited places, rather than visiting the same places. They also mention that by focusing for instance only on non-compliant companies, the inspectorate risks not seeing the food safety situation in general. Interviewee #6 was aware that with their inspection strategy, some companies might not get inspected for a long time. In order to avoid this, they included the time without visit as a factor in their risk calculation and thereby when it has been too long without a visit their model makes sure that those places get a higher ranking. On the other hand, Interviewee #5 said that in their system, organizations that were visited recently were excluded from their strategy. They also expressed the importance of identifying the risk factors accurately. Interviewee #4 besides the selection of FBOs brings up that the selection of pathogens they investigate is where bias starts.

They mentioned that some risks are specially chosen because looking at that risk will reveal others even if the prevalence is not so high, they refer to these selections as a chosen bias. The biases that are addressed are related to the middle layer of bias as interviewees and the fairness of selection of the FBOs to visit. Hereby, where this is recognized inspectee selection also includes the duration since the last visit. Moreover, inspectorates are looking for ways to reduce the imbalance of biased data and ways to mitigate this.

5.6 Mitigating Bias

Farrell et al. (2013) provides certain ways to counteract these biases as well. The 3 methods proposed are:

- Raising awareness of bias for risk assessors
- Improving transparency of risk assessment by obtaining and using as much unbiased quantitative data as possible.
- Making sure there are enough people in risk assessment to challenge each other

These ways to mitigate bias are also related to the identified layers.

Whether or not it is fair to use data from other FBOs depends on how this data is collected. The data collection step of the inspection process can affect the fairness to inspect other organizations based on this biased data. First of all, since data available to the inspectorates such as the size of the company and sales numbers are equivalent values we assume that there is no bias in this data. Records of compliance, however, might lead to biased data since it might take time to collect this data from all inspectees and this data collection is not done simultaneously so there might be external factors affecting this data e.g. companies warning each other that inspectors have visited. Raising awareness of bias among inspectors can help to mitigate bias in this layer by making them aware of how bias can affect their evaluation.

Whether or not the data collected is biased or carries imbalance affects the representativeness aspect and the ability to deduct trends about the market from this data, which relates to the mapping step of the inspection process. This is the middle layer of bias. Mitigation strategies here are as Farrell et al. (2013) mentioned to use unbiased quantitative data. Another way to avoid unbalanced data is ensuring to have some monitoring in each category in the model (Cannon, 2009).

The top layer is related to the inspection strategy planning and performing of risk assessments. Especially when expert judgments are needed it is useful to include knowledgeable people that can challenge themselves in the process to come up with the least biased decisions. Furthermore, combination strategies are also helpful to mitigate bias.

A representation of the ways to mitigate bias is provided as follows:

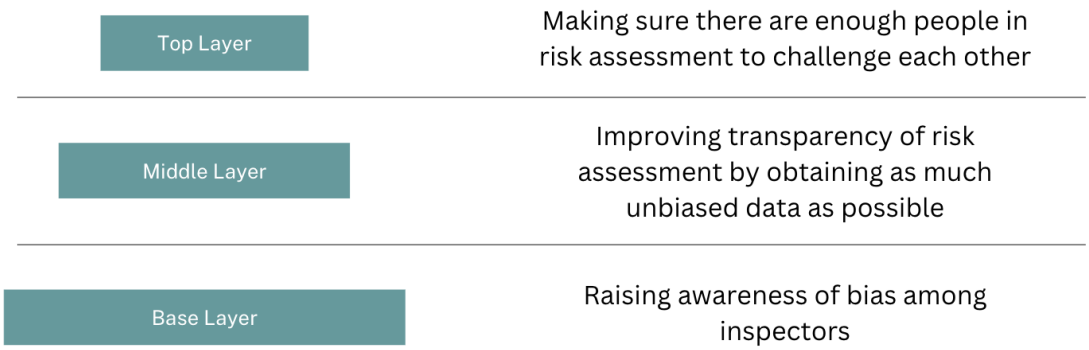

Figure 4: Mitigating Bias

5.7 Conclusions on Conception of Bias

Inspired by Eckhouse et al. (2019)'s layers of bias in the criminal judgment risk assessment, bias has been conceptualized in the context of food safety risk assessment. The layers of bias were adapted to the inspectorate's

perspective. Hereby, an understanding is gained of the role of bias in risk-based approaches. Risk-based inspections by definition need to have some sort of assessment to identify and rank risks. Even though this approach is useful in catching high-risk events there are some limitations to it. One of them is the fact that lower-risk areas are left unexplored and unsupervised. This is approached by the question of improving representativeness of inspections and is elaborated on in the subsequent chapter. Another is that risk assessment itself is prone to bias. By going deeper into where in the risk assessment bias can be found with the layers of bias, an understanding is gained. These layers, with their hierarchical order, need to be considered during risk analysis. This conception is important for the development of inspection plans since it helps to understand why risk-analysis is prone to bias and provides ways to counteract this bias from happening.

6 Methods that Support Inspection Strategies

Developing inspection plans and strategies requires many considerations and decisions. These decisions can be supported with various methods. Several studies were found that investigate and review methods used for this purpose as well as studies that apply decision or optimization models to certain areas of food safety. Even though the focus was on food safety inspections, some studies from different fields such as education and infrastructure were also considered relevant and included in this review. The literature search aimed to reveal the key methods that are used in the context of inspections in order to assess the potential of these methods to develop inspection strategies. A distinction is made between methods that are directly used for the selection of inspecting or sampling and methods that are and can be part of the decisions. The reason why the latter is investigated is for the purpose of evaluating the potential of the method to find the combination of random and risk-based inspections.

This chapter presents an overview of the key methods that are being used and have the potential to be used to support the decision-making on inspection strategies such as a combination of risk-based and random inspections.

6.1 Methods for Inspections and Sampling

Since the inspection process consists of both sampling and inspecting several sampling methods can be applied. These methods can also be applied to the selection of places to be inspected. Mainly, there are two ways of sampling; probability sampling and non-probability sampling. When elements of the population have a known and non-zero probability of being chosen, this is probability sampling. When the elements do not have a known probability of being selected this is non-probability sampling (Sekaran & Bougie, 2016). Literature about these methods with food-safety inspections has not been found however these methods can be applied to achieve the purpose of inspecting. The following sampling methods are mentioned in Sekaran and Bougie (2016).

- **Simple Random Sampling:** When all elements of the population have an equal chance of being selected. Taking a list of places to visit and selecting them completely randomly with for instance a random number generator. This method is a probability sampling method and the obtained results are highly generalizable.
- **Stratified Random Sampling:** In this method the population is first divided into meaningful parts also called stratum. Elements are then chosen from each of these strata. The number of selections can be either proportionate to the size of the segments. This is a probability sampling method as well, this method allows for comparisons among segments and it is the most efficient probability sampling design. However, how the stratification is done is crucial.
- **Weighted Stratified Random Sampling:** Weighted stratified sampling, is when the sampling is not done proportionate to the size of the stratum but higher or lover weights are attached to strata.
- **Convenience Sampling:** This method is used when the selection of elements is done by the convenience of access. This is a no non-probability sampling method. Because the selection is made by accessibility, most of the time the results are not generalizable.

These methods can be used in inspection strategies. These can range from complete random to complete risk-based strategies and the combination can be done on different levels as well. Several methods that can be used for inspection strategies are as follows:

6.1.1 Random Inspections

Random inspections can be performed by using 3 of these methods. Simple random and stratified random sampling both will provide representativeness. Stratification is only possible when information to form segments is available. With random sampling, the randomness even though does not target a certain aspect and therefore, aims for representativeness, stratification can be useful to make sure the obtained samples are represented from each different stratum. Convenience sampling is also used in random sampling due to reasons such as accessibility but this will not deliver representative results.

6.1.2 Risk-Based Inspections

Strata can be developed based on risk factors and a selection can be done on which strata to inspect from. With risk-based inspections higher risk strata will get a higher weight. Risk-based inspections require more consideration than random inspections because consideration of risk need to be done. Van Asselt et al. (2021)

defines 3 categories of risk-based inspection programs, namely risk-ranking, risk-based inspections, and cost-effective monitoring. These are about describing what types of food need to be inspected, which organizations should be inspected, and the determination of the place of the food chain respectively.

6.1.3 Combination Methods

Combining RB and random can be achieved with stratifying. Different risk categories can be established and from each stratum random selection can be made. Stratified sampling can also be used to combine random and risk-based inspections. Blickenstorfer et al. (2011) claims that randomizing within risk strata respects the representativeness of the population but they also mention that random sampling disregards the uneven distribution of risks. Therefore, they say that random sampling is the best way only when there is a lack of information about the risks within the population. A stratified random sampling model is proposed to combine risk-based and random sampling. The stratified model proposed in this paper does not only target the high-risk strata but distributes probabilities as they show within the population. The main method to combine these two is the stratified sampling approach. However, there is a need to determine how many strata, at what percentage to sample from each stratum, what risk factors, and how to prioritize are the main questions.

Explicit combination methods have not been found in literature. That is why methods that have potential in finding this combination are investigated. The question here is how much to weigh each stratum. Furthermore, how to decide which risks to prioritize are also important questions for the development of the inspection plan. Therefore, besides the sampling methods, publications that apply decision models or simulation tools that can support these decisions are investigated.

6.2 Methods Supporting the Inspection Strategy

An overview of the publications found is presented in Table 4. As illustrated in this table various methods are found which have different purposes. Methods that resulted from this literature review mostly comprise risk assessment methods, methods to identify risks, and decision-making methods with a risk-based approach. Several papers provide an overview of certain methods, while others propose certain decision models or a combination of models to be used for a specific area of inspections.

Scenario Tree Model

With risk-based sampling applications, a method that comes forward from the literature is Scenario Tree Modeling (STM). This method helps to analyse different inspection scenarios and works by dividing the population to smaller groups and associating each unit with the same likelihood of being detected as a violation. Various articles mention scenario tree modeling as a method to simulate possible scenarios of surveillance. Some reasons to use these kinds of models are to help the decision-making by comparing sampling strategies or estimating sampling sizes.

Alban et al. (2016) compares risk-based and random sampling on the detection of antimicrobial residues in pigs. 2 random scenarios and 4 risk-based scenarios with different sample sizes and relative risks are compared based on their costs and effects. The goal was to see whether or not risk-based approaches could reach similar results as the currently used random approach with smaller sample sizes and thereby reducing costs. They conclude that risk-based inspections did result in lower costs and STM facilitated this comparison. Blickenstorfer et al. (2011) compares risk-based and a combination of risk-based and random sampling in terms of performance and cost-effectiveness. Two diseases are investigated by first identifying risk factors and relative risks based on literature review and expert opinions. Blickenstorfer et al. (2011) uses STM to estimate a sample size with given sensitivity and prevalence as input. By calculating sample sizes a comparison of costs to gain certain sensitivity was possible. The authors state that randomizing samples leads to an increase in representativeness but that this way disregards that there are different levels of risks. They compare a stratified random approach with a complete risk-based approach. They conclude by recommending combination sampling. Martin et al. (2007) propose a combination of a representative survey of the population and qualitative assessments from expert opinions and complex sources of evidence that are non-representative by using a scenario tree model. The reason to combine these is to compensate for the weaknesses of the two methods, which are the expense and difficulty to carry out representative surveys and the difficulty of transparency and repeatability of non-representative surveys.

This method is one of the only methods that was mentioned with the purpose of combining risk-based and random inspections in the literature. However, this method does not combine inspections but helps to combine and evaluate the strategies. The mathod has a larger use in the sample size calculation, especially within

Table 4: Literature on Methods, Their Purpose and Application Area

Source	Model	Purpose of the model	Area
(Alban et al., 2016)	Scenario Tree Model	estimation of costs and effects of changed sampling and testing strategies	Food safety: antimicrobial residues
(Al Qubaisi et al., 2016)	Analytic Hierarchy Process (AHP)	to establish criteria weights	Education
(Blickenstorfer et al., 2011)	Scenario Tree Model	demonstrating freedom from disease	Food Safety: Animal Health
(Chermiti, 2019)	Chi-square Automatic Interaction Detector (CHAID) decision tree	to uncover new information in large databases, to detect unspecified interactions between variables, and to create predictive models	Customs
(De Carlo et al., 2011)	Bayesian Belief Network (BBN)	to model RBI's to evaluate the likelihood factors	Industrial Safety
(Geng et al., 2017)	Analytic hierarchy process (AHP) integrated extreme learning machine (ELM) (AHP-ELM)	to identify of potentially emerging food safety issues	Food Safety
(Greda, 2009)	Analytic Hierarchy/Network Process (AHP/ANP)	to structure a decision-making problem concerning the selection of the the best combination of quality management systems in food companies.	Food Safety
(Martin et al., 2007)	STM	demonstrating freedom from disease	Animal Health
(Pielaat et al., 2018)	a monitoring program containing pathogen/retail product combinations that detects a maximum amount of disability-adjusted life years(DALY's) for a given budget	foodborne pathogen in retail products	Retail Products
(van Asselt et al., 2016)	Agent-Based Modelling (ABM)	to simulate compliance behaviour of entrepreneurs	Food Safety
(Van Asselt et al., 2021)	Overview: Risk ranking methods	-	Food Safety
(van Asselt et al., 2012)	Overview: Risk ranking methods	-	Food Safety
(Van Der Fels-Klerx et al., 2018)	Overview: Risk ranking methods	Ranking food-related hazards, based on their impact on human health	Food Safety
(X. Wang et al., 2022)	Overview of Machine Learning applications in food safety	-	Food Safety
(X. Wang et al., 2023)	Weighted Bayesian Network	to improve the model prediction accuracy for the presence of food and feed safety hazards using unbalanceeed monitoring data, specifically for the presence of heavy metals in feed.	Food Safety
(Z. Wang, van der Fels-Klerx, & Lansink, 2022)	Bayesian network and integer programming	predicting the conditional probability of suspect samples, (samples with contamination levels over threshold limits), under different conditions and estimating the number of samples to be analyzed yearly for each food product	Food Safety

sampling applications. With probability data available about risk factors in an area, several combination possibilities can be simulated and compared in order to choose the most feasible or efficient one among those. However, a tree needs to be constructed for each scenario which could be time-consuming.

Agent-Based Modelling

Agent-Based Modelling (ABM) is a tool to simulate behavior of autonomous, heterogeneous individuals, called agents, and their interaction with the environment and with each other. ABM is used to model interactions within systems (people, places, objects) in space and time (De Marchi & Page, 2014). ABM can help in decision-making by providing an overview of a system.

ABM was applied to a case study on the compliance behavior of pig farmers to comply with the withdrawal period of antibiotics (van Asselt et al., 2016). The agents that were used were farmers with heterogeneous compliance levels. This model was aimed to simulate compliance behavior by modeling factors of compliance. The outcome was for inspection agents to decide what to do; e.g. increase fines(enforcement) or education etc)The model was not validated because of a lack of data. Furthermore, a variable called risk-based inspections was applied which was represented by a 0-1 interval, 0 for completely random and 1 for completely risk-based inspections. The limitations of this model is that it is difficult to simulate a real-life setting and that it is time-consuming to build such a model due to its complexity. However, with appropriate time investment, it could deliver useful results.

Analytical Hierarchy Process

The Analytical Hierarchy Process (AHP) is another method that has been seen in inspection decisions. Since this method uses pairwise comparisons and is mostly used for organizing decisions it is commonly applied in combination with other methods. AHP is used by itself for criteria weight determination by Al Qubaisi et al. (2016) in the context of school inspections. Furthermore, AHP was used together with an analytical network process (ANP) for the selection of quality management systems in food safety by Greda (2009). This application aims for the selection of the most efficient quality management system for the food industry. On top of that, AHP is also used in combination with a machine learning application, with the objective to develop an optimization and prediction model where AHP is used to bring out the variables to be used in an Extreme Learning Machine (ELM) (Geng et al., 2017).

The Analytical Hierarchy Process (AHP) is used to assist in the determination of criteria weights in inspections (Al Qubaisi et al., 2016). They quote: *"By reducing complex decisions to a series of pairwise comparisons, and then synthesizing the results, the AHP helps to capture both subjective and objective aspects of a decision. In addition, the AHP incorporates a useful technique for checking the consistency of the decision maker's evaluations, thus reducing the bias in the decision-making process"*. Greda (2009) uses the Analytic Network Process (ANP), which is a broader version of the Analytic Hierarchy Process (AHP), in the context of the selection of the most efficient quality management system. This model permits the categorization of the factors that is analyzed, criteria and subcriteria are defined, and connections are made. Then the elements are subject to pairwise comparisons which allows for the prioritization of the categories. This method is useful for decision-making problems however the main decisions are based on comparisons and no historical data is used. Therefore, this method could be helpful for risk ranking methods.

Risk Ranking Methods

The overviews and critical reviews provided by van Asselt et al. (2012), Van Asselt et al. (2021) and Van Der Fels-Klerx et al. (2018) focus on risk ranking and risk categorizing methods. Risk ranking methods used in the area of food safety are reviewed by Van Der Fels-Klerx et al. (2018). The authors conduct a literature review on what methods are used for risk-based inspections and analyze them. Methods reviewed in this paper are categorized as risk assessment, comparative risk assessment, risk ratio method, scoring method, cost of illness, health adjusted life years (HALY), multi-criteria decision analysis (MCDA), risk matrix, flow charts/decision trees, willingness to pay and expert judgement methods Van Der Fels-Klerx et al. (2018). Risk assessment, comparative risk assessment, and MCDA require large amounts of quantitative data whereas methods such as risk matrix and risk ratio have the ability to function with little data, even though it would be preferred to have larger amounts of data. They conclude that there is no one risk ranking method and the method selection requires consideration of the availability of data, requirements of the risk managers, resource constraints and features of the methods (Van Der Fels-Klerx et al., 2018). Another overview is provided by van Asselt et al. (2012), who propose a systematic approach to risk-based controls and determine two steps. Their first step is risk categorization where the most important hazards are identified along with in which food product they can be found. The second step is called risk-based surveillance, which refers to the determination of the inspection frequency. This is done by considering the results of the first step and some intrinsic factors such as historical data and information on the food safety management system of the company. Furthermore, Van Asselt et al. (2021) develop on the previous steps and add another one to come up with 3 steps of risk-based control plans: risk ranking, risk-based inspections, and cost-effective monitoring. Their article focuses on the second part and especially zooms in on the food safety culture and food fraud aspects.

Machine Learning Models

Machine learning(ML) is a way of teaching a computer to learn from experiences. In machine language, these experiences are represented in the form of data. ML uses computational methods to derive patterns and make predictions from the data that it is given (Zhou, 2021). Furthermore, ML models are used for classification purposes or regression. There are various models of ML and some of these models have been reviewed in the context of food safety as well. ML is able to use structured and unstructured data and learn from this data to give outputs such as predictions or classifications X. Wang et al. (2022).

Machine Learning methods used in the area of food safety are summarised and reviewed by X. Wang et al. (2022). The authors identify Bayesian Networks, Neural Networks, Support Vector Machines, and Decision Trees as the most commonly studied ML applications in the food safety area and elaborate on their applications. From their analysis, they conclude that ML models show potential to be used in monitoring food safety and making predictions (X. Wang et al., 2022). Besides this overview, applications of Bayesian Network are presented by De Carlo et al. (2011), Z. Wang et al. (2022), and X. Wang et al. (2023). De Carlo et al. (2011) applied a Bayesian

Belief Network in the area of industrial safety in order to model qualitative risk-based inspections. The aim of this application is to evaluate the practicality of qualitative risk-based inspections. Z. Wang et al. (2022) combine Bayesian Networks and integer programming with the objective to improve food safety monitoring plans. The goal is to reduce costs by predicting the probability of non-compliant samples. The model is built by using 10-year monitoring data on animal-derived food products to develop the BN which produced probabilities. These probabilities were applied to the optimization model. Another application of BN is Weighted Bayesian Networks, which are used for better prediction accuracy in the prediction of hazards (X. Wang et al., 2023). The authors claim that when data is unbalanced, the classification is unbalanced as well, which is why they use a weight-added BN. An additional Machine Learning algorithm which is a Decision Tree is demonstrated by Chermiti (2019). Their application presents a Chi-square Automatic Interaction Detector (CHAID) decision tree in order to create predictive models in customs.

The use of ML algorithms in food safety has been used for different purposes such as the prediction of food safety hazards and events by using previous inspection data or the prediction of food fraud (X. Wang et al., 2022).

ML is useful for domains where large amounts of data are processed and where complexities and non-linearities exist between variables (Chermiti, 2019). ML is classified as supervised and unsupervised learning which relates to if the outputs of corresponding inputs are taught to the model or not. X. Wang et al. (2022) provides an overview of ML methods used to monitor food safety. ML is being used for data analysis in various domains among which food safety as well even though it has not yet reached a wide use area. The reasons for this mainly are the lack of digitalization of the collected data in food safety, the fact that ML applications are very recent, the fact that food safety encompasses various domains and that it is difficult to assess which variables can be associated with modeling (X. Wang et al., 2022). Three ML methods come forward in the literature which are Bayesian Networks, Decision Trees and Neural Networks.

- **Bayesian Network**

  Bayesian Network (BN) is a classification and prediction tool. BN models are used to represent the connections and interactions between variables and use conditional distributions. The model can be used for both classification and prediction purposes. It provides a graphical representation of the variables and their relationships by using nodes and arcs. Expert opinions are valuable for the construction of the model, data such as historical or empirical data, and data obtained from literature or simulations can be used for the identification of probability distributions (X. Wang et al., 2022).

  Several applications are present in the area of food safety on the prediction of food safety hazards (X. Wang et al., 2023). Z. Wang et al. (2022) use a BN together with integer programming (IP) to optimize food monitoring plans. Their reason for using a BN is its ability to deal with various data. The authors apply BN to predict the probabilities of suspected samples under given conditions. Then they use the results as input for the IP model of cost optimization. According to X. Wang et al. (2022) BNs are capable of dealing with incomplete data sets are easy to understand and easy to update with new data or new variables. Furthermore, X. Wang et al. (2023) used a BN to classify sampling data as contaminated or uncontaminated. The classification results were unbalanceed in the sense that some can have a high rate of contamination and some low which refers to high and low-risk classes which is related to the data being unbalanceed. To correct the unbalanceedness, the authors apply a Weighted Bayesian Network to find a better balancee. BNs are flexible and are able to be updated with new variables easily (De Carlo et al., 2011). However, if a very large amount of data needs to be included it can be complicated to make the new connections. According to De Carlo et al. (2011) time-consumption is the only limitation of the model.

- **Neural Network**

  A Neural Network (NN) is constructed with a graphical model that consists of nodes, representing neurons and edges, representing links. The output of one node is the input for the next node it is connected to, which is how the network is built. This model is used to solve complex computations X. Wang et al. (2022). Extreme Learning Machine is a type of NN which has been applied by Geng et al. (2017). As ML models can also be used in combination with another model, Geng et al. (2017) combines an Extreme Learning Machine neural network with AHP. The authors express that data produced from the inspection process has high complexity and can be non-linear and that's why only based the inspection strategy on ELM is not sufficient. In order to counteract this problem the authors apply AHP together with ELM. According to X. Wang et al. (2022) NNs are capable of dealing with incomplete datasets and have a fault tolerance which means that when some cells of the model are lacking or are not performing properly, the

model is still able to produce a result. However, X. Wang et al. (2022) states that it is not clear how the results are obtained and therefore, lacks transparency.

- **Decision Trees**

  Decision trees (DT) are supervised algorithms that are used to make classifications of data or make predictions. The model is structured like a tree, composed of leaves, nodes, and branches representing, outcomes, tests, and relationships respectively. An example is the Chi-square Automatic Interaction Detector (CHAID) decision tree method which has been used by Chermiti (2019) to predict risk factors and risk profiles applied to customs data. This specific DT model is used for classification purposes and its difference with other DTs is its ability to develop non-binary DTs. With this model, the authors aim to help customs administration to improve its ability to detect high risk. The aim of the algorithm is to predict the revenue risk of importing activities and model risk factors. Large number of categories can make the model illegible and complex (Chermiti, 2019). Furthermore, if the data that is used for this model contains high complexity, the structure might become too complex as well (X. Wang et al., 2022).

6.3 Methods Used in Practice in Inspectorates

Most of the time theoretical methods are not easy to apply in the practical setting. This is why interviews with experts from the sector were conducted. It was observed that even in different departments of the same inspectorate, different approaches were taken. The most common method used was expert consultation.

Borraz et al. (2022) compare and discuss risk-based food safety inspections in 4 countries. Because the EU regulation that requires risk-based approaches does not provide guidelines on how this should be done, differences are seen in how countries apply this to their inspection system. From the 4 countries analyzed in this article, France's food safety inspection system focused on hazards, while the Dutch system focused only on non-compliance behavior whereas German and English systems encompassed both aspects at the same time.

Stratified Weighted Random Sampling

Interviewee #6 mentioned that it is difficult to come by probability estimates in order to build an STM which is one reason that they were not using this model to determine their inspection strategy. They use stratified weighted random sampling, weighted by the risk factors. They calculate the sample size from random samples but their goal is to achieve high efficiency and they then focus on the high risks. Interviewee #1 said that they lack the data to analyze risks based on probability and consequences and that in practice they use expert opinions to estimate risks for their inspection strategy. Previously they were using a risk model based on only noncompliance.

Expert Consultation

Experts are consulted in order to establish risk factors and to rank hazards Van Asselt et al. (2021). This method is mostly used in risk-based inspections and can be used in combination with random. Experts usually are asked to rank risk on an ordinal scale and experts are also able to decide how much to weigh higher or lower risk categories, in order to ascertain randomization.

6.4 Categorisation of Methods

After the investigation of several methods, those can be distinguished based on their use and how they can support the inspection strategy. Most of the literature is focused on risk-based inspections and those methods are mostly based on risk ranking, risk identification, or risk prediction. Predictive modeling is useful to identify which products and hazards to focus on for the control plan (X. Wang et al., 2022).

- **Mapping**

  Mapping is done to get an overview of a sector, which is why representativeness is needed. Methods that can achieve this are presented in this category. According to the presentation of the NVWA, a representative method is stratified sampling. Probability sampling is a key method to get representative results as well (Blickenstorfer et al., 2011). These methods permit the mapping of sectors and markets to get a general view of what is happening. Random approaches are taken when there is no targeting included. Doing complete probability sampling can be quite difficult and costly and non-probabilistic sampling methods can be more convenient (Wiśniowski, Sakshaug, Perez Ruiz, & Blom, 2020). On top of this, Interviewee #3 mentions that in practice it can happen that sample taking and the selection of visited places can be based on convenience such as going to a location where multiple inspectees are

present. However, since the purpose of mapping is to achieve representativeness, convenience sampling is not included in this category.

- **Risk Ranking**

  As seen from the publications on overviews of methods, within the risk ranking category, there is an abundance of methods. Risk matrices, scoring tools, decision analysis tools, and decision trees are examples of methods to use to rank risks and based on risk factors and risk score calculations.

- **Risk Prediction**

  Risk prediction methods require the model to not only make inferences but also make future estimations based on the given data. Examples of these as mentioned earlier are Bayesian Networks (WBN from X. Wang et al. (2023), Neural Networks (AHP-ELM model from Geng et al. (2017)), Decision Trees (CHIAD from Chermiti (2019).

- **Combination Methods**

  In order to combine representative and random approaches stratified sampling and STMs can be useful. After stratification there still needs to be a decision on how much to sample from each stratum. STM can support this by analyzing various scenarios and evaluation their costs and efficiency. Some examples of combinations are done with scenario trees Martin et al. (2007) and Bayesian inference Wiśniowski et al. (2020). However, in practice, there are not many examples of a combination of methods but expert consultations are used in the industry in the determination of the monitoring plan (Interviewee #3).

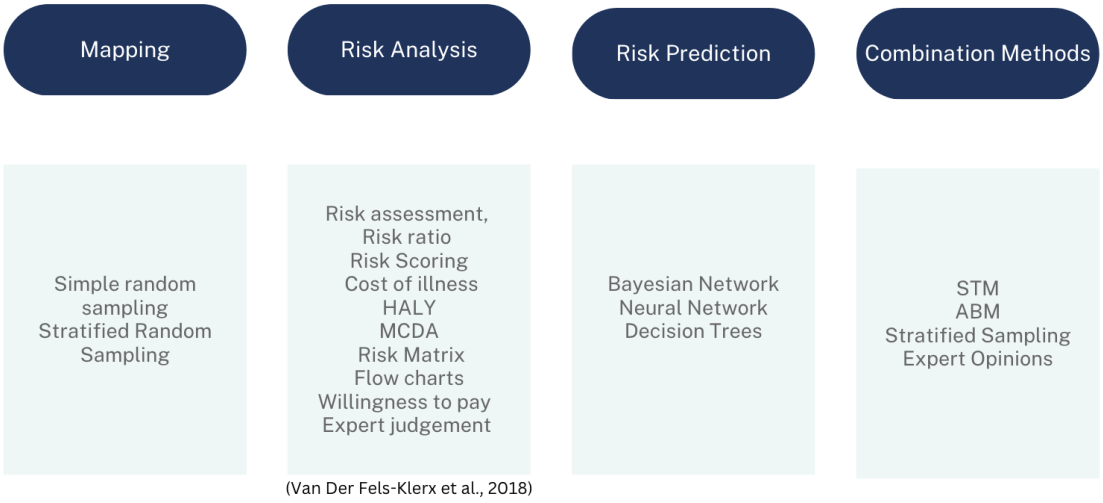

Figure 5: Method categorisation

This categorization of the purposes of the methods permits distinguishing these within inspection strategies as well. First of all, combination methods can be simulating methods in order to find how to combine risk-based and random inspections. As previously mentioned the mapping purpose is achieved with representative random inspections. Risk analysis and risk-prediction methods can be used in risk-based inspection and the combination strategy.

6.5 Conclusions

Various methods have been identified with different potentials for their implementation in the inspection process. The examples presented on the application of these methods are mainly used for risk and hazard predictions of food safety applications. The results of prediction models can be used by governments and inspectorates to build risk-based inspection plans. What is aimed of this study is to see which models can be used to find a strategy of inspecting risk-based and to get representativeness out of it. It is seen that these models have the potential in predicting risks, therefore, they also have the potential to incorporate representativeness when it is asked of them. Models to predict food fraud could also help to detect and prevent food fraud. This relates back to the 1st and 2nd goals of inspecting, namely to impose the values of public safety and encourage

compliance. All these methods are supportive of the inspection process and facilitate the development of inspection strategies. However, these methods have their strengths and weaknesses and not all are applicable to all situations. Furthermore, as seen from the variety of methods and method categories and the differences in the uses, there is no one fits all method that can be applied. Applying combinations of these methods is useful for inspection strategies to make use of the strengths of the methods and mitigate the weaknesses.

7 The Assessment Framework

The previous chapter provided an overview of several methods that have different roles in the development of inspection plans. Random and risk-based methods are available however, additionally, an exploration of methods to combine risk-based and random inspections was performed. It is important to note that no singular method can be deemed the definitive approach for combining random and risk-based inspections.

This chapter provides a tentative assessment of methods and further develops certain steps to consider to develop inspection strategies. The assessment criteria for methods are used to develop an assessment framework after an analysis of the methods found in various publications. This assessment will be done on three levels. First, sampling methods are evaluated based on their contribution to representativeness. Furthermore, the inspection process consists of several decisions and certain methods exist to help this decision. As seen from the literature review and interviews there are various methods to do risk-based allocation, especially risk assessment methods are largely available. Criteria to assess these methods are developed based on insights from literature and interviews. On the third layer of this assessment, the decision flow of the inspection plan is provided along with due considerations.

7.1 Methods of Inspections and Sampling

Sampling methods as explained in 6.1 are used to perform the inspections. These methods rely highly on the population and can be assessed cannot be assessed in the same framework as the decision-supporting models, as the criteria for decision models do not apply. However, their contribution to representativeness can be given in generalistic terms.

Simple random sampling by definition does not target and is used for the reason of representativeness. Stratified random sampling, however, is a more efficient way to get representativeness since it helps to ensure that every category is proportionally represented in the sample. However, weighted stratified sampling is not representative because the obtained results will be unbalanced and will not represent the low-weighted areas sufficiently. Furthermore, convenience sampling is not representative either since non-convenient places are left out.

However, the possibility of achieving representativeness and efficiency depends on the availability of information and feasibility. Therefore, simply using these methods does not guarantee representativeness.

Method	Representative	Condition
Simple Random Sampling	yes	If the taken sample is truly random
Stratified Random Sampling	yes	By making sure to sample from all strata
Weighted Stratified Sampling	no	
Convenience sampling	no	

Table 5: Assessment of Methods of Inspections and Sampling

7.2 Criteria to Assess Methods Supporting Inspection Strategies

All these methods mentioned in Chapter 6 can be implemented to support the decision process of the inspection strategy process. Therefore, the choice of the method is a decision problem in itself. To make this decision, there are aspects to take into account.

Van Der Fels-Klerx et al. (2018) have reviewed and assessed methods of risk analysis in the context of food safety. The authors discuss several criteria that need to be considered for such methods to help risk assessors in their decision of choosing the appropriate method. The risk considerations in such assessment are focused on health hazards and a distinction is made on microbiological, chemical, and nutritional hazards. The 11 risk ranking methods are considered in their ability to rank these hazards individually and which methods are more suitable to rank when a combination of these hazards is available. Furthermore, these methods are reviewed on their data needs as well. Since these methods have been assessed by Van Der Fels-Klerx et al. (2018), they are not included in the assessment framework provided in this thesis. However, the criteria provided by the authors are relevant to the assessed methods as well. Data availability is not a strong feature in inspections. As per interviews the lack of data is seen as one of the challenges in the decision process as well. Furthermore, updating the model with new information is important too. Most of the time, in order to update the results with new information, the analysis needs to be done again (Van Der Fels-Klerx et al., 2018), therefore updating the model

yearly is not easy. But some methods have the potential to have the ability to update the model easily. These considerations are important to assess the supportive methods of inspection strategies as well.

- **Data availability**

  The availability of data is important for the selection of the methods. In cases where there is a lot of data, methods that can handle such large amounts need to be chosen. For the case of food safety, interviewees mentioned the lack of data available which leads to difficulties to do risk assessments. Therefore the ability of a method to deal with little data (the ability to get accurate results even from little data) is relevant. Furthermore, methods that require lots of data have the risk of wrong correlations that this data may have or bias from this data. Requiring a lot of data could therefore be a vulnerability. And also from the fact that lack of data is mentioned, it is needed to see if the method can work with little data.

- **Updating**

  Because inspections are not of singular occurrence, and by doing inspections new information is obtained it is important that the inspection process gets updated with the new information. Therefore, the method for decision-making should not be difficult to update with new information.

- **Accuracy**

  The methods should be able to deliver accurate results. This can be verified with validation methods. X. Wang et al. (2022) provides ML validation for prediction accuracy. This is an important criterion for methods, however, because claims on accuracy require testing and validating the model it can only be claimed that based on the overview of X. Wang et al. (2022) ML methods provide accurate prediction results for risks. However, in order to be able to claim accuracy in deciding between risk-based and random inspections applications need to be tested. Furthermore, also the ABM model developed by van Asselt et al. (2016) was not validated due to a lack of data. Therefore, although this criterion is important, it will not be included in the assessment framework.

- **Transparency**

  Especially for the reason of avoiding biased decisions, it is important that the way the method works is clear and transparent. It is important that how conclusions are deducted are shown and justified in a clear way (Van Der Fels-Klerx et al., 2018).

- **Implementability**

  Inspection agencies need to be able to work with the method and therefore, the method should not be hard to implement. When asked about certain methods interviewees said that methods such as STM can require too much effort (Interviewee #5). And that, simple models are much preferred. Furthermore, the simplicity of the ERA model was mentioned.

7.3 Assessment of Methods

This assessment is a tentative attempt to evaluate the methods based on questions developed for these criteria. The judgments made are based on the publications examined in Chapter 5. These methods are analyzed because of their potential to be used in the exploration of the combination of risk-based and random inspections such as comparing scenarios or simulating inspection plans with the objective to find the optimal plan.

Qualitative methods require less data than quantitative methods and can be performed in less time Van Asselt et al. (2021). However, quantitative methods are more objective and transparent. STM uses quantitative data in the form of probability estimates.

Scenario Tree Models require probability estimates to be made. It might be difficult to come by these probability estimates which makes the implementation of the model difficult. However, if the probability estimates are available for risk factors the model would provide objective results. Furthermore, it is possible to compare fully risk-based and a combination of risk-based and random inspection plans. Therefore, scenarios of different inspection strategies where the weighing of the stratification is made differently could be compared in order to find the best way to sample. Moreover, to add new incoming information, new scenarios need to be built. Therefore, the model cannot be updated easily. A judgment about transparency cannot be made, however, if the calculation of the probability estimates is made objectively and it is clearly documented how these are calculated, the model could be said to be transparent.

Agent-Based Modeling requires variables to be set which ultimately consist of quantitative values but qualitative values can also be used if they are translated appropriately. Limitations of this model are that it is time-consuming to build the model and that it is difficult to reflect real-life situations. However, this method could be useful to simulate the implications of how different inspection plans can deliver results.

Bayesian Networks, Neural Networks, and Decision Trees are ML models. Therefore, most requirements are similar however, as stated by X. Wang et al. (2022) neural networks are referred to as a "black box" in the sense that it is not known what happens inside. Therefore, transparency is not this method's strong suit. However, these methods are capable of functioning with incomplete data. This means that assumptions on these incomplete data will be made based on the rest of the data. Furthermore, ML models need large amounts of data to make sense and to be able to predict anything. Therefore, since as per the interviews, data is missing most of the time, this indicates suitability for food safety inspections. However, this method can be used in combination with other methods to facilitate decisions.

Decision Trees can be useful for the decision of random or risk-based inspections as well. However, large amounts of variables can make the model complex and illegible. Furthermore, developing the model takes time and consideration.

Expert Consultation is a commonly used method to estimate risks, prioritize them and decide on inspection plans. This method is convenient to use since there is no requirement for a model to be built. Experts will evaluate based on their knowledge and the collected data on what needs the most attention. The ease of use makes this method attractive in practice, however, this method lacks transparency.

AHP is a method to rank certain aspects based on pairwise comparisons. It is easy to apply in practice and does not require large amounts of data. However, this method is more suitable to be used in ranking certain objects or elements rather than deciding on risk-based and random inspections.

A summary of the assessment is provided in the Assessment Framework in Figure 6. The cells that are filled with a "1" represent the answers to the questions.

	Questions	Answer	STM	ABM	BN	NN	DT	Expert consultation	AHP
Data Availability	Level of input needed	Quantitative	1	1			1	1	1
		Qualitative					1	1	1
	Amount of data needed	Large			1	1	1		
		Small	1	1				1	1
Updating	Can the model easiliy be updated with new data?	Yes			1	1			
		No	1					1	1
Implementability	Does it take a long time to develop the method	Yes	1	1	1	1	1	1	
		No							
	Is it easy to implement in practice?	Yes						1	1
		No	1	1	1	1	1		
Transparency	Is it clear how the model delivers the output?	Yes							
		No				1		1	1

Figure 6: Assessment Framework

7.4 Factors Developing an Inspection Plan

The assessment framework helps to decide on inspection strategies. Although, an inspection plan does not only consist of this decision. There are steps that should be taken before coming to this decision since the method to inspect cannot be haphazardly selected without due consideration. The careful consideration of relevant factors, thorough analysis of available options, and adherence to best practices are imperative in this context to ensure a well-informed and effective decision-making process. This section is dedicated to a comprehensive explication of a road map toward an inspection plan. Within this section, not only are the steps clearly defined, but also the

nuanced considerations associated with the execution of these steps are explored, providing a robust framework for informed decision-making and effective implementation of the inspection plan.

7.5 Defining the Steps of the Inspection Plan

So far, sampling methods have been evaluated on their contribution on representativeness and decision methods have been assessed based on certain criteria about data, implementability and transparency which are important criteria for these methods. However, this assessment framework can achieve its meaning when it is implemented in the right place during the development of an inspection plan. There are certain steps that need to be taken before the assessment on methods can be performed. Furthermore, there are certain considerations that need to be taken into account during this development.

First of all, to start this process, data about what to inspect is needed. Information about what products are produced, handled, or sold at which establishment or any information about upcoming health hazards happening in different countries that need attention are needed. These data can be data such as name, address, sector, type of operation, and types of products the company works with. Therefore, first, such data is collected in a database which is used as input for the rest of the inspection process. After this, the purpose should be defined which will define the inspection strategy. Supportive methods aim to help with the decision on inspection strategies. This is done after the collection of data since for instance if there is not much information about a sector, the purpose will be mapping the sector. In practice, when there is no information about risks or when representative results are aimed, random inspections are performed. This helps inspectorates to get an overview of the sector and is also referred to as mapping to get a representation of the market or sector. If risks are known and if the aim is to inspect high risks, then a risk-based approach is taken. Then the method is selected to define where to inspect. After the selection and prioritization of where to inspect and how often, at the final step, the inspections are performed. These inspections are a source of new data as well such as compliance of the company and the inspection process continues. The random inspection part is both important to get an overall view of the market or the country, but it also helps to discover trends in the obtained data. These trends can be used in a risk-based inspection as well.

1. **Data Collection:** A database of companies that are involved in food production, food handling or retail needs to be established. Collection of data can be done by using databases of establishments known to the inspectorate, literature reviews, and use of previous inspection data. This step involves the process of building the database where the companies to visit will be chosen from. Most of the time companies need to declare themselves to the inspectorate, without this they are not included in the database which means that the inspectorate is not aware of their existence (interview #3). This database gets updated with information on new companies. Furthermore, information about a new disease or certain risks can be received from other countries or can be found in the literature. Inspections are a key source of information as well, after they are performed information is gathered about the visited companies. These are collectively defined as the data collection category. The data collected serves as input for the next methods in the process and it is important that the data is coherent.
2. **Defining the Purpose of Inspection:** Inspection plans are designed around specific purposes, and also need to consider the higher objectives. The purpose can be:
    - Mapping: Representative methods can be used in this step to get insights from the population. This part is important to get a system view of the market or sector where the inspection is done. It is important to be able to gain information about the sector to get overall information on the population such as how compliant the meat production market is.
    - Catching Violations: When the aim of inspections is to catch as many violations as possible focusing on high risks will be the way to go.
    - Mapping and Catching Violations: As previously mentioned the two purposes are related and can be aimed as a combination. However, this requires some additional considerations.
3. **Chose Inspection Strategy:** In order to choose the inspection strategy supportive methods can be used such as simulation or decision methods in order to help the inspectorate decide which strategy to choose. Especially for the purpose of combining these methods have the potential to be helpful in the decision on whether to allocate resources more on random or risk-based inspections.
    - Random: If the purpose is to get information about a sector or a domain the inspection strategy would be random. This is especially the case when there is no information about what wants to be

inspected. Since without information, a risk assessment is not possible.

- Risk-Based: When there is a very dangerous disease that needs to be inspected on, or when a specific request is present to focus on risks, a fully risk-based approach can be taken.
- Combination: As mentioned in section 3.4, are to have an inspection plan that both targets risk while also considering representativeness.

4. **Method Selection:** Once the inspection strategy is decided upon, the sampling method needs to be chosen.
   - Random: Simple Random sampling, Stratified Random Sampling
   - Risk-Based: Risk ranking methods (Van Der Fels-Klerx et al., 2018) can be used to rank and assess risks. Risk prediction methods can be used to evaluate which risks to focus on.
   - Combination: Stratified Sampling
5. **Perform Inspection:** This is the step where inspectors visit companies and physical inspections are performed.

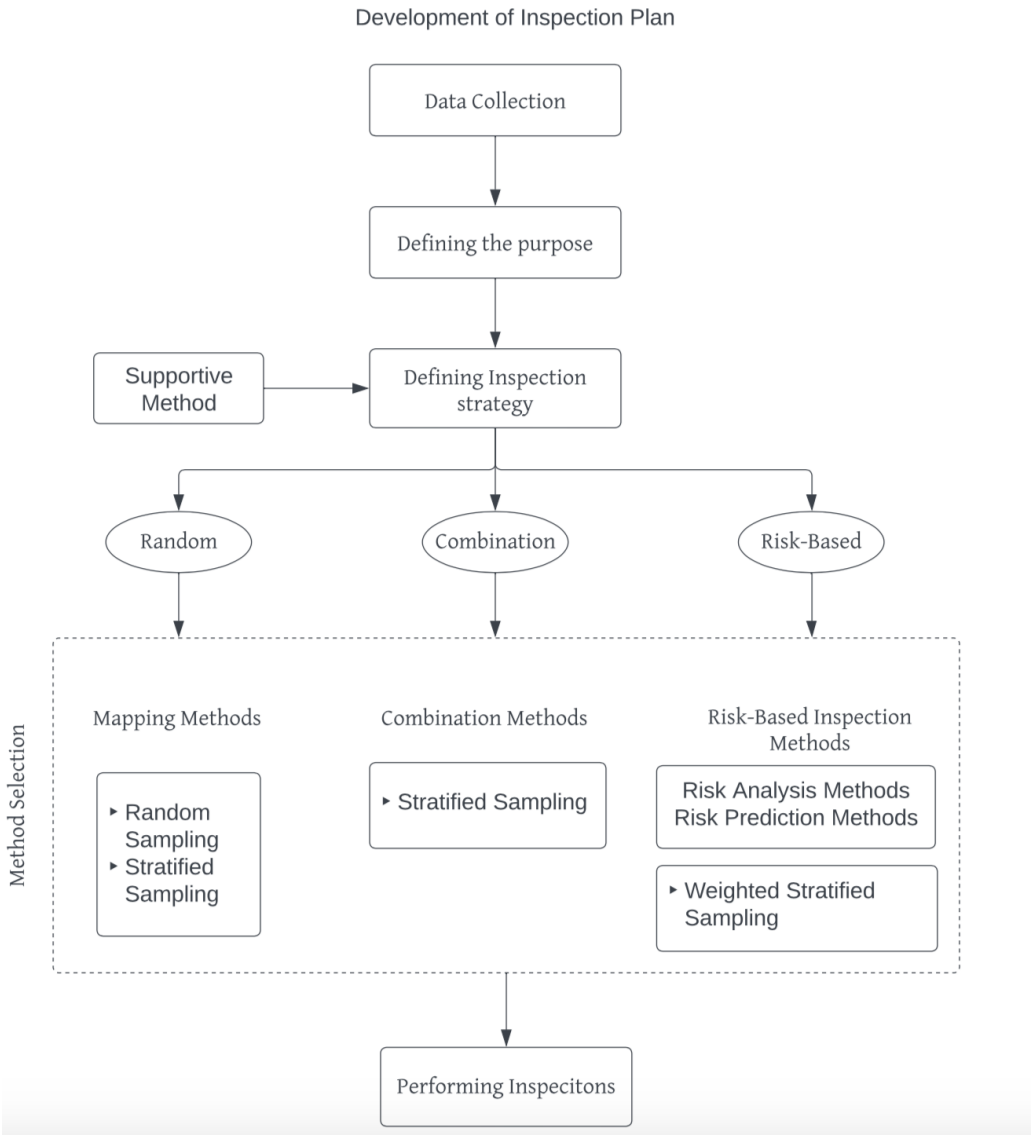

Figure 7: Inspection Plan

7.6 Considerations for Developing an Inspection Plan

When undertaking the implementation of these steps, it is essential to give careful thought to a variety of considerations.

- **Purposes of Inspecting**

  The hierarchy of purposes is important in order to define the purpose of inspecting. The selection of an inspection strategy depends on the purpose of inspecting. In order to respect the hierarchy of purposes a combination strategy of representative and risk-based approaches is found to be more suitable. However, in cases when a new market is needed to be analyzed, the purpose will be purely mapping. In such a situation there will be no information on risk to do a risk assessment. Therefore the combination of the two will revert to a sole representative approach. However, the higher purposes of encouraging compliance and imposing higher values should always be minded during the development of inspection plans.

- **Respecting Representativeness**

  Representativeness is a complex concept as well. This depends highly on the purpose of inspecting as well and needs to be considered in random and combination strategies.

- **Tolerance for Multi-Actor Perceptions of Risk**

  Even within a single organization the definition and perception of risk can differ. The inspection strategy should respect and be able to tolerate these differences. Furthermore, besides actuarial risks, the inspectorate needs to consider perceptual risks such as political and societal risks as well. These relate to the multi-actor component of risk and the inspectorate needs to take into account the actors of society and the inspected when considering risks as well.

- **Layers of Bias**

  Especially for combination and risk-based inspection strategies, since there is a risk analysis involved, the layers of bias need to be taken into account. First of all, in the data collection step, the objectiveness of the data needs to be considered. Therefore, appropriate measures need to be taken to ensure unbiased data collection. Furthermore, bias that can occur from the method needs to be prevented by making sure to include people to challenge each other in the risk assessment process.

A representation of where these considerations are applied to the inspection plan is presented in Figure 8.

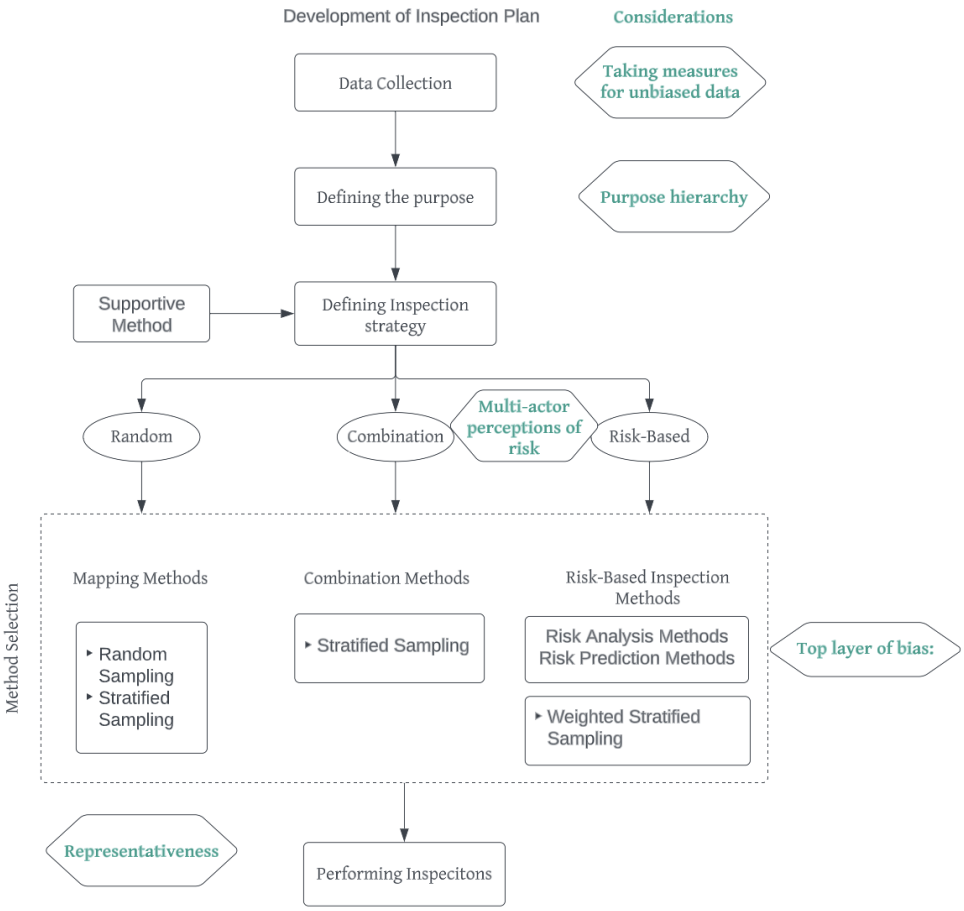

Figure 8: Considerations for the Inspection Plan

Furthermore, at all steps where methods are applied, the method should be applied objectively and the choices made should be documented to improve transparency.

8 Discussion and Reflection

This thesis explored the concepts of risk and bias in the context of inspections and analyzed methods that can be used to develop inspection plans. The research was designed in two parts. First of all, the examination of concepts was performed. Risk and bias were two concepts that came forward in discussions of risk-based inspections. A deeper exploration of these concepts was performed to better understand their implications on inspections. The findings underscore the importance of comprehending various perceptions of risk, Furthermore, analyzing bias showed how subjective perspectives in risk assessment can impact resource allocation.

The second part consisted of the identification of methods used for inspection strategies. With the aim to find methods to combine risk-based and random inspections. A literature review was performed to reveal methods that are used in food safety inspections. The initial objective was to look into methods that combine risk-based and random approaches, however, when it was observed that literature on this topic was scarce, the search was directed to risk-based approaches and decision and prediction tools used in inspection plans.

As Van Der Fels-Klerx et al. (2018) concludes that there is no single best method to do risk-based inspections, there is also no single best method to decide on inspection strategies. The steps for deciding on the inspection strategies is built with the aim to facilitate this decision by distinguishing which decisions need to be taken at each step.

8.1 Research Limitations

While this study has contributed to a comprehensive understanding of the concept of risk, the concept of bias, inspection methods, and considerations for inspection plan development, it is crucial to acknowledge its limitations.

The lack of literature on combination methods underscored a notable limitation in this study. However, this constraint was effectively addressed by delving into decision-making methods within the context of food safety inspections. Various methods for risk ranking or for comparing risk-based inspections with random inspections were encountered which mostly promoted risk-based inspections, combination methods were hard to find. Therefore, simulation and decision methods were explored. Through this exploration, the potential of these decision methods to combine risk-based and random inspection strategies was evaluated.

Although the ideal method for an inspectorate would be a perfect algorithm that can decide which products to inspect in which frequency, this could not be achieved in this thesis due to time and resource limitations, as was expected from the beginning of this research. Therefore, this thesis aimed to analyze what methods might have the potential in designing such an algorithm.

8.2 Generalizations & Recommendations for Future Research

This research was focused on food safety inspections and therefore considerations are made specifically on food safety inspections as well. Although the assessment of methods has the potential to be generalizable across all domains of inspections, the considerations made based on risk will differ per inspectorate.

The assessment framework is generalizable with necessary considerations. For instance, in food safety inspections lack of data is mentioned however, if different inspectorates such as Health have access to more data different methods will be suitable for their inspection process.

This research was the first attempt to combine the concepts of risk and bias in the exploration of methods for a combination of risk-based and random inspections. The assessment framework and the steps for developing an inspection plan serve as a starting point for regulatory bodies, practitioners, and researchers to enhance their approach to food safety inspections. The framework has been built tentatively and not all the cells have been filled. A future application where the methods can be tested on case studies of food safety inspections could provide a better assessment of these methods and would support the validity of this assessment framework. Furthermore, the tentativeness of the assessment framework could be improved by conducting additional research by using a Delphi method to consult multiple experts in order to validate the assessment.

By analyzing the case study approach it could be possible to apply a simulation method in order to see the implications on the decision of combining random and risk-based inspections.

9 Conclusion

9.1 Conclusions on the Study

This thesis developed conceptions of purposes, risk, and bias within the context of food safety inspections. Further, an investigation on methods used in the inspection process is analyzed. The goal of this thesis was to explore these concepts with their implications of developing inspection plans.

This thesis aimed to provide an understanding of inspection strategies, what methods can be used to facilitate these strategies, and more importantly to explore what aspects and criteria need to be taken into account during the development of inspection strategies. This is done by investigating the abstractness of the concepts of risk and bias. Because of the fuzziness of these concepts, the choice of an inspection strategy is not that straightforward. Furthermore, the high complexity of food safety sectors does not make the task any easier.

The exploration of criteria leads to various considerations that need to be kept in mind during the development of inspection strategies. The main concepts analyzed are the bias that is assumed to lead from risk-based inspections and the concept of risk. The goal of risk-based approaches is to minimize these risks as much as possible. Different types of risk that affect the inspection strategy have been defined and therefore the inspection strategy needs to tolerate these differences. Furthermore, it is not easy to recognize bias but in selection processes, especially if a human factor is involved, there might be bias. Risk assessment is also such a decision method that involves humans in the process. Even though decision algorithms are in place, with an objective to reduce this bias, the question of whether the method is biased comes to mind. To analyse this 3 layers where bias can be found in risk-assessment methods have been investigated and mitigations for each of these layers are proposed.

Because of the constraints of inspectorates, inspection strategies need to include a selection and resource allocation process. This is why there will always be some bias in the results. It is therefore important that the inspection strategy mitigates these biases as much as possible and that the method of decision-making takes this into account. In order to reduce bias in food safety controls, the inspection strategy should try to reduce them within the risk assessment process by considering the collection of objective unbiased data and including representativeness in the inspection strategy.

9.2 Conclusions on the Sub-questions

RQ1: Why is there a need to combine risk-based and random inspections?

Risk-based inspections are more efficient in finding and catching violations where risks are known. On the other hand, they do not provide a representative picture that supports the further inspection process. Random inspections if done properly will lead to a representation of the whole population. The disadvantage of inspecting randomly is that it disregards the uneven distribution of risks and has the chance to miss violations of regulations completely. Inspectorates and the government would like to make sure that resources don't go to waste. On the other hand, doing only risk-based inspections means looking at known risks and new emerging risks can be missed. Furthermore, if the inspection strategy will consist of only risk-based inspections, the information gathered from there will only be about the risks and nothing will be learned about other areas. To address this combining random and risk-based in a way to do both risk-based and gain some insights from other areas is preferred.

RQ2: How is risk perceived within food safety inspections?

As seen from interviews from different departments of the food safety inspectorates different risks were considered for different areas of food safety. Furthermore, definitions of risk differed per area as well. In some cases risk is defined as probability-based whereas in some it is defined as consequence-based and in other applications both probability and consequences are taken into account. These differences in defining risk have implications for inspection strategies such as when consequences are unavoidable, a risk-based approach can be aimed. However, there are also different types of risk that affect different actors. Health risk, misinformation risk, compliance risk, political risk, societal risk, and risk of discrimination all affect the inspection process. These risks can be distinguished as actuarial or perceptual and process or impact-focused risks.

RQ3: What kinds of biases are seen in risk-based inspections and what causes these biases?

Firstly, the reason why risk-based and random approaches want to be combined is the bias that by focusing on high risks, lower risks are disregarded. This is caused by the lack of representativeness of the risk-based

inspection approach. Furthermore, the risk analysis process that is done within risk-based inspection is also prone to bias. This bias can be caused by human error if there is people involved in the process. Furthermore, even with methods for risk analysis that are specifically built to avoid human biases bias in the data can cause biased results and the applied method can also be biased because in some way human judgment is still involved.

RQ4: How can representativeness be improved with risk-based inspections?

Representativeness is the strong suit of several random inspection methods. To get this with risk-based inspection a combination of the two should be implemented. So far within this research, it is seen that inspectorates are mostly using expert consulting and risk assessment methods to develop inspection strategies. The inspectorate is looking for a way to combine random and risk-based approaches, but it is not possible to provide a straightforward solution as a single option. Because of the diversity of the food sector, there needs to be a method that helps the decision of which method to choose. Some methods distinguished in this thesis that show promise in the possibility of deciding on the combination of risk-based and random inspections are as follows. Scenario Tree Models can be used to generate multiple scenarios where scenarios combining risk-based and random could be compared and the optimal one could be chosen per inspected area. Agent-Based Modeling could be used to simulate the inspection plan scenarios of risk-based and random combinations could be simulated.

RQ5: What are important considerations to develop inspection plans and assess inspection methods?

The identification of purposes is important for inspection strategies. Especially when the purpose is to do mapping, or to combine mapping with risk-based approaches representativeness needs to be respected. To do this combination of random and risk-based approaches can be taken. Furthermore, methods to be used in the development of inspection strategies need to be assessed to see if they can be applied. This assessment is done on three levels. First sampling methods are assessed on their representativeness. The methods that support the decision on inspection strategies are assessed on certain criteria such as data requirements to see if they are applicable. These criteria can also be taken as requirements to use such methods. Furthermore, the conceptions of risk and bias provide valuable considerations for the development of inspection plans as well. These considerations are that depending on the purpose the inspection strategy needs to consider representativeness while choosing the methods. Furthermore, risk does not contain a single definition or perception. A multitude of perceptions are present and these need to be taken into account in the process of developing inspection plans. Finally, bias is an important concept that has been analyzed and the layers of bias need to be considered and the mitigation methods need to be used especially while using risk assessment methods.

9.3 Relation to MOT Master's Programme

This thesis has been written within the MSc Management of Technology program. The goal of this master's study is to teach students with a technical background how technology can be used as a corporate resource. It is important that organizations carry their responsibility to deliver no harm to their consumer, which is a key value that MOT students receive during their studies. It is important that inspections are carried out to fulfill the purpose of consumer safety and public welfare values. Furthermore, organizational decision-making is also the topic of one of the courses provided in this program. Therefore, this thesis investigates how inspectorates make decisions to inspect, what values come into play, and analyses methods of the decision process and how an organization can make use of such algorithmic methods.

A Interview Plan

A.1 Interviewee Selection

The interviewees from the industry are selected based on their experience in the inspection field and are recommended by the NVWA and AGES themselves. Furthermore, the interviewees are also asked to give recommendations to contact. The interviewees will not be mentioned by name for privacy reasons and will be referred to by a number. The interviewee numbers and their work area are presented in Table 1.

Table 6: Interviewees

Number	**Department/Role**
1	Risk Assessment – Animal Welfare
2	Risk Assessment – Chemistry
3	Enforcement - Chemistry
4	Enforcement -Microbiology
5	Statistics
6	Enforcement - Industrial Production
7	Statistics
8	Health Inspectorate

A.2 Analysis of Interviews

To analyze qualitative data it is important to categorize the data in a structured way. Coding is a way to organize and label the collected qualitative data in order to help the analysis of them. Since the interviews are semi-structured the coding themes are determined according to the expected outcomes for the thesis and are adjusted according to obtained information. The questions are formed in order to reveal the method used, ways for bias mitigation, and types and definitions of risks. Therefore the following list of codes is selected:

Table 7: Codes to Analyze Interviews

Code	Reason
Risk Model	To understand what kind of models and methods are used to measure risk in the inspection agency.
Risk Perception	To explore what is considered a risk in the areas interviewees are working at.
Bias	To investigate whether or not inspectorates are aware of the bias caused by risk-based inspections.
Decision Methods Used	To see what methods are used in the decision of inspection strategies
Advantage/Limitation of the Method	To see if the interviewee notices any practical limitations or advantages of the model.

A.3 Interview Questions

A.3.1 Questions to experts from the industry:

1. How are possible biases addressed in inspection resource allocation and decision-making process?
2. How do you both address known risky areas and explore new or less familiar areas?
3. How do you define risk?

4. How do you address possible biases that are associated with risk-based inspections?
5. What methods are used for making an inspection plan?

A.3.2 Questions to Academic Experts:

1. What types of risks do you see in food-safety?
2. Why are risk-based inspections important?
3. What are the main methods for RB inspections?
4. How do you categorize the types of methods for risk-based inspections?
5. What are the advantages and limitations of risk-based inspections?
6. Do you see examples of bias in risk-based inspections?
7. What are ways to address bias in risk-based inspections? Are there methods to do so?
8. What are ways to get a representative picture with risk-based approaches?
9. Can you think of methods that can combine random and risk-based inspections?

B Literature Overview of Methods

This table was developen in order to be able to collectively see what methods were found in the literature, for what reason they were used and in which area the method was applied.

Source	Purpose of article	Model	Purpose of the model	Area	Inspection Approach
(Alban et al., 2016)	Investigating a risk-based approach to monitor antimicrobial residues	Scenario Tree Model	estimation of costs and effects of changed sampling and testing strategies	Food safety: antimicrobial residues	Comparing risk-based and random
(Al Qubaisi et al., 2016)	to develop an AHP model for school performance inspection and explore its implementation in a private school system to provide an unbiased assessment of the candidate private and public schools in Abu Dhabi	Analytic Hierarchy Process (AHP)	to establish criteria weights	Education	
(Blickenstorfer et al., 2011)	Comparing full targeted sampling with part targeted, part random sampling	Scenario Tree Model	demonstrating freedom from disease	Food Safety: Animal Health	Comparing risk-based and combination of risk-based and random
(Chermiti, 2019)	to determine the customs risk factors associated with import declarations recorded in the customs clearance system.	Chi-square Automatic Interaction Detector (CHAID) decision tree	to uncover new information in large databases, to detect unspecified interactions between variables, and to create predictive models	Customs	Risk-Based Determining risk factors
(Boeck et al., 2015)	Define food safety climate and culture and develop a tool to assess the food safety climate in food companies	Self-assessment tool	providing a tool for FBOs to check themselves including the human dimension in food safety	Food safety culture & climate	-
(Boeck et al., 2019)	perform a method triangulation to gain insight in the food safety culture prevailing in a Belgian food service operation as a case study.	3 methods (combined): - verification of monitoring data of critical control points - internal audits - People related verification: food safety climate survey	assess FS culture at restaurants	Food safety culture	-
(De Carlo et al., 2011)	assess the usefulness of the integration of a qualitative risk-based inspection (RBI) procedure	Bayesian Belief Network (BBN)	to model RBI's to evaluate the likelihood factors	Industrial Safety	Risk-Based
(Geng et al., 2017)	to propose a model to help build optimization and prediction model of food safety inspection data(?)	Analytic hierarchy process (AHP) integrated extreme learning machine (ELM) (AHP-ELM)	to identify of potentially emerging food safety issues	Food Safety	
(Greda, 2009)	to demonstrate the application of multicriteria decision-making methods in selecting the most efficient option of quality management system in the food industry.	Analytic Hierarchy/Network Process (AHP/ANP)	to structure a decision-making problem concerning the selection of the the best combination of quality management systems in food companies.	Food Safety	
(Lin, Cui, Han, Geng, & Zhong, 2019)	propose a model to hierarchically analyze influencing factors of food safety	interpretative structural modeling (ISM) method based on the grey relational analysis (GRA)	The correlation coefficient between influencing factors is calculated by the GRA The ISM is used to stratify the influencing factors of food safety	Food Safety: Sterilized milk	
(Martin et al., 2007)	to present a methodology for objective quantitative analysis of multiple complex data sources to support claims of freedom from disease.	STM	demonstrating freedom from disease	Animal Health	

(Pielaat et al., 2018)	to present a methodology for risk-based sampling that includes an optimization procedure to monitor the prevalence of foodborne pathogens at the retail level in relation to their burden of disease.	optimize a sampling plan	a monitoring program containing pathogen/retail product combinations that detects a maximum amount of disability-adjusted life years(DALY's) for a given budget	foodborne pathogen in retail products	Risk-Based
(van Asselt et al., 2016)	to determine whether ABM could be useful for inspection agencies to optimize their intervention strategies	Agent-Based Modelling (ABM)	to simulate compliance behaviour of entrepreneurs	Food Safety	
(Van Asselt et al., 2021)	overview of methods	Overview: Risk ranking methods	-	Food Safety	
(van Asselt et al., 2012)	overview of methods	Overview: Risk ranking methods	-	Food Safety	
(Van Der Fels-Klerx et al., 2018)	to review available methods for ranking risks associated with food on the basis of anticipated health impact, to characterize the methods and to provide recommendations for their use	Overview: Risk ranking methods	Ranking food-related hazards, based on their impact on human health	Food Safety	
(L. Wang, 2018)	propose and test a model to support optimization problems on food safety monitoring design an optimal monitoring network for the administrational department of food safety regulation with consideration of the complexity of food supply networks and the limitation of monitoring resources	a directed graph-based social network model 0–1 linear programming model	design optimization of hazard monitoring network selection of the optimal monitoring points	Food Safety	
(X. Wang et al., 2022)	overview of ML applications in food safety	Machine Learning	-	Food Safety	
(X. Wang et al., 2023)	to explore the use of weight-added BN classifier to improve the model classification accuracy in the context of unbalanced food safety monitoring data	Weighted Bayesian Network	to improve the model prediction accuracy for the presence of food and feed safety hazards using unbalanced monitoring data, specifically for the presence of heavy metals in feed.	Food Safety	
(Z. Wang et al., 2022)	to develop a framework for optimizing food safety monitoring schemes to reduce monitoring costs while guaranteeing the identification of non-compliant samples	Bayesian network and integer programming	predicting the conditional probability of suspect samples, (samples with contamination levels over threshold limits), under different conditions and estimating the number of samples to be analyzed yearly for each food product	Food Safety	
(Wiśniowski et al., 2020)	to evaluate a method of integrating relatively small probability samples with non-probability samples to improve the efficiency (i.e., reduce variability) and reduce the mean squared error for estimated regression coefficients	Bayesian Inference Model	combining both probability and non-probability samples in a way that exploits their strengths to overcome their weaknesses	Survey Collection	Combining probability and non-probability sampling

C Interview Results

Number	Department / Role	Risk Measuring / Risk Model	Risk Perception	Bias	Area	Method used	Advantage / Limitation of Method
1	Risk Assessment – Animal Welfare	Probability of occurence within animals * impact on animal welfare	in enforcement they see risk as: is the law complied with yes or no in the risk assessment department they see risk more broadly, as opportunity and effect, which is then the risk regardless of whether or not it is stated in the law.	random inspections are done to see what happens in the sector	Animal welfare		likelihood*impact works in theory but in practice we lack the data and move with expert estimates
2	Risk Assessment – Chemistry	-	Risk is a situation or event when something of human value, including human themselves has been put at stake and where the outcome is uncertain.		Chemicals		
3	Enforcement - Chemistry	Decision based on the occurrence of substance in the in the past if it is found a lot it should be high. They have no system for it	There are differences in the definition of risk, pain medication is not a problem for us but for animal welfare, it is	Bias towards the companies that are not known Only including noncompliant companies, does not provide an overview of the food safety situation in general.	Chemicals	No system for prioritizing risks but looking at historical data and deciding based on high-prevalence of substances what is a high risk.	
4	Enforcement - Microbiology	Not only probabilities or consequences but whether a factor is an indicator of many other factors is important	consequence-based Cost of illness, disease burden	bias in the selection of the pathogens	microbiology / pathogens	Selection of pathogen Selection of the place in the foodchain (where to sample) Selection of type of product Within the selection as random as possible to be able to say something about the prevalence of these pathogens in these types of products in the chain	
5	Statistics	Risk factor identification by expert opinions or common sense. Risk factors are included in sampling probability allocated per farm (e.g. High risk, higher probability of being selected) Prioritization is probability-based and not regarding consequence except for zoonotic diseases(if humans can contract them)	Probability based	usually farms that were selected in the previous year are also not included in the sample to avoid systematic bias. They don't think there is bias in risk-based inspections. They think risk-based is the right way to go here. The only question is are risk factors are defined correctly? There's always a chance of missing the disease.	Animal health, animal disease surveillance	stratified weighted random sampling, weighted by the risk factors. Sample size calculation based on random sampling. Than defining risk factors based on expert opinions.	There is lack of data to identify risk factors Scenario tree models don't use it because basically you need a lot of estimates for probabilities of different of these different scenario branches which we found very hard to come by
6	Enforcement - Industrial Production	risk categorisation adapted from a South Austrailan model	non compliance	for us the risk was that we saw a companies in the corner of our eyes and we never visited them. And sometimes you have very low-risk companies who only import lemonades or something like that and only take the box and so you don't have to come there every year, but every once in a certain period of time, you should at least contact them. Therefore adding the new factor helps with this	Industrial Products	Adapted model of ERA with a factor of the time the company has not been inspected as a risk factor.	limitation when there are external demands on inspections
7	Statistics	a risk ranking of the risk strata of the categories is discussed by experts.	non-compliance	They investigate all areas, ones that have high risk more frequently and lower risks maybe once in 10 years.	Feed inspections	Risk scoring to categorize risks. Control frequency is set by trial and error.	-
8	Health	Risk assessment based on legislation and experts	Consequence based	With risk-based it is not possible to get a feel of how it is going in general	Health	Comparison method to compare random and risk-based	-

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