Impact of context on food safety management systems in fresh produce chains

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Table of contents

Chapter 1:
General introduction

1.1. Veg-i-Trade project

This research was a part of a project within the 7th Framework Programme of the European Commission called VEG-i-TRADE that was aimed at identifying impacts of climate change and globalisation on food safety, microbiological and chemical hazards, of fresh produce and derived food products. VEG-i-TRADE formed a multidisciplinary network between experts in food science (food microbiology, food chemistry, food technology, food quality management), climate change, logistics, food industry (SMEs, as well as large industrial companies) and representatives of stakeholders from the European Union (EU) and third party countries.

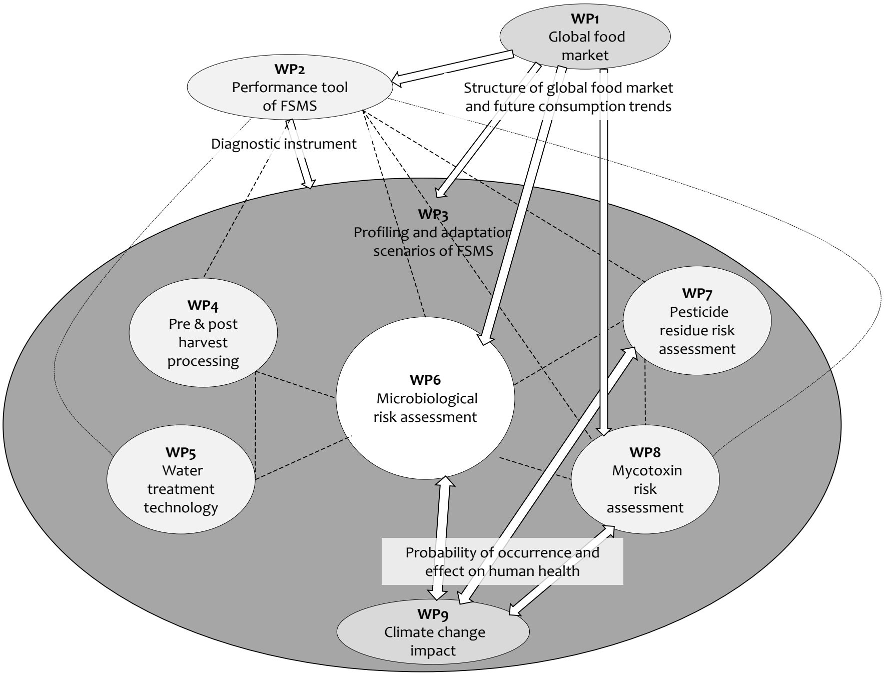

Figure 1.1: VEG-i-TRADE universe

Overall, the project encompassed development of food safety management strategies and guidance on their implementation, and sought to provide problem solving by fundamental and applied research studies, modelling approaches and observational studies, analytical lab testing and field studies, control measures and quality assurance systems, risk assessment and risk communication.

The research described in this thesis was performed as part of work packages two and three (Figure 1.1), focused on studying food safety management systems (FSMS). FSMS are this part of the quality management system of a company that is specifically addressing food safety *(295)*. The aim of the research was to analyse performance of FSMS in fresh produce chains, in Europe and globally, in order to identify opportunities for improvement. Another objective was to identify the possible consequences of changing climatic and trading conditions for FSMS in fresh produce chains, and to develop adaptation strategies. Data collection and analysis were performed in close collaboration with the partners in VEG-i-TRADE project.

1.2. Food safety hazards in fresh produce

Fresh produce encompasses a diversity of products (fruits and vegetables) including whole unprocessed heads, mixed cut and ready-to-eat fresh products, bulk as well as pre-packaged or minimally processed. In the last years the demand for convenient, healthy and tasty fresh and derived food products has increased. Between 2000 and 2011, the world production of fresh fruits and vegetables grew by 38% *(138)*. However, international, European and national concerns have emerged with regard to safety of fresh produce in response to recent outbreaks and reported emerging hazards linked to fresh produce and derived food products.

Several food safety hazards are related to the consumption of fresh produce and derived food products. Enteric bacteria such as *Salmonella* spp. (*e.g.* tomato-cilantro-peppers outbreak in US in the summer of 2008), *Escherichia coli* 0157:H7 (*e.g.* spinach outbreak in the US in 2006, 2011 outbreak in Germany finally linked to bean sprouts), *Listeria monocytogenes* (*e.g.* cantaloupe outbreak in the US in September 2011) and more recent, but no less relevant, also enteric viruses such as Norovirus and protozoa such as *Cyclospora cayatanensis* have been identified being of concern in fresh produce *(15, 33, 271)*. Because of the absence of an adequate heat treatment before consumption of fresh produce the risk cannot be circumvented by the consumer. Another group of hazards associated with fresh produce is mycotoxins, which are a group of chemical substances that are produced by toxigenic moulds that commonly grow on a number of fruits *(465)*. Pesticide residues are also still of concern among consumers *(464)*. All these hazards were taken into account in the analysis of activities in the FSMS.

1.3. Food safety management in the fresh produce chain

While the food safety hazards represent the inherent characteristics of the biological or chemical agent, the risk to food safety represents the probability of an adverse health effect to happen and the severity of that effect *(64)*. To address this risk, every food company, including these in the fresh produce chain, has to implement a food safety management system (FSMS). FSMS are based on various standards and guidelines (*e.g.* Codex Alimentarius codes of practice, GlobalGAP, Q&S) posed by public and private (*e.g.* retailers) stakeholders, which need to be translated by food producers into their specific production circumstances. The food safety governance and control by third parties (*e.g.* governmental agencies, audit companies) have experienced difficulties due to, among others, fragmentation and diversity of the supply chains of fresh and derived products *(165, 392)*. Fresh produce is grown, processed and consumed in multiple ways and produced in diverse conditions throughout the world but also within the EU with its many cultural differences and richness in regional products and ways of preparation *(23, 417)*. Produce is grown in farms and distributed in supply chains that vary from very small to very large, small and industrial scale. Moreover, legislation and quality assurance guidelines for the fresh fruits and vegetables sector are not as well defined and organised as these for the meat and dairy industries *(229)*. Quality assurance requirements or guidelines *(e.g. 66, 176)* are general in nature, lacking a scientific base, and difficult to translate into a specific FSMS. Implemented FSMS along the produce chain are not always performing satisfactory, related to inadequate sanitation, improper practices, etc. *(220, 244, 275, 280)*. Therefore, insight is needed on the factors affecting the status of FSMS along fresh produce chains, to identify their weaknesses and opportunities for improvement.

1.4. Systems theory and structure of FSMS diagnostic tool

To understand the performance of any system, we need to first understand and specify the system with its elements. A system has been previously defined as an organised whole of related elements, which creates emergent properties and has a purpose *(415)*. All systems have a structure of subsystems and their elements, and form part of other systems in a hierarchy of systems *(415)*.

According to Luning et al. *(286, 291, 295)* an FSMS consists of:

- control activities including all strategies aimed at keeping product and process conditions within acceptable safety limits, and
- assurance activities aimed at providing evidence and confidence to stakeholders about meeting the requirements.

Furthermore, the contingency theory, which is stemming from the general systems theory, is stating that there is no best way to organize or manage a system. Instead, it explains that performance of the system and its optimal course of action are dependent on the internal and external situation *(273, 440)*. Contingency research has been aimed to find structural devices and operating methods that ensure long-term survival of the systems in different types of contexts *(319)*. Contributions of this approach have been achieved in theory and practice by identifying important contingency variables that distinguish between contexts, grouping different contexts based on the contingency variables, and determining the most effective internal organization designs or responses in each major group *(423)*.

Figure 1.2: Contingency research principles *(423)*

The theory has a long history of use in organisation sciences, with extensive application in operations and quality management. In those studies three types of variables are commonly involved *(*Figure 1.2; *423)*:

- Contextual (or contingency) variables represent situational characteristics usually exogenous to the system. In most instances, the opportunity to control or manipulate these variables is, at best, limited or indirect. However, in some cases, there is a possibility to change these variables, but it is only possible in the long-term and with substantial effort (*i.e.* they are variables with high inertia);
- Response variables represent the system or management actions taken in response to the current or anticipated contingency factors;
- Effectiveness variables are the dependent measures and represent specific aspect of effectiveness, which are appropriate to evaluate the fit between contextual variables and response variables for the situation under consideration.

In a similar vein, studies provided evidence that performance of food quality management systems is related to characteristics of a company's context *(98, 424)* such as size, organisation, technology and environment. Recently, a diagnostic tool was developed to diagnose microbiological FSMS implemented in food processing meat and dairy companies in view of their context *(230, 237, 286, 294, 295)*. The tool includes an assessment of the contextual situation with its variables (*i.e.* context factors) in terms of the decision-making during FSMS activities *(294, 295)*. The response variables are represented by systematic analysis of which core control and assurance activities are addressed within the company specific FSMS and an assessment of the levels at which these activities are executed *(286, 295)*. The assessment of the effectiveness variables (*i.e.* system output) is done through key food safety performance indicators *(230)*.

The contingency theory is in the heart of this research, as we focus on the main contextual variables that affect the status (response and effectiveness) of FSMS in the fresh produce chains.

1.5. Principles behind FSMS diagnosing

To diagnose the status of FSMS, the relation between the context and the FSMS is described in terms of riskiness to decision making within the FSMS. The riskiness has been represented by *uncertainty* due to lack of information, *ambiguity* due to lack of understanding, and *vulnerability* due to inherent risk in the product, process or organisation *(294)*. The uncertainty is reduced by adequate information and systematic methods, ambiguity – by scientific information, and vulnerability – by systematic methods and independent positions *(294)*. Therefore, three levels have been defined to assess the FSMS activities by using the differentiation criteria: use of scientific knowledge, specific information, critical analysis, procedural methods, systematic activities, and independent positions *(286, 295)*. Following the contingency theory, the concept behind the diagnostic tool is: if there is high risk in the context situation then advanced FSMS activities are required to result in a predictable and controllable output. The system output represents the probability of failure in the FSMS, leading to adverse health effects. Structured information about the FSMS output through its key food safety performance indicators, according to very strict and specific criteria will provide better insight in the actual performance, because food safety hazards will be more systematically detected *(230)*. The assessment with the diagnostic tool provides insight into the relations between the context, FSMS activities and the system output.

This previously developed tool is aimed primarily on microbial food safety performance of meat and dairy processing industries and catering but is not covering the FSMS across the supply chain *(287, 289)*. It is not suitable for the specifics of the fresh produce industry, and is not considering chemical hazards such as pesticides and mycotoxins. Moreover, the FSMS diagnostic tool is aimed at measuring performance of FSMS at the lowest sub-system level – the food business operators (companies). It is not considering the hierarchy of systems and the existing superior suprasystems, as described by the system theory. A hierarchy consists of sub-systems that in turn structure the system, and the latter is also part of a superior suprasystem *(415)*. Studies highlighted the strong link between physical, social, and economic systems and associated risks *(382)*. The concept of *systemic risks* has been established to define the risks formed at the intersection between natural events, technological, economic and social developments, and policy-driven actions on domestic and international level *(224, 263, 344)*. Systemic risks related to climate change and globalisation of trade are expected to affect food safety of fresh produce on a middle and long-term *(229)*. There is a need to study the impact of such suprasystems on the status of FSMS in fresh produce.

1.6. Context of food safety governance

One such superior suprasystem is food safety governance. By governance are understood all the institutions, structures and collaboration between stakeholders, put in place to control and coordinate a certain activity *(431)*. Food safety governance enforces the implementation and operation of FSMS in food companies.

The ex-ante regulatory enforcement was previously conceptualized by May & Burby *(308)* into enforcement philosophy, strategy and practices (Figure 1.3). The enforcement philosophies were described as ranging between facilitative, which use standardized rules, supervision and deterrent techniques, and systematic – based on discretionary enforcement and incentives (May & Burby, 1998). The strategy represents the choices taken by the agency, and defines the practices, which can involve inspections, sanctions, and information (Rouvière & Caswell, 2012).

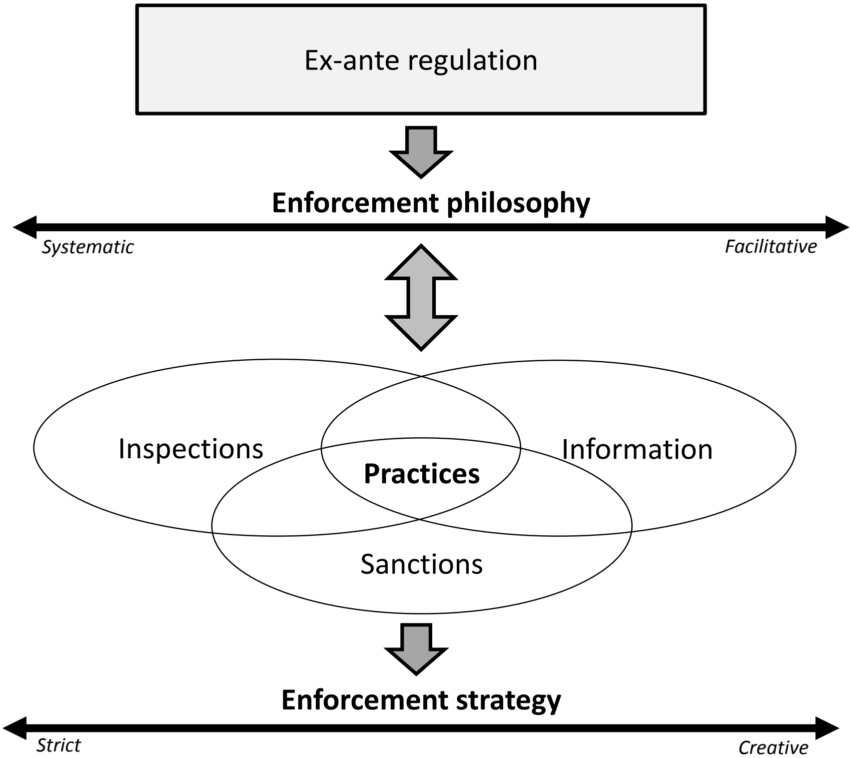

Figure 1.3: Conceptualization of enforcement *(308, 391)*

Food safety governance, however, can include public and private actors, standards and codes of practice *(164)*. Three types of enforcement strategies have been described by Ménard & Valceschini *(314)*:

1) The first traditional approach, which relies on public regulations and their enforcement by a public agency;
2) The second approach, which mixes public and private actors; and
3) The third approach, which relies on private standards and codes of practice.

Selecting one of these strategies is a major challenge for legislators and executives in the food sector, because each of these follows a different underlying philosophy and involves different enforcement practices. Moreover, there is no clear evidence about the effect of each strategy on the final food safety management on a company level. Recent studies focus on the mechanisms behind public and private food safety governance *(164, 391)*.

However, research is lacking on the actual effect of food safety governance on FSMS in food companies.

1.7. Supply chain context

FSMS are implemented in companies that are part of supply chains. Supply chains are organised and managed differently in the quest to achieve better alignment of goals, resource sharing and collaboration. Previous research suggests that different approaches of supply chain management can affect quality management alignment *(378, 478)*.

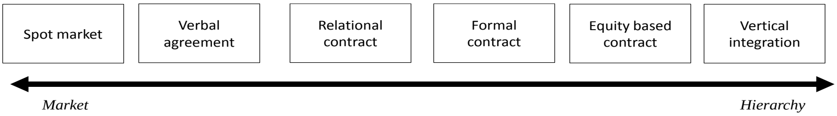

Figure 1.4: Transaction-cost-economics typology of supply chain management *(378)*

Different types of supply chain management have been defined from a transaction-cost-economics perspective, ranging between spot market and vertical integration *(*Figure 1.4; *378)*:

- In the case of a spot market the goods are exchanged immediately and the identity of the partners is irrelevant, and often unknown;
- Verbal agreements are not legally enforceable, but rely on reputational and social ties;
- Relational contracts are established with qualified partners (*e.g.* certified);
- Formal contracts are legally enforceable and can have different duration;
- Equity based contracts are concluded in cases when one company has shares in a partner company, but is still legally independent;
- Vertical integration brings two or more stages of the supply chain into common management and ownership.

This typology is established according to the extent of which one actor controls other stages of the supply chain *(482)*. However, questions arise regarding the effect of different types of supply chain management on actual design and operation of FSMS, especially in companies located upstream in the supply chain (that is, primary production).

1.8. Context pressures due to climate change

FSMS at primary production are exposed to climate and other environmental influences. In the last years worries have emerged regarding climate change and the effect on food safety. Questions were raised regarding adequacy of current FSMS to the changed (climate) circumstances, would FSMS be able to respond to the new challenges posed by climate change, and how that should be done. Climate adaptation studies focus on response to climate change in terms of agricultural production *(62, 469)*. However, systematic information about responses in view of food safety and quality assurance are lacking.

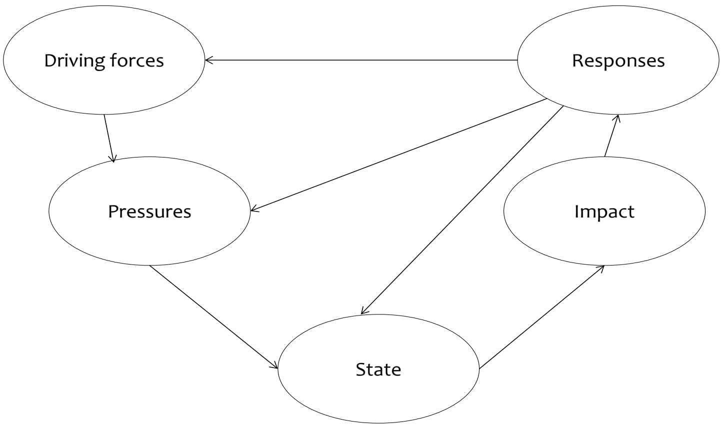

Figure 1.5: DPSIR framework *(345)*

An analytical framework has been used in climate change studies to investigate the pressures put on human systems due to the driving force of climate change *(*Figure 1.5.; *345)*. These pressures are exerted on its current state, which has an impact on humans and society. The framework is used to define indicators and generate response strategies on different levels. This framework does not include analysis of food safety and FSMS, and was therefore modified for the needs of this research.

1.9. Integrative use of theories within the techno-managerial approach

FSMS are complex systems conditioned by behaviour and interaction of food and humans *(290)*. Moreover, FSMS are influenced by the context in which they operate, consisting of complex natural (such as climate) and social suprasystems (such as food safety governance). A variety of approaches, methods and techniques exists to investigate these (supra)systems, originating from various disciplines and following different paradigms. Mingers & Brocklesby *(322)* proposed the following possibilities for using methodologies to deal with complex, multi-dimensional problems and design more effective interventions:

- Methodological isolationism – using only one methodology from only one paradigm;
- Methodology enhancement – using techniques from one methodology to enhance another within the same paradigm;
- Methodology selection – selecting several methodologies appropriate for one situation;
- Methodology combination – combining several methodologies into one intervention;
- Multimethodology – combining parts of different methodologies.

Similarly, Luning & Marcelis *(290)* advocated the integrative use of theories to study the complex problems in food quality management. They developed the techno-managerial approach, which involves the connection of technological and managerial models to analyse how human behaviour influences food and vice versa *(290)*. Moreover, the approach allows to study the dependence of food safety on the dynamics of food and food safety hazards related to the technological and environmental conditions, and dynamic properties of people as related to the administrative conditions. The authors assumed that this approach will bring broader insights than analysing food quality and safety problems from technological perspective alone.

By following this approach, a model was developed to support analysis of companies' organisation in their environment, and the interaction between technological and managerial functions aimed at food quality *(*Figure 1.6; *291)*. In the model it is assumed that the environment of the organisation, including social, political, economic, and technological circumstances, has an impact on decision-making regarding food quality and safety, through power and interests *(291)*. However, the suprasystems in this environment and relationships with organisations and their implemented food quality and safety systems need to be further investigated and defined.

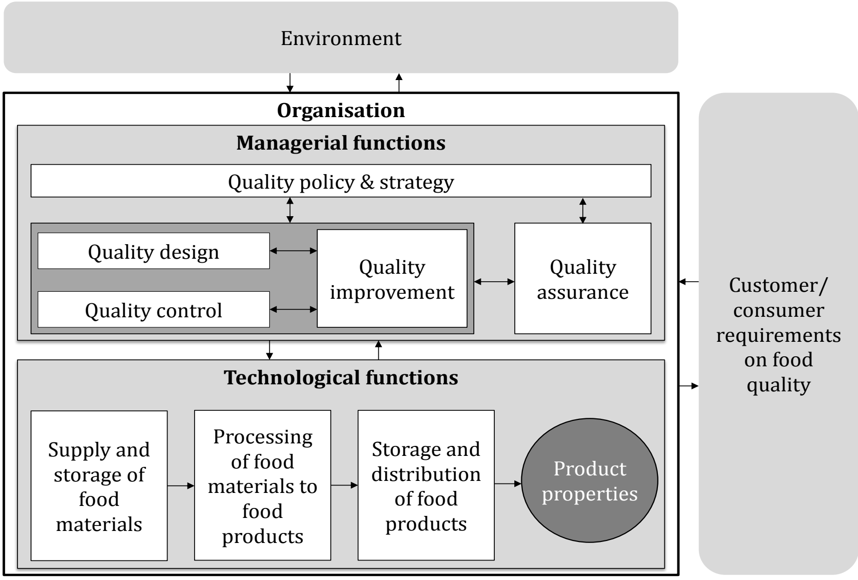

Figure 1.6: Food quality management functions model *(291)*

1.10. Objective and outline

The objective of this thesis was to investigate the impact of context on FSMS in the fresh produce chain. Under context we aimed to study the broad context in which companies operate, including suprasystems (*i.e.* policy, supply chain management, climate) that may directly and indirectly influence the actual set-up and operation of FSMS. The research was based on the techno-managerial approach, which involves the integrative use of theories from technological and social sciences to explain the dynamic mechanisms of food and human behaviour, and their interaction *(290)*. By following this methodology, this research involved systematic analysis of theoretical concepts/models (as described in the previous sections) and practical data/information (*e.g.* interviews with experts, reports of national agencies).

Furthermore, several research questions were defined:

Q1) Which FSMS activities (control and assurance) are crucial for prevention and reduction of microbial and chemical (natural and manmade) contamination of fresh produce along the chain?

Q2) Which context factors on a company level are critically influencing FSMS in the fresh produce companies?

Q3) Which sub-systems in the broad context of a sector and country can have an impact on companies and their FSMS?
Q4) How can these influence the FSMS and their output?
Q5) What are the major pressures posed by climate change on FSMS activities in fresh produce?
Q6) How should FSMS respond to face these emerging pressures of climate change?

The *broad context* in a sector and country involves different social, political, economic, and technological circumstances. Therefore, interdisciplinary approach was needed to link concepts from different fields, and provide scientific evidence about the systems in the *broad context* that can impact the set-up and operation of FSMS. The scientific challenge was to bridge the gap between disciplines such as food technology, quality management, political economy and supply chain management. The approach could also be defined as transdisciplinary, as it related stakeholders/problem owners and scientists from different domains to develop novel conceptual and methodological frameworks with the potential to produce transcendent theoretical approaches *(389)*. The research was problem-oriented and involved companies, sector organisations and academia.

Figure 1.7 presents the sequence of the different chapters with their main focus, in the pursuit to answer the research questions. The research started with the development of a 'diagnostic tool' to systematically assess performance of current company and farm specific FSMS in the fresh produce chain (chapters 2 and 3). Identification of the indicators for the diagnostic tool for fresh produce was done through a comprehensive literature study and semi-structured expert interviews. The tool was validated through an expert evaluation on relevance, validity and reliability of selected indicators and developed grids. Further validation was performed by pre-tests at different chain actors in the fresh produce chain to test understandability and availability of information, and pilot tests to evaluate validity of the tool. In the next three chapters validated diagnostic tool was used for data collection. In **chapter 4** a theoretical framework was developed to investigate the influence of the *broad context*, encompassing agro-climatic environment, market environment, public policy environment and food safety governance. It was applied in three case studies where the influence of the *broad context* was investigated, with a stress on food safety governance. The aim of **chapter 5** was to study the effect of market and supply chain management on FSMS implemented at farms in three differently organised marketing cooperatives, with different size and governance of transactions. The main context factors defining the variability of the FSMS over companies, supply chains, and countries were studied in **chapter 6**, where a quantitative statistical study of all data collected within VEG-i-TRADE project was performed. Based on the principles of DPSIR the pressures exerted from climate change on FSMS at farm level were investigated and response options were defined in **chapter 7**. The final **chapter 8** summarizes the main findings of this thesis, followed by a critical discussion about the implications for theory and methodology, companies and policy. Furthermore, directions for future research are suggested.

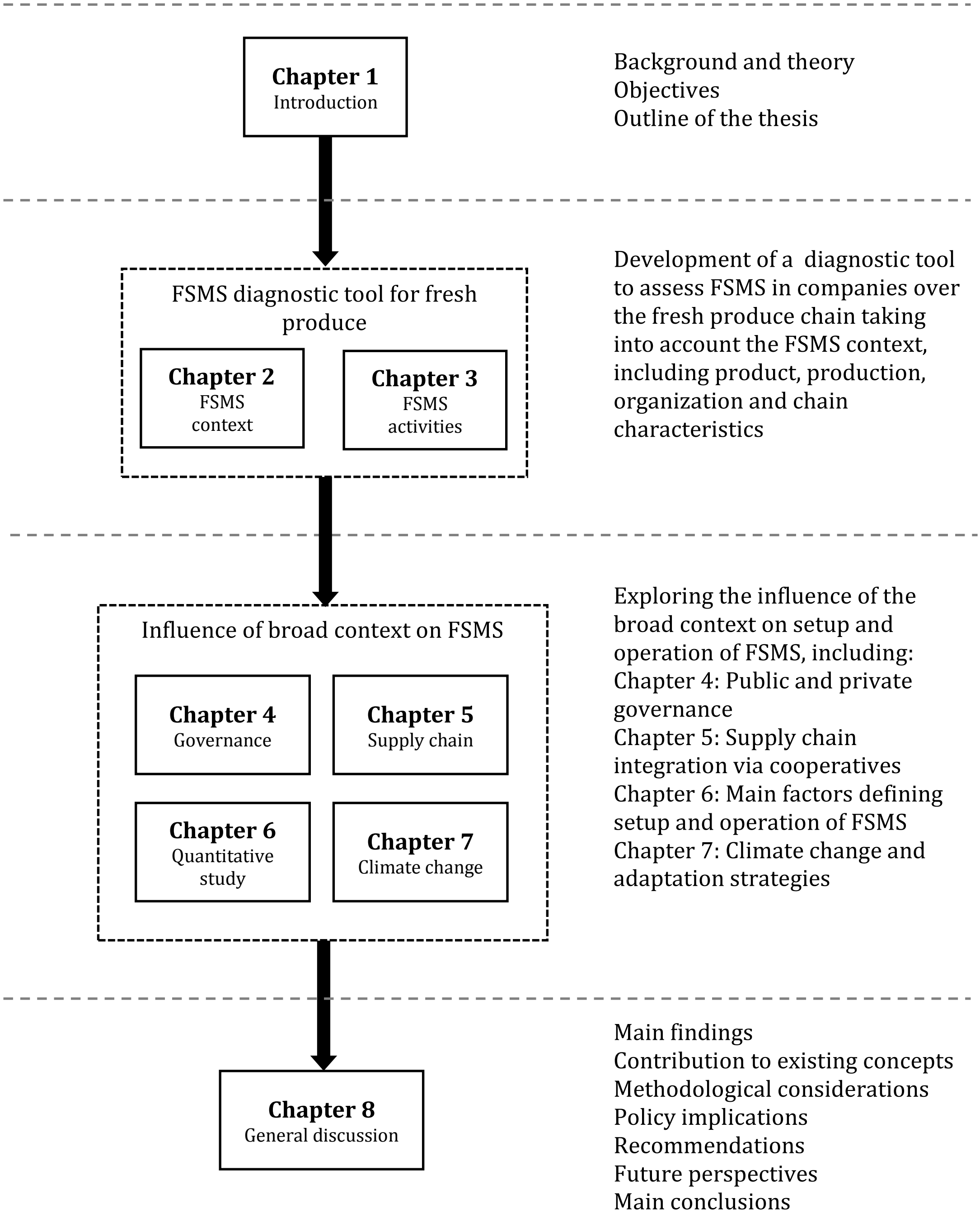

Figure 1.7: Outline of the thesis

Chapter 2:
Assessment of Food Safety Management Systems in the global fresh produce chain

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Abstract

Foodborne outbreaks appear to increase with more incidences linked to fresh produce and derived food products. This indicates inadequacies in Food Safety Management Systems (FSMSs), which are currently implemented in companies along the fresh produce chain. However, the information related to these inadequacies is restricted and little is known about the status of the FSMS. This paper describes the development of a tool for assessment of FSMS implemented in the fresh produce chain. The tool consists of indicators and grids to assess activities that are important for fresh produce, and the system output in terms of microbiological and chemical food safety (that is, pesticide residues and emerging mycotoxins). Three sets of indicators, one for each stage of the production chain (primary production, processing and trade), have been validated by experts and tested in companies. The tool enables an integral and comprehensive assessment of FSMS across the entire supply chain. Users of the tool can identify improvement opportunities and learn how to develop towards more advanced levels of activities. For research purposes differences in FSMS can be identified and linked to type of commodity, production system, country, etc.

2.1. Introduction

For more than a decade the focus of food safety management in Europe has been on animals and animal products *(12, 69)*. Concomitantly, trade and consumption of produce have notably increased *(116)*. Foodborne outbreaks also appear to increase with more incidences linked to produce and derived food products *(297, 414, 437)*. Fruits and vegetables are often consumed raw, fresh-cut or minimally processed, whereat elimination of contamination is impossible or limited. Primary production, processing and trade activities occur in diverse climates around the globe, in different administrative conditions, in a traditional, structured or industrialized food systems, and the actors in the supply chains vary from very small to very large *(310)*. Every operator in these chains is advised to implement a specific Food Safety Management System (FSMS) *(65)*. An FSMS is the result of the implementation of available and relevant quality assurance guidelines and standards (like, Codex Alimentarius, hygiene legislation, guidelines on good practices, GLOBALGAP, BRC, IFS, etc.). At primary production these FSMS are a result from implementing good agricultural and hygiene practices, while, at processing and trade, the FSMS includes good manufacturing and hygienic practices, and HACCP-based principles. FSMS comprises the equipment, procedures, programs, tools, organizational measures, and people necessary to execute the control and assurance activities aimed at ensuring chemical and microbial safety of fresh produce.

The translation of these requirements into a company-specific system remains a challenge, because requirements and guidelines are often general in nature, not specific to the type of production, differing per region or lacking scientific base; therefore, food business operators lack guidance for the implementation into their own FSMS *(192, 355, 430, 454)*.

Several studies have already indicated inadequacies in currently implemented Food Safety Management Systems (FSMS) in fresh produce chains, related to insufficient sanitation, hygiene deficiencies, and improper production practices *(220, 221, 244, 275, 280)*. Information is nevertheless restricted and little is known about the status of core control and assurance activities in implemented FSMS in view of the system output. Therefore, insight is needed into the status of FSMS in fresh produce chains, which is independent of the implemented legislation and quality assurance standards. For a similar purpose a diagnostic tool has been developed previously to assess microbial FSMS in the manufacturing sector of animal derived products (that is, meat processing and dairy companies) *(230, 286, 295)*. However, the tool as such is not suitable for the specifics of the fresh produce industry, not considering specific activities associated with primary production or processing of fresh produce, such as washing, the use of irrigation water, etc. Moreover, it does not consider pertinent to fresh produce chemical hazards such as pesticides and mycotoxins.

The objective of this study was to gain insight into the activities important for (fresh) produce that determine the chemical status in terms of pesticide residues and mycotoxins, and the microbial status of the FSMS. The outcome of an international discussion forum in January 2011 helped to identify the risks of biggest concern in the fresh produce chain *(464)*. Furthermore, the aim was to develop a diagnostic tool to enable assessment of the FSMS implemented in companies working with fresh produce and derived products across the supply chain.

2.2. Materials and methods

2.2.1. Main principles for FSMS assessment

The assessment tool for FSMS in (fresh) produce has been developed in alignment with principles for analysis of FSMS considering both technological and managerial factors *(290, 292)*. It involves the assessment of core ***control*** and ***assurance*** activities, where both types of activities contribute to the ***system output*** *(286, 292)*. Control activities are aimed at keeping product and process conditions within certain limits and assurance activities are focused on setting, evaluating and modifying the system *(291)*.

The assessment of the system output is based on information from external (i.e. audits, complaints) and internal activities (i.e. sampling information, non-conformity) for judging the FSMS *(230)*. All control and assurance activities and system output activities are assessed through indicators with corresponding grids. The indicators aim to collect information about essential aspects of an activity that gives evidence about the actual situation. The grids depict typical situations in which companies can be placed.

Control activities are grouped into three types according to their function: preventive, intervention and monitoring. Preventive control activities are aimed at preventing product contamination; intervention activities are directed towards eliminating the contamination, and monitoring activities provide information about the status of the product and the process to enable corrections *(286)*. The assessment of core control activities distinguishes design and actual operation. Indicators for core assurance activities include defining system set-up, validation, verification, and documentation and record keeping. Four situations are specified for each indicator of control and assurance activities; these are low (level 1), basic (level 2), average (level 3), and advanced (level 4) level. The criteria to differentiate the levels are: use of scientific knowledge, specific information, critical analysis, procedural methods, systematic activities, and independent positions *(294)*. In the current tool, the low level reflects that an activity is not possible/applicable (for instance, that no full intervention is possible for fresh salads), or is not applied/not done, although it is possible (for example, water control), or is unknown (such as the actual operation of activities). The basic level of control activities is characterized by standard equipment, unknown capability, use of own experience/general knowledge, and incomplete methods; these result in restricted specific information, a lack of critical analysis, and a non-procedure-driven activities. The basic level of assurance activities is typified as reactive; ad-hoc; using historical data; using non-independent judgments; lacking data analysis; unstructured; and undocumented. The average level for control activities is typified as best available in practice; potentially capable equipment; methods and programs supported by suppliers; based on expert knowledge/(sector) guidelines; structured; and standardized. The average level for assurance activities is typified as active; based on expert knowledge or regulatory information; using additional analysis; regularly reported; structured; and up-to-date. The advanced level for control activities is typified as equipment, methods and programs that are tailored/modified for specific circumstances; capability that is tested; information that is specific; activities that are based on scientific sources or knowledge; activities that are procedure-driven and comprehensively reported; measuring equipment that is standardized and internationally acknowledged. The advanced level for assurance activities is typified as pro-active; using feedback from own FSMS; using specific information sources; using own tests or trials; using independent judgments; performing additional analysis; using actual performance measurement; structured; up-to-date and extensively documented.

The four situations for the system output indicators reflect no indication on system output (level 1), poor (level 2), moderate (level 3), and good (level 4) system output. The criteria to differentiate the levels are: structured evaluation, according to very strict and specific criteria, leading to systematic detection of the food safety problems *(230)*. In the current tool, a level of 1 is given when the activity is absent, not done, or not present. Level 2 relates to limited external system evaluation, ad-hoc sampling, using only compulsory judgment criteria, and several major food safety problems because of various causes in the FSMS. Level 3 represents multiple external system evaluation, regular sampling, using several judgment criteria, and some safety concerns, but is restricted to one aspect in the functioning of the FSMS. Level 4 corresponds to comprehensive external system evaluation, structured and comprehensive sampling, using all-encompassing judgment criteria, and no safety concerns in the FSMS.

It is important to note that the tool is not an 'audit tool' or an 'inspection tool' with detailed technical questions, as used for auditing commercial standards or governmental inspections. The assessment is independent of the implemented and certified legislation, guidelines and quality assurance standards. The tool is used as a self-assessment, where users of the tool need to assess which situation best represents that of their company. The assessment tool also functions as a research tool and the data collected at various farms or food businesses, enables to identify strengths and weaknesses common for a country, subsector, or food system. The self-assessment tool is useful as an internal audit system to track the "maturity" of the systems in place. It provides insights to the users about the status of the FSMS, independently from the implemented guidelines and quality assurance standards in place. The assessment provides insight into underlying mechanisms, and shows the different ways (levels) in which activities can be implemented. It gives first indication about possible points for improvement that need to be further investigated.

2.2.2. Identification of indicators and development of grids

Any assessment tool must be reliable and valid, and we have considered this throughout the development process. We have started by identifying the content material, and then selected indicators and formulated the grid descriptions. This process was based on a comprehensive analysis of the literature addressing crucial aspects of control and assurance of the chemical and microbial safety of fresh produce. Moreover, semi-structured interviews were conducted with experts (n=6) in the fields of food quality management, microbial and chemical food safety, the processing and handling of fruits and vegetables, and water technologies. The interviews aimed to confirm, discuss and modify the initially selected indicators and corresponding grid descriptions, and identify omitted indicators or issues in the grids.

2.2.3. Introduction to the assessment of the FSMS

In the beginning of the assessment an introduction was also included; this contained general questions about the companies: size, location, applied and certified quality assurance standards, number of employees, other activities (such as mixed farming), training of the owner/quality assurance manager. This information can be used later on to perform a secondary analysis; for example to investigate the impact of certification, mixed farming activities, company size, and so on.

2.2.4. Validation by experts

To further validate the tool, we invited 22 experts to complete a questionnaire, in order to confirm the selected indicators with their underlying assumptions, which reflected the advanced level in the grids. The invited experts were different from those involved in selecting the indicators, and were asked to assess the indicators for relevance (does the indicator add to the understanding of FSMS performance in the fresh produce chain?); reliability (is the indicator/question clear and unambiguous?); and validity (does the question measure important activity of FSMS in the fresh produce chain?) *(96)*. The experts were recruited via the consortium of the EU FP7 project VEG-i-TRADE. They were intentionally selected to include fresh produce experts from the industry (representatives of produce organizations), institutes/laboratories and universities. Experts from industrial organizations have been selected according to their extensive experience in fruit and vegetable production and distribution, and their experience in implementation of quality assurance standards in the sector. Moreover, they were intended to represent those for whom the topic is most salient. Experts from academia were chosen according to their years of experience and their renowned work published in scientific journals. The indicators that were found relevant by half or less than half of the experts were considered for deletion. The experts were given the opportunity to suggest new, more relevant indicators. They also attributed an importance rating to each indicator for primary production, processing and trade companies, using an interval ranking *(218)* with a four point Likert scale (not important, somewhat important, important, very important; 0-3).

In total, 14 experts responded to the validation study (response rate: 64%). The experts were representatives of produce organizations (n=5), institutes/ laboratories (4) and universities (5), from Belgium (4), Brazil (2), the Netherlands (1), Norway (2), Serbia (1), Spain (3), and Egypt (1).

2.3. Testing in practice

As a first test of the understandability and availability of information from companies within the produce chain, we performed assessments at three companies in a fresh-cut lettuce production chain. The first company was a small-scale farm cultivating lettuce in Belgium, and mainly supplying nearby processing plant of fresh-cut lettuce salads. This processing plant was the second participating company. It was a medium-sized processing plant for fresh-cut salads and vegetable mixes, using lettuce supplied from farms in Belgium and the Netherlands. The third company was a large wholesaler of fresh-cut salads, and was located in the Netherlands. The assessments were performed as an interview with the farm or quality assurance manager.

After the first tests, we continued with a large-scale application of the tool to further test its robustness. To help companies in selecting the most representative situation for them, we created supporting statements. All tests were aimed to check whether obtained results fit with reality *(96)*. After each assessment the results were communicated to the participant and feedback was acquired about availability of information, understandability of the indicators and the grids, and how well the results represented the real-life situation.

2.4. Results and discussion

2.4.1. Indicators and grids for the assessment of control activities

Figure 2.1 shows the structure of the assessment tool to assess the core control and core assurance activities in the FSMS, and the system output. The indicators used to assess the design of preventive, intervention and monitoring control activities, and their actual operation, along with the assurance activities, and the system output, are summed up. The overall assumption is that a more advanced level of the core activities will lead to a more predictable and controllable system output, and implies a lower risk of unexpected microbial and chemical safety problems *(288, 352)*.

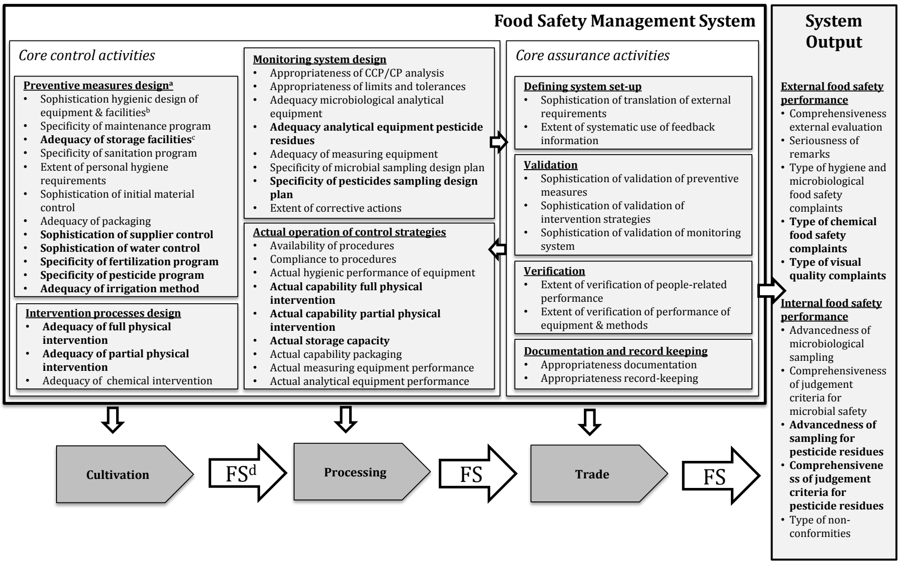

Figure 2.1: Structure of the instrument to diagnose performance of FSMS in fresh produce chains

[a] *Type of activity.*
[b] *Indicator to assess the activity.*
[c] *In bold – new indicators added to the main principles for FSMS assessment (286).*
[d] *System output of one FSMS.*

2.4.2. Preventive control activities

The indicators of the hygienic design of the equipment and facilities, maintenance and calibration program, sanitation program, incoming materials control, and personal hygiene requirements, were found relevant to assess the design of preventive measures in companies in the (fresh) produce chain. Studies in the fruit and vegetable sector have demonstrated the importance of the hygienic design of equipment and the sanitation of equipment *(e.g., 275, 376, 445)*, and the personal, and especially hand hygiene of workers in the field and in companies *(e.g., 149, 317, 444)*. Moreover, the maintenance of sprayers, packaging and other equipment *(e.g., 2, 167)*, and the incoming control of materials (such as, planting materials, fertilizers, pesticides at primary production), produce and ingredients in the next chain stages *(e.g., 155, 276)* have been stated as important measures for preventing microbial and chemical contamination of fresh produce. Therefore, the indicators to assess these activities from the main principles for FSMS assessment have been included in our tool *(286)*.

Table 2.1 shows the new indicators that refer to activities important to the produce sector. The indicator 'adequacy of storage facilities' addresses the way in which storage facilities are designed within a company or at a farm. Several studies underpin the importance of cooling and air conditions control in preventing the growth of microorganisms and fungi *(e.g. 130, 380)*. Storage facilities that are able to maintain strict temperature and/or atmosphere conditions, and have been adapted to and tested for the specific circumstances better prevent the growth of microorganisms, and are considered to be at the advanced level. Typical for the average level are the best available industrial storage facilities that make it possible to control the temperature, humidity, and/or gas composition, with known but untested principal storage capacity. The basic level, on the other hand, is typified by uncontrolled storage facility conditions, which are typically ambient conditions, bulk storage, and storage in non-separated areas. 'Sophistication of supplier control' gives an indication about how companies select their suppliers in order to prevent the contamination of their inputs. Supplier control is especially important for companies that process and trade fresh produce, due to the inherent seasonality and the fact that supplies come from different world locations to provide for year-round availability. At primary production, supplier control is aimed at inputs such as pesticides, fertilizers and planting materials. Supplier selection is an important activity that segregates safe suppliers from unsafe ones, and leads to improvements in the safety of purchased initial materials *(284, 428)*. The effective control of suppliers is not only achieved by establishing long-term relationships with selected suppliers, but should also be paired with regular audits and oversight *(166, 293, 390)*. Thus, sophisticated supplier control is typified by systematic supplier selection based on pre-defined criteria, and the regular evaluation of suppliers' actual status based on audits and statistically underpinned analyses of food safety data, which is defined as the advanced level. Typical for the average level is supplier selection based on certification(s), and evaluation is based on conformity to specifications, but without the use of actual data. The basic level refers to a lack of specific selection of suppliers, and ad-hoc control. 'Sophistication of water control' gives an indication of how water quality is controlled and treated. During primary production water is used for irrigation, to apply pesticides and fungicides, to wash and rinse produce, to ice-cool, and to wash harvesting equipment. Moreover, across the whole chain workers use water for hand washing, and it can be also applied as an ingredient in processing. Studies have demonstrated and discussed that inadequacies in water control can cause food safety problems in fresh produce *(e.g., 212, 454)*. Water control with structured sampling for measuring the contamination risks in relation to the water source (or previous use) and intended use of the water is critical *(429)*. This is valid even when potable water is used, because water quality can deteriorate at all stages through improper storage or cross-contamination *(171, 172)*. Moreover, sampling information is of high importance for selecting the most effective water treatment technologies *(126, 212, 355)*. Sophisticated water control (advanced level) is typified by water control based on statistically underpinned sampling, and treatment that is tailored and tested for efficacy in the company-specific circumstances. Typical for the average level is a water control that is based on expert knowledge or (sector) guidelines, but without structured inspections; water treatment is defined by considering the source and intended application of water. The basic level involves control based on the historical experience of water source, ad-hoc testing (upon problems), and water treatment that is not adapted and only ad-hoc applied.

Several indicators constructed specifically for companies at primary production (farms) address the fertilization program, pesticide program, and irrigation method. ‘Specificity of fertilization program’ gives an impression of how the application of organic fertilizers (such as manure, compost, guano, worm castings) is organized at primary production. The effectiveness of a fertilization program depends on several elements. Organic fertilizers that are disinfected for use in crops, especially in a context in which the edible part comes into direct contact with the soil (for example, leafy greens, herbs, carrots radishes, green onions, strawberries), depends on the capability of the composting process *(321, 327)*. Studies have demonstrated that considering the actual at-site soil type, pH, moisture factors and saturation during composting and fertilizer application contributes to preventing the survival of enteric pathogens and avoiding contamination *(236, 276, 399)*. At farms, the storage of organic fertilizers in a specific place that avoids contact with water, cultivation and handling sites further prevents cross-contamination *(86)*. The assumption is that a site-specific organic fertilizer program, with capable composting, and supporting instructions, better prevents cross-contamination, and positively contributes to food safety. A highly specific fertilization program (advanced level) is tailored for the specific cultivation site, wherein the capability of the composting process is tested for actual circumstances, and instructions on the storage, frequency and method of application are established based on test results. Characteristic for the average level is a program based on (sector) guidelines, using 'best standard' composting, and not tested in the own production field, while the basic level refers to a program based on own or common knowledge, with unknown composting capability and instructions based on experience.

The indicator 'specificity of pesticide program' provides insight into the use of pesticides during fruit and vegetable production, and how it is designed to prevent the occurrence of pesticide residues in the final product. The effectiveness of pesticide management depends on selecting and applying chemicals that are effective in the specific situation *(e.g. 2, 170, 348)*. An effective program is based on an iterative process of pest identification, sampling, analysis, management alternatives (chemicals and their application), implementation, and re-evaluation *(411)*. Therefore, the situation is considered as advanced level when a site-specific, scientifically based program is in place, tested in the companies' specific circumstances and uses approved pesticides, Typical of the average level is a pesticide program based on expert knowledge (advice from suppliers, sector organization), which uses approved pesticides. The basic level programs are based on common knowledge, with no information about the approval status of applied pesticides.

Further on, 'adequacy of irrigation method' indicates the risk of microbiological contamination due to water application. Irrigation practices have a critical influence on product safety, especially when a water source of uncertain quality is used *(171)*. Subsurface irrigation methods, where a permanently or temporarily buried dripper line or drip tape is placed below the plant roots, do not provide for contact with the edible parts of produce, thus preventing contamination *(235, 350, 454)*. This is typified in our tool as advanced level. Common for the average level is when water is applied on the surface, close to the roots of the plants – for example through tubes. The basic level refers to common surface methods such as sprinklers and flood irrigation, which have been shown to contribute to crop contamination *(16, 171, 434)*.

Table 2.1: Established indicators with grids at three levels to assess preventive measures design in FSMS in fresh produce chain.

Indicators	Supporting statements	Basic level[a]	Average level[a]	Advanced level[a]
Adequacy of storage facilities	• When industrial storage facilities are controlled, they are at an average or advanced level. • It is crucial for advanced level that storage facilities are adapted (modified) and tested for the specific company circumstances, and actual temperature, and/or relative humidity, and/or gas composition are checked for different circumstances	Uncontrolled conditions of storage facilities; typically ambient conditions, bulk, non-separated areas	Industrial storage facilities (controlled temperature, and/or humidity, and/or gas composition). Information about principal storage capacity is known but the actual capability is not tested	Industrial storage facilities specifically modified for companies' specific circumstances and actual storage capacity is tested (e.g., for temperature, humidity, gas composition) for typical company circumstances
Sophistication of supplier control	• When suppliers are regularly controlled, they are at an average or advanced level. • It is crucial for advanced level that the suppliers' control is systematic, based on pre-defined criteria	No specific supplier selection (i.e., supply based on current availability); supplier control is ad-hoc when problems arise	Supplier selection based on certification(s); regular evaluation of suppliers is based on conformance to specifications	Systematic supplier selection based on pre-defined criteria. Regular evaluation of suppliers' actual performance based on audits and statistically underpinned analysis of food safety data
Sophistication of water control	• When water control is based on considerations of the source and intended application of water, then they are at an average or advanced level. • It is crucial for advanced level that water control is tailored to specific production circumstances and is structurally implemented in practice	Water testing is ad hoc (when problems arise) and based on historical experience of the water source	Water program is based on expert knowledge or (sector) guidelines, but is not part of structured inspections; water treatment considering the source and intended application of water	Water control based on statistically underpinned sampling and is strictly/structurally implemented in (daily) practice; water treatment is tailored and tested for effectiveness in company-specific circumstances

Indicators	Supporting statements	Basic level[a]	Average level[a]	Advanced level[a]
Specificity of organic fertilization program[b]	• When a fertilizer program is implemented and based on relevant growing conditions, then it will be at an average or advanced level. • It is crucial for advanced level that the program is tailored and the actual compositing process capability is tested for the specific circumstances	Program is available and is developed based on common/in-farm knowledge; capability of the composting process is not known; instructions for storage, frequency, and method of application are derived from own experience	Program is developed and implemented based on (sector) guidelines. Composting process is based on 'best standard', but not tested for the company's own production circumstances. Instructions about storage, frequency and application based on 'best practice' or advice from suppliers	Program is tailored for the specific growing site and implemented; composting process capability is tested for actual circumstances; instructions on storage, frequency and method of application, based on test results
Specificity of pesticide program[b]	• When the pesticide program is specific for the type of produce and approved pesticides are used, then it will be at an average or advanced level. • It is crucial for advanced level that the program is modified and tested for the concrete cultivation site	Pesticide program is available and developed based on common knowledge; no information about approval status of applied pesticides; instructions about storage, application, and frequency derived are based on own experience	Pesticide program is developed and implemented based on expert knowledge (advice from suppliers, sector organization); common approved pesticides for type of produce; instructions derived from information on label, advice from suppliers	Scientific based site-specific program implemented, tested in companies' specific circumstances, and using approved pesticides; specific instructions about storage, application and frequency
Adequacy of irrigation method[b]	• When the irrigation method is specifically aimed at preventing microbial contamination, then it will be at an average or advanced level. • It is crucial for advanced level that contact with the edible part is avoided, in order to better prevent microbial contamination	Common surface irrigation methods such as gravity-flow/flood/furrow and sprinkler irrigation	Irrigation methods where water is applied directly onto the soil/plant roots such as drip/trickle irrigation	Irrigation methods that reduce microbial contamination by avoiding contact with edible part (subsurface irrigation methods, where permanently or temporarily buried dripper line is used below the plant roots)

[a] Situations 1,2,3, and 4 correspond to the following levels: Advanced level (situation 4) → scientifically underpinned (accurate, complete), stable, predictable, and tailored for the specific food production situation; Average level (situation 3) → best practice knowledge/equipment, sometimes variable, not always predictable, based on generic information/guidelines for the product sector; Basic level (situation 2) → lack of scientific evidence, use of company experience/ history, variable, unknown, unpredictable, based on common materials/equipment; Low level (situation 1) → absent, not applicable, unknown.

[b] Indicator applicable only at primary production.

2.4.3. Intervention activities

Next in the tool we addressed ‘intervention processes’, which, according to the main principles for FSMS assessment are aimed at inactivating or eliminating hazards in order to reduce them to acceptable levels *(286)*. In fresh produce they may be physical (such as thermal treatments, irradiation, high-pressure) or chemical (disinfection by *e.g.* chlorine, ozone) interventions. We distinguish indicators for partial and full physical intervention. By partial physical intervention we are referring to processes that are aimed at reducing the microbial load (such as disinfection, the removal of outer leaves, sorting out for moulds or other visual contamination), which could be applied at any point of the fresh produce chain. Within full intervention, we are addressing processes that inactivate or eliminate microorganisms to acceptable levels, such as heat treatments (such as. blanching, pasteurization, sterilization, drying), and which can be applied only during processing. The assumption behind the indicators measuring ‘adequacy of intervention’ is that the effectiveness of any intervention treatment is dependent on its suitability to the particular product and concrete production circumstances. Studies have demonstrated that inadequate intervention equipment or ineffective methods may lead to food safety problems in fruit and vegetable products *(e.g. 174, 278)*. Typical for the basic level is the use of general, non-product-specific intervention, without known capability, while the average level uses ‘best standard’ product-specific intervention, with capability that is described in specifications (provided by equipment suppliers), but is not tested for the company’s own production. The advanced design of these activities is defined as being modified for the company-specific circumstances and the actual capability tested.

2.4.4. Monitoring system design

Important elements of monitoring include the identification of hazards, the evaluation of risks, the allocation of critical control and other points in which hazards need to be controlled *(215)*. Companies active in the fresh and minimally processed produce sector have been using the HACCP approach for years; however, in this sector no definite inactivation step can be achieved, and efforts are mainly directed towards the reduction of potential contamination through pre-requisite programs (e.g. GMP) or partial intervention *(91)*. Hazards are commonly addressed through control points (CP) to prevent the growth of pathogens, microbiological or chemical contamination (in practice also called critical prevention points). Various studies have demonstrated that inadequacies in the monitoring systems can cause food safety problems in the production of fruits and vegetables *(e.g. 195, 454)*. Therefore, the indicators 'appropriateness of CCP or CP analysis', 'appropriateness of limits and tolerances assessment', 'adequacy of measuring equipment' and 'extent of corrective actions' have been found useful for assessment of the FSMS within the fresh produce chain. Furthermore, the indicators about analytical methods for microbiological hazards and microbiological sampling plan are address the microbial analysis conducted in the companies in the chain (Table 2.2). Studies have stressed the importance of these monitoring issues in fresh produce production, especially postharvest *(53, 212, 219, 275)*. Typical for advanced levels of the indicators for monitoring systems design is the use of scientific knowledge, which is adapted to own production, systematic and tested (by challenge testing, for example) for the specific food production. The average levels are typified by the use of the 'best available' knowledge for the sector, but are not tailored for own production, whereas, at low levels, scientific support and a systematic approach are lacking *(286)*.

To address chemical food safety in monitoring, we defined the indicators 'adequacy of analytical methods for pesticide residues' and 'specificity of sampling plan for pesticide residues'. Within the latter we refer to the samples for routine analysis of the pesticide residues that could be taken by the company itself or by a third party. The trustworthiness of the sampling data is determined by the quality of the analytical methods used for the analysis *(88, 441)*. An advanced level for this activity is attributed to samples analysed by an accredited laboratory, using internationally accredited methods (Table 2.2).

2.4.5. Actual operation of control activities

The indicators 'availability of procedures' and 'actual compliance to procedures' (Figure 2.1) have been found useful for fresh produce, in line with studies discussing the variability of sanitary behaviour among fresh produce workers *(317, 394, 418)*. Typical for the advanced level is procedures that are available at location, and are easy to understand, accurate, and specific to the workers who will follow them. Similarly, for compliance to procedures the advanced level is typified by workers who have a good understanding of their tasks and the procedures, and they are internalized *(286)*. The basic level is characterized by procedures that are difficult to understand, are not updated, and their availability is limited, and tasks that are executed according to the worker's own insights. The average level refers to easily understandable procedures, which are available on location and updated on an ad-hoc basis, and compliance based on habits but controlled on a regular basis *(286)*.

The operational capability of crucial control equipment and facilities (for example, intervention equipment, packaging equipment, cooling and storage facilities) *(286)* also has an important impact on the actual system output in fresh produce *(13, 84, 380)*. Stable equipment performance at different production situations, which is systematically monitored and analysed, is characteristic for the advanced level, whereas regularly unstable equipment with unexplainable deviations, which is not monitored or analysed, is typical for the basic level *(286)*.

2.4.6. Indicators and grids for the assessment of assurance activities

The indicator 'sophistication of translating external requirements' focuses at assessing how the external assurance requirements are transposed into a company's own FSMS. When new requirements need to be implemented, the current activities in the system have to be compared and modified accordingly. Requirements and guidelines for the fresh produce sector can be general, and also commodity specific *(e.g. 59, 67, 458, 477)*. In the coming years more demands are expected to be placed on the sector due to increased concerns and augmented production and consumption of produce and derived products *(e.g. 193, 262, 463)*. Sophisticated translation (advanced level) is typified by a pro-active approach, which is based on systematic analysis of possible changes (such as new legislation, new branch demands) and evaluated on critical aspects of the producer's own food production system *(295)*. The basic level is characterized by reactive translation of stakeholder requirements, after problems or after changes in legislation or demands *(295)*. Moreover, the modification and adaptation of the FSMS is not a one-time activity and the indicator 'extent of systematic use of feedback information to improve the FSMS' was included to address the ongoing changes derived from the system itself. Systematic analysis of information from validation and verification reports, and translations into concrete FSMS modifications that are established in clear procedures with assigned responsibilities, and well documented, are typical of the advanced level, while the activities at the basic level are done after problems *(295)*.

The indicators for validation assess the 'sophistication of validating preventive measures', '-intervention methods', and '-monitoring systems'. For verification they address the 'extent of verifying people-related performance', and '-equipment and method-related performance'. Both types of activities are crucial for the preventive approach, since they check every step of the process for effectiveness in advance (Luning and Marcelis, 2007). They are especially important for fresh or minimally processed produce, where full intervention is not possible *(91)*. An example of this is the washing of vegetables during fresh-cut processing, which is defined as partial intervention in our tool, and is often ineffectively done in practice, because factors influencing its effectiveness are not fully understood by companies and validation is ineffective *(212, 407)*. The advanced levels are typified by systematic and independent (that is, by external expert) validation, which is based on specific scientific sources, and conducted systematically and after modifications in the FSMS, while the basic levels are validated on an ad-hoc basis, based on historical knowledge, and only judged by internal to the company people (Luning et al., 2009). Next, verifying the compliance of the people and methods has been stated as an important activity in meeting safety export standards at primary production *(234, 346)*, but is also important within processing and trade companies for guaranteeing product safety *(167, 204, 209, 217)*. The advanced levels are typified by the use of analysis and by actual testing or observations, which are done by independent experts, with defined frequency, and upon system modifications, while the basic level verification is based upon checking for presence, which is conducted on an ad-hoc basis by people who work in the system *(295)*.

Finally, the indicators 'appropriateness of record-keeping system' and 'appropriateness of documentation system' address the activities that are aimed at keeping knowledge about the FSMS by collecting product and process data and keeping information in the form of procedures, instructions, manuals, etc. The advanced levels are typified by structured and complete documentation, which is kept-up-to-date with assigned responsibilities, and is centrally organized, automated and online available for all, while the basic levels are characterized by unstructured and ad-hoc documentation and record keeping *(295)*. The above-described assurance activities are crucial for any FSMS in providing transparency and confidence to stakeholders that the system is designed and operating according to the necessary standards *(438, 491)*.

2.4.7. Indicators and grids for the assessment of the system output

In Figure 2.1, indicators for the external and internal system output are listed. Similarly to the other food sectors, external audits of companies in the fresh produce chain can be conducted by various parties: national authorities perform (regular) inspections, and accredited bodies conduct audits against various quality assurance standards, such as GlobalGAP, BRC, IFS, etc. For this reason, the indicators 'comprehensiveness of external evaluation' and 'seriousness of remarks' have been found useful to assess the status of FSMS in the fresh produce chain. The good output levels are typified by audits or inspections performed by several accredited third parties and national food safety agencies, with no major remarks, or only minor remarks. On the contrary, the poor output is characterized by inspections performed by only the national food safety agency, with major remarks on various aspects of the FSMS *(230)*. Another indicator is addressing the 'type of microbiological safety and hygiene-related complaints' from client companies. Complaint registration in companies, as well as the analysis of these, can give an important feedback information for the improvement of the FSMS, and increased attention is given to this in quality assurance standards for the food industry, without bypassing the fresh produce sector *(176, 450)*. The good output level is typified by a lack of complaints, while poor output is characterized by various complaints which can be dedicated to multiple problems in the FSMS *(230)*.

The indicators 'advancedness of product sampling', 'comprehensiveness of microbiological criteria', and 'type of non-conformities' aim to provide intra-company information about the output of the system. Within non-conformities, we include initial materials, intermediate or final products that do not meet the required specifications (identified by the company itself) towards hygiene, pathogens, mycotoxins, pesticide residues, or quality aspects (i.e. mould, rot, bruises), and the products are not delivered to the customers. Taking samples and registering non-conformities enable companies in the fresh produce sector to judge the performance of their quality management systems *(153)*. Typical for good output is a structured company-specific sampling plan, which is conducted on the final food product, initial material(s) and environmental samples, and interpreted using a combination of legal criteria, requirements, specifications by external parties and additional company-specific specifications. Poor output is characterized by ad-hoc sampling (upon request), which is only conducted on the final food product, and is interpreted using a restricted number of criteria (*e.g.* only legal criteria) *(230)*.

We have constructed four similar indicators that specifically give indication about the chemical safety output. 'Advancedness of product sampling for pesticide residues' and 'comprehensiveness of judgment criteria for pesticide residues' assess the type of samples taken and how they are used to judge the chemical safety status of the FSMS. Testing for pesticide residues can be done on a governmental level, by external organizations (such as branch organizations or, retailers), or by producers themselves. Typical for good output is structured sampling, at a company level, and regular monitoring at a sector level (which is statistically underpinned). The moderate output is characterized by structured sampling, with fixed frequency, at company level or sector level, and poor output is based on ad-hoc sampling, due to demands of customers or legislation, which is done on particular lot(s)/batch(es). The results can be interpreted based on pesticide residue limits set in guidelines or legislation *(e.g. 68, 115)*, sometimes in conjunction with even more stringent private codes *(347)*.

'Type of customer complaints to chemical safety (pesticide residues and mycotoxins)' and 'type of customer complaints regarding visual quality' of final products address the chemical safety related complaints. The latter include complaints regarding moulds, rotten parts, bruises, etc. and give an important indication about problems in the quality system. Complaint registration provides feedback information from client companies about the operation of a quality assurance system *(153, 166)*. In the case of visual quality at the end of the supply chain, final consumer complaints can also be included.

2.4.8. Validation by experts

Table 2.2 shows the results from the expert validation of control activities. Overall, all indicators received higher importance scores for processing, compared to primary production and trade. This could be related to the more common use of HACCP-based systems in processing companies *(91)*. Indicators for the design of preventive measures received scores for importance of between 1.8 and 2.9, and for processing the scores ranged between 2.6 and 2.9. At primary production, the highest scores were received for hygienically designed equipment (2.6), a sanitation program (2.6), incoming material control (2.7), packaging (2.8), water control (2.8), supplier control (2.6), and irrigation methods (2.6). At trade, the highest importance scores were given for storage facilities (2.8), personal hygiene requirements (2.5) and supplier control (2.7). The indicators for full and chemical intervention were excluded for primary production and trade, where they could not be applied, but at processing they received an importance rating of 2.6. For monitoring activities, at processing the mean scores were between 2.6 and 2.9, while the scores were lower for the rest of the chain - between 1.7 and 2.6 for primary production, and between 2.2 and 2.6 for trade. Fewer than seven experts supported the relevance of the indicator 'adequacy of measuring equipment' for both primary production and trade. However, we preserved this indicator in the tool for trade, because measuring equipment is commonly used for measuring temperature and other atmospheric conditions in storage facilities. Moreover, after tests in farms, this indicator was also preserved for primary production, where measuring equipment is also used in areas such as storage and water control. For primary production and trade, the highest scores (2.6 and 2.9) were given for analytical methods. Furthermore, at primary production a high score (2.6) was received for corrective measures.

Table 2.3 shows the results from the expert validation of assurance activities. Experts gave lower points to the relevance of the indicator for validating the monitoring system at primary production. Scores were again higher for processing (between 2.6 and 2.9) than for primary production (1.4–2.6) and trade (2.1–2.8). High scores were given for documentation and record-keeping for all the three chain stages (2.6 and 2.5 for primary production; 2.9 for processing and 2.8 for trade).

Table 2.4 shows the results from the expert validation for the system output. Importance rating scores were again higher at processing (2.1–2.8) than for primary production (2.1–2.6) and trade (2.1–2.7). Highest scores at processing were given for microbiological complaints (2.8), microbiological sampling (2.7), and non-conformities (2.7). For primary production, the highest scores were assigned to indicators about the external evaluation of FSMS through audits (2.6), and complaints on microbiological (2.5) and chemical (2.6) aspects, which is an aspect included in the quality assurance standards for primary production (such as GlobalGAP). Similarly for trade, experts gave high scores to the indicators for customer complaints regarding microbiological (2.6) and chemical food safety (2.7).

Table 2.2: Expert validation of indicators for control activities for **Primary Production**, **P**rocessing and **T**rading companies: relevance points and importance rating (mean and standard deviation)

Indicator	**Assumed mechanism**	**Relevance (n=14)**			**Importance rating (0 → 3, not to very important)**		
		PP	**P**	**T**	**PP**	**P**	**T**
	Preventive measures design						
Sophistication hygienic design equipment & facilities[a]	Advanced hygienic design of critical equipment and facilities tailored and tested for specific circumstances decreases the chance of (cross-) contamination and enables effective cleaning, which will positively contribute to food safety	12	14	12	**2.6** (0.6)	**2.9** (0.3)	2.2 (0.7)
Specificity of maintenance and calibration program[b]	Structural and tailored programs for maintenance with specific instructions about frequency and tasks will cause fewer unexpected safety problems due to unreliable equipment, which will positively contribute to food safety	14	14	13	1.9 (1.1)	**2.8** (0.4)	2.3 (0.7)
Adequacy of storage facilities[c]	Adequate storage facilities maintain strict temperature and/or atmosphere conditions and prevent growth of microorganisms, which will positively contribute to food safety	12	14	14	1.9 (1.2)	**2.9** (0.4)	**2.8** (0.4)
Specificity of sanitation program[b]	Specific, full-step and tailored sanitation programs with appropriate cleaning agents, supported with appropriate instructions better prevent contamination, which will positively contribute to food safety	13	14	13	**2.6** (0.6)	**2.7** (0.4)	2.1 (0.7)
Extent of personal hygiene requirements[b]	High and specific personal hygiene requirements and specific instructions reduce the chance of contamination, which will positively contribute to food safety	14	14	12	2.1 (1.1)	**2.9** (0.3)	**2.5** (0.7)
Sophistication of incoming materials control[a]	Systematic and adequate incoming material control will prevent (high and variable initial) acceptance of contaminated incoming materials, which will reduce the chance of (cross-) contamination of the production process, which will positively contribute to food safety	10	14	11	**2.7** (0.6)	**2.9** (0.3)	2.4 (0.8)
Adequacy of packaging[b]	Packaging equipment with adequate and tested capability enables less unpredictable process variation and better compliance to standards, which will positively contribute to food safety	9	14	13	**2.8** (0.4)	2.6 (0.5)	2.4 (0.6)
Sophistication of water control	Systematic monitoring and water treatment that considers the water source and intended application of the water will prevent (high and variable initial) contamination, which will positively contribute to food safety	14	14	10	**2.8** (0.4)	**2.9** (0.4)	1.8 (1.2)

Indicator	Assumed mechanism	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
		PP	P	T	PP	P	T
Sophistication of supplier control	Systematic supplier selection and evaluation will lead to more predictable safety levels of incoming materials, which will positively contribute to food safety	9	13	11	**2.6** (0.6)	**2.9** (0.4)	**2.7** (0.6)
Specificity of fertilizer program[d]	Site-specific organic fertilizer program, with capable composting, supported by appropriate instructions, better prevents cross-contamination, which will positively contribute to **microbiological** food safety	14	-	-	1.9 (1.1)	-	-
Specificity of pesticide program[d]	Specific and tailored pesticides program with specific instructions and use of authorized chemical(s) and/or methods helps to better prevent pesticide residues, which will positively contribute to **chemical** food safety	14	-	-	1.9 (1.2)	-	-
Adequacy of irrigation method[d]	Irrigation methods that specifically aim to avoid direct contact with edible part of produce will better prevent microbiological contamination, which will positively contribute to food safety	14	-	-	**2.6** (0.6)	-	-
	Intervention processes design						
Adequacy of full physical intervention[e]	Full intervention equipment that is specific and has had its capability tested enables less unpredictable process variation and better compliance to standards, which will positively contribute to food safety	-	13	-	-	**2.6** (0.9)	-
Adequacy of partial physical intervention	Specific and tested partial physical intervention enables less unpredictable process variation and better compliance to standards, which will positively contribute to food safety	13	14	10	2.1 (1.0)	**2.6** (0.7)	1.4 (1.2)
Adequacy of chemical intervention[b,e]	Specific chemical intervention methods better reduce the contamination load of (initial) materials, which will positively contribute to food safety	-	13	-	-	**2.6** (0.7)	-
	Monitoring systems design						
Appropriateness of CCP/CP analysis[b]	Higher level of scientific evidence and a more systematic way of analysing hazards and associated risk, together with actual testing of CCP and CPs, will result in more reliable and accurate control points, which will positively contribute to food safety	9	13	11	1.6 (1.1)	**2.9** (0.3)	2.2 (1.1)

Indicator	Assumed mechanism	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
		PP	P	T	PP	P	T
Appropriateness of limits and tolerances assessment[b]	More complete specification of standards and tolerances for critical process and product parameters, supported by scientific data, will result in more accurate determination and adjustment of product/process deviations, which will positively contribute to food safety	7	13	10	1.7 (1.1)	**2.8** (0.4)	2.4 (0.8)
Adequacy of microbiological analytical methods[b]	Sensitive, specific, repeatable, reproducible and rapid methods to assess pathogens will result in more adequate determination of pathogens, which will positively contribute to food safety	12	14	12	**2.6** (0.9)	**2.9** (0.3)	2.3 (0.8)
Adequacy of analytical methods for pesticides[a]	More sensitive, specific, repeatable, reproducible and rapid methods to assess chemical contaminants will result in more adequate determination, which will positively contribute to food safety	12	13	13	**2.6** (0.8)	**2.9** (0.3)	**2.6** (0.7)
Adequacy of measuring equipment[b]	Accurate and responsive equipment to monitor critical process and or product parameters will result in more adequate monitoring, which will positively contribute to food safety	**6**	13	**6**	1.8 (1.1)	**2.8** (0.4)	2.3 (0.7)
Specificity of microbiological sampling plan[b]	A statistically underpinned and tailored sampling plan increases the reliability of information about the actual product/process status, which will positively contribute to food safety	12	14	10	2.4 (0.9)	**2.9** (0.4)	2.3 (0.8)
Specificity of pesticides' sampling plan[a]	A statistically underpinned and tailored sampling design increases the reliability of information about the actual product/process status, which will positively contribute to food safety	11	12	12	2.3 (1.0)	**2.6** (0.5)	2.4 (0.7)
Extent of corrective actions[b]	A complete and differentiated description of corrective actions linking the severity of deviations to the type of corrective actions will positively contribute to food safety	13	14	11	**2.6** (0.8)	**2.7** (0.5)	2.2 (0.8)

[a] *Modified from the original concept for assessment of FSMS.*
[b] *Indicators retained from the original concept for assessment of FSMS (286)*
[c] *In bold – new indicators.*
[d] *Indicator relevant only for primary production.*
[e] *Indicator relevant only for processing.*

Table 2.3: Expert validation of indicators for assurance activities for Primary Production, Processing and Trading companies: relevance points and importance rating (mean and standard deviation).

Indicator[a]	**Assumed mechanism**	**Relevance (n=14)**			**Importance rating (0 → 3, not to very important)**		
		PP	**P**	**T**	**PP**	**P**	**T**
Defining system set-up							
Sophistication of translation of external requirements	Systematic and precise translation of stakeholder requirements will result in suitable requirements on the FSMS, which will contribute to assurance of product safety	14	12	12	2.4 (0.7)	2.6 (0.8)	2.4 (0.7)
Extent of systematic use of feedback information	Systematic use of valid feedback information from control system will result in appropriate system modifications, which will contribute to assurance of product safety	14	14	13	**2.5** (0.7)	**2.9** (0.4)	**2.7** (0.6)
Validation							
Sophistication of validation of preventive measures	A scientific-evidence-based, systematic, and independent validation of the effectiveness of selected preventive measure will result in an effective FSMS, which will positively contribute to assurance of product safety	13	14	13	2.4 (0.6)	**2.9** (0.4)	2.3 (0.5)
Sophistication of validation of intervention strategies	A scientific-evidence-based, systematic, and independent validation of the effectiveness of selected intervention processes will result in an effective FSMS, which will positively contribute to assurance of product safety	12	14	13	2.3 (0.8)	**2.8** (0.4)	2.2 (0.7)
Sophistication of validation of monitoring system	A scientific-evidence-based, systematic, and independent validation of CCPs' and/or CPs' determination and establishment of control circles will result in an effective FSMS, which will positively contribute to assurance of product safety	7	13	12	1.4 (1.2)	**2.8** (0.4)	2.4 (0.6)
Verification							
Extent of verification of people-related performance	Specific, systematic, and independent verification of procedure characteristics and compliance will result in a reliable FSMS, which will positively contribute to assurance of product safety	13	14	12	2.4 (0.6)	2.6 (0.5)	2.3 (0.7)
Extent of verification of performance of equipment and methods	Specific, systematic, and independent verification of equipment and methods performance will result in a reliable FSMS, which positively contributes to the assurance of product safety	12	14	11	2.1 (0.7)	**2.8** (0.4)	2.1 (0.8)

Indicator[a]	Assumed mechanism	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
		PP	**P**	**T**	**PP**	**P**	**T**
	Documentation						
Appropriateness documentation	An integrated, up-to-date and accessible documentation system will improve information (experience, scientific knowledge, legislative requirements) supply for FSMS, which will support validation and verification activities, which will positively contribute to the assurance of product safety	14	14	13	**2.6** (0.6)	**2.9** (0.4)	**2.8** (0.4)
Appropriateness record-keeping system	A structured, integrated, and accessible record-keeping system will support validation and verification activities, which will positively contribute to the assurance of product safety	14	14	14	**2.5** (0.7)	**2.9** (0.4)	**2.8** (0.4)

[a] All indicators are retained from the original concept (295).

Table 2.4: Expert validation of the system output indicators for Primary Production, Processing and Trading companies: relevance points and importance rating (mean and standard deviation).

Indicator	Assumed mechanism	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
		PP	P	T	PP	P	T
	External FSMS performance						
Comprehensiveness external evaluation[a]	Evaluation by both national food safety agencies and certification audit by a third party provides a comprehensive external FSMS evaluation	14	14	13	**2.6** (0.5)	2.5 (0.5)	2.2 (0.7)
Seriousness of remarks[a]	Positive evaluations (without serious remarks) of the FSMS by various national food safety agencies and accredited third parties indicate a good safety performance (i.e., all requirements of the stakeholders are met)	14	14	14	2.4 (0.6)	2.4 (0.5)	2.4 (0.6)
Type of hygiene and microbiological food safety complaints[b]	Low number or no complaints about hygiene and microbiological food safety indicate a good performance when a good complaint registration and evaluation system are in place	13	14	12	**2.5** (0.5)	**2.8** (0.4)	**2.6** (0.6)
Type of chemical food safety complaints[c]	Low number or no complaints about chemical food safety indicate a good performance when a good complaint registration and evaluation system are in place	14	14	13	**2.6** (0.5)	2.5 (0.5)	**2.7** (0.5)
Type of visual quality complaints	Low number or no complaints of visual quality indicate a good performance when a good complaint registration and evaluation system are in place	11	12	12	2.0 (1.0)	2.1 (0.8)	2.2 (0.8)
	Internal FSMS performance						
Advancedness of microbiological sampling[a]	Structured sampling and different types of samples provides a more comprehensive and accurate indication of the actual microbiological performance of your FSMS	11	14	10	2.1 (0.8)	**2.7** (0.4)	2.1 (0.9)
Comprehensiveness judgement criteria microbial FS[a]	Using more criteria to critically interpret obtained results of microbiological analyses gives a more accurate indication of the microbiological performance of the FSMS	13	13	12	2.1 (0.8)	2.4 (0.7)	2.4 (0.7)
Advancedness of pesticides sampling	Structured sampling on both the company and sector levels will provide a more representative indication of the actual chemical performance of your FSMS	12	14	11	2.1 (1.0)	2.4 (0.5)	2.2 (0.8)

Indicator	Assumed mechanism	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
		PP	P	T	PP	P	T
Comprehensiveness judgement criteria chemical FS	Using more criteria to critically interpret obtained results of chemical analyses provides a more accurate indication of the microbiological performance of the FSMS	12	13	12	2.1 (0.9)	2.4 (0.5)	2.2 (0.8)
Type of non-conformities[a]	Low number or no non conformities indicate a good food safety performance when a good system for non-conformities registration and evaluation is present	14	14	13	2.1 (0.5)	**2.7** (0.4)	2.4 (0.5)

[a] *Indicators retained from the original concept for assessment of FSMS (230).*
[b] *Modified from the original concept for assessment of FSMS.*
[c] *In bold – new indicators added to the main principles for FSMS assessment (286)*

The expert validation confirmed the entire set, and provided information about the representativeness and clarity of each indicator. The experts gave concrete suggestions for improvement, which were used in the version for the companies.

2.4.9. Testing in practice

Figure 2.2 illustrates the results from the first testing in three companies in a fresh-cut lettuce production chain. The indicators for the system output gradually increased from primary production to trade, from 3 (moderate output) to 4 (good output). At primary production the levels were 4 (good output) for seriousness of remarks from external FSMS evaluation, microbiological complaints from customers and non-conformities. However, visual complaints and judgment criteria for sampling results for pesticide residues received a level of 2 (poor output), and microbiological sampling received a level of 1 (no data). Indicators aimed at chemical safety (for chemical complaints, and sampling plans for pesticides) received level 4 for both primary production and trade. However, at processing the same indicators received a level of 3 (moderate output), together with the indicators for hygiene and microbiological complaints. Non-conformities and visual complaints were both given a level of 2. The system output indicators at trade obtained a level 4, except for seriousness of remarks and non-conformities, which received level 3, and judgment criteria for pesticide residues sampling, which were evaluated to be level 2.

Similar to the system output indicators, the levels for FSMS activities increased from 3 (average level) to 4 (advanced level) as we moved further downstream within the production chain, and the trading company was found to be operating at the most advanced levels of control and assurance activities. Control and assurance activities received lower levels (mostly level2 and 3) at primary production, compared to processing and trade (mostly level3 and 4). Many indicators for control activities received a level of 1, because they were not applied. Examples of such indicators include those for storage facilities, packaging, organic fertilization, microbiological sampling and corrective actions. Crucial activities for primary production, such as water control and pesticide program, obtained level 3, while irrigation method received level 2. Control activities at processing and trade were mostly assessed with levels of 3 and 4. A level of 3 (average) was given to the hygienic design of equipment and storage facilities at processing and trade. At processing, many crucial control activities, such as initial materials control, supplier control, packaging, water control, and microbial sampling plan, also received level 3. Exceptions were maintenance program, sanitation program, and personal hygiene requirements, which each reached level 4. Assurance activities scored increasingly higher as we moved further downstream in the production chain, with levels of 2–3 at primary production, to 3–4 at processing, and 4 at trade. Validation and verification activities at processing obtained level 3. At trade most activities received level 4 (advanced level), but the hygienic design of equipment, storage facilities and personal hygiene requirements still were evaluated at level 3, while maintenance program at level 2.

Overall, the output of the FSMS increases along the production chain, and the trading company operates at advanced levels of control and assurance activities. At primary production, opportunities for improvement to advanced level (from the detected average levels) lie within several crucial preventive measures (such as water control, irrigation method, pesticide program), and validation of the preventive measures in general. At processing and trade, hygienic design of equipment and facilities, and storage facilities also obtained an average level, meaning that they are not checked or adapted for specific products or company conditions. Moreover, validation and verification received an average level in the processing company, which, together with the average levels for the design of control activities, calls their effectiveness into question. However, the assurance activities achieved the advanced level at trade. Thus, questions arise as to whether implemented in companies FSMS are adequately designed and operated, and whether risk is managed at the most appropriate and effective points of the production chain.

The participants in this test stated that, overall, the terms were clear and easy to understand. We have made only minor changes in the definitions and formulations to improve the understanding, especially in the tool for primary production. Furthermore, the tool for primary production was converted into a questionnaire, which improved the understandability and reduced the time for filling in the assessment. When we have communicated the results back to the participants in the assessments, they confirmed that the picture corresponds with the actual situation in the companies.

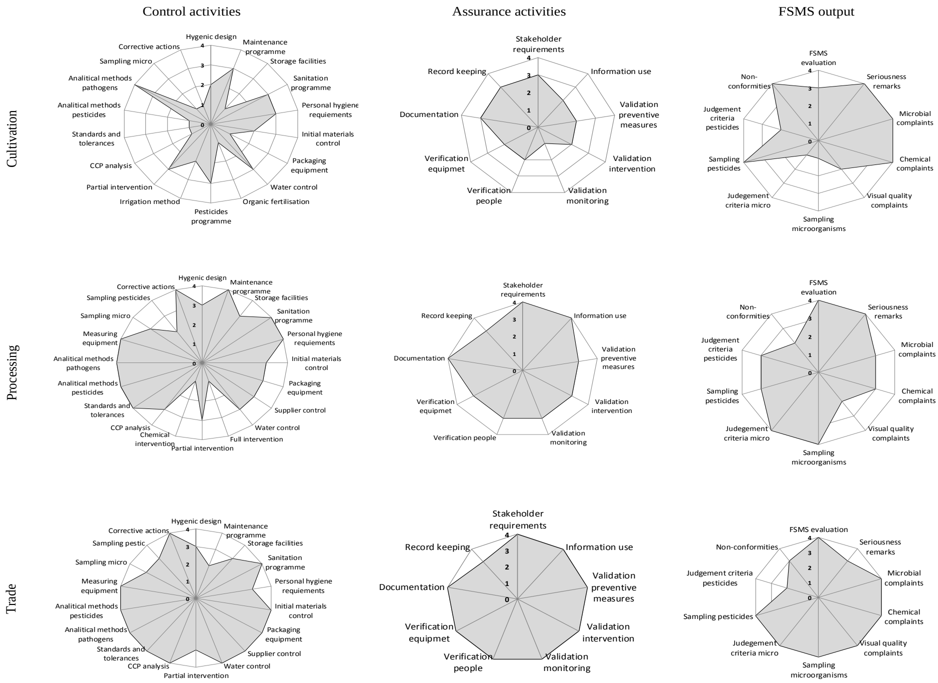

Figure 2.2: Results of testing the tool in a pre-cut lettuce supply chain, primary production, processing and trading company. A more highly coloured web diagram is associated with a higher, more sophisticated level of control and assurance activities, and better system output.

2.5. Conclusions and future perspectives

The overall objective of this study was to gain insight into the activities that are important for fresh produce and derived food products with respect to microbial and chemical safety. Moreover, an assessment tool was developed to assess the FSMS in the sector, independent from the implemented quality assurance guidelines or standards. The assessment tool addresses crucial control and assurance activities, and shows their underlying mechanisms It provides an integral and comprehensive assessment of the FSMS, and the system output for individual chain actors and for a supply chain as a whole. It enables the mapping of the FSMS activities, and the analysis of weak and strong points of one FSMS or several FSMS (for instance in a supply chain, production sector, or region. Users of the tool can recognize the different ways (levels) in which activities can be implemented, and can identify improvement opportunities and see how to develop towards more advanced levels of the FSMS.

A large-scale application of the tools is ongoing which further confirmed the robustness of the assessment tool, and tested how well the results obtained when using the instrument fitted with the real situation. The tools were translated and assessments were performed in ten countries (Belgium, Brazil, China, Kenya, the Netherlands, Norway, Serbia, South Africa, Spain, Uganda) through individual interviews and workshops. The data from these studies will be presented in the near future.

2.6. Acknowledgements

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Chapter 3:
Context factors affecting design and operation of Food Safety Management Systems in the fresh produce chain

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Abstract

Recent foodborne outbreaks and cases of non-compliances to maximum residue limits of pesticides, indicated that food safety management systems (FSMS) in fresh produce chain are not yet performing in a satisfactory manner. However, the system output is not only dependent on the system design and operation but also on the context wherein it operates. The major context factors that create risk to decision-making in FSMS in the fresh produce chain have been defined in this study, and a tool was developed for their systematic analysis. The tool supports a differentiated assessment of context riskiness, enabling actors in fresh produce chains to take measures in their FSMS or reduce riskiness in the context. The tool can be used at primary production, processing, and trade, and can thus provide insights in the changes of context riskiness over the supply chain. It enables systematic analysis of the context in a product group, sector, or country.

2.7. Introduction

Fresh fruits and vegetables are an important part of a healthy diet and their demand has increased markedly in the last decades, including whole and derived convenient products. As a result, between 2000 and 2011, the world production of fresh fruits and vegetables grew by 38% *(138)*. The production and supply chain of fresh produce is rather complex and comprises cultivation, processing, trade and distribution companies in different countries. Moreover, consumption of fresh produce has been associated with several food scares, such as recent deadly outbreaks of *Listeria monocytogenes* in cantaloupe in the United States *(85)*, and *Escherichia coli* O104 outbreak in Europe, finally linked to sprouted seeds *(123)*. To address microbial and chemical safety of their products, companies implement Food Safety Management Systems (FSMS) *(65)*, and in many countries this is even a legal requirement *(113, 140)*. Additionally, many voluntary certifications (such as GlobalGAP, BRC) and benchmarked national standards (like, KenyaGAP, ChinaGAP, FlandriaGAP) are widely adopted as a licence to trade.

Each FSMS is company specific and results from translating various quality assurance guidelines *(*such as *65)* and requirements (like, GMP, PRP, HACCP, BRC, GlobalGAP, etc.) into the particular company, with its specific production circumstances. Moreover, context factors related to type of product and production, organisation of company and chain environment, put demands on the level of design and operation of such systems *(294)*. For example, vulnerable to microbial contamination products (such as leafy greens, fresh herbs, strawberries), which are grown in open field and in contact with soil entail specific requirements for manure management in the FSMS *(321)*. Knowledge and motivation of personnel are affecting translation of external requirements, implementation, and maintenance of FSMS *(488)*. How a food sector is organised in a country or chain also plays a role. McCullough, Prabhu, & Kostas *(310)* defined three types: traditional with less established rules and regulations, structured with more regulations and market infrastructure, and industrialised with a significant degree of coordination and regulation. Such context factors can impact design and operation of FSMS and directly influence its output *(98, 288, 396, 397)*.

Previously a tool was developed to assess context factors and the impact they have on crucial control and assurance activities, and the microbiological safety output of an FSMS in manufacturing of animal products *(294)*. Production of fruit and vegetables is, however, different from animal products, because it is strongly influenced by environmental factors such as temperature, humidity, precipitation, and surroundings *(132, 135, 137)*. Additionally, changes in context such as globalization of trade and climate change are expected to put pressure in the near future on FSMS in fresh produce chains *(229, 443)*. Therefore, insight is needed in the specific contexts in which current FSMS in fresh produce chain operate, to reveal their constraints and opportunities, and enable risk management at most appropriate and effective points of the supply chain.

The objective of this study was to get insight in context characteristics and the risk they create for decisions taken in FSMS in fresh produce chains (at primary production, processing and trade), in order to develop a tool to systematically analyse and assess riskiness of the context. The FSMS was considered in terms of microbial and chemical safety (pesticide residues and mycotoxins). This choice was made as a result of an international discussion forum in January 2011 on emerging risks of the biggest concern in the fresh produce chain *(464)*.

3.1. Main principles for assessment of the Food Safety Management System context

3.1.1. Riskiness of the context factors

Context factors are characteristics of a system environment that can affect its performance and cannot be (easily) changed. The FSMS context is narrower than the overall environment of a company and encompasses major context factors affecting the food safety output of the system (i.e. FSMS output) via activities in the system *(294)*. There is little opportunity to control or modify the context factors, in some cases there is a possibility to change them, but it is mainly possible in the long-term and with significant investments and efforts *(423)*. According to the contingency theory *(273, 440)*, the most effective organisation of a system is when it fits with the context. Luning & Marcelis *(290, 294)* defined this fit in terms of riskiness of context factors to decision making in an FSMS. They described a more risky situation to correspond with more vulnerability regarding food safety problems (*i.e.* due to high likelihood of contamination or bad communication within the chain while decisions must be taken), uncertainty (*i.e.* due to lack of information) and ambiguity (i.e. due to lack of insight into underlying mechanisms). They identified product and production characteristics, organisational, and chain environment characteristics as main context factors, affecting the output of a safety/quality management system *(294)*. Product characteristics refer to properties of initial materials and final products. Production characteristics refer to the conditions during primary production, processing, or handling. Organisational characteristics refer to administrative conditions, such as people characteristics (*e.g.* competence), organisational structures (*e.g.* division of tasks, responsibilities, rules, procedures), and information systems, which affect peoples' decision-making behaviour. Chain characteristics refer to the conditions during supply, and relationships with other companies and organisations in the chain *(291, 292)*.

3.1.2. Control and assurance activities in the food safety management system

Companies can respond to the context riskiness with their FSMS, which consist of control and assurance activities (Figure 3.1). Control activities are aimed at keeping products and processes within acceptable tolerances, while assurance activities aim at providing evidence and confidence that control activities are effective and function well in actual practice *(286, 295)*. Control activities comprise of preventive measures, intervention processes, and monitoring systems that differ in their approach to food safety. Preventive measures seek to prevent microbial or chemical contamination entering into the product, intervention processes – to eliminate it, and monitoring systems – to provide information about the actual conditions and enable corrections *(286)*. Following the principles of the contingency theory, the assumption behind the assessment is that high context riskiness requires control and assurance activities based on scientific knowledge, adequate information, systematic methods, and independent positions, to result in a predictable and controllable system output *(290, 294)*.

3.1.3. Indicators and grids

To assess each context factor, indicators and grids with three situation descriptions were established. The indicators address important characteristics of the context factor that can affect the FSMS activities. The grids represent three stereotype situations, corresponding with different riskiness (low, moderate, high), based on the underlying criteria of vulnerability, uncertainty, and ambiguity. For the product and production characteristics, low, moderate and high riskiness represent low, potential, and high chance of microbial contamination, growth or survival, or chemical contamination. For organisational characteristics, low, moderate, and high riskiness represent low, constrained, and high supportive administrative conditions for decision-making. For the chain characteristics, low, moderate, and high riskiness represent low, restricted, and high vulnerability and or dependency on other chain actors *(288, 294)*.

3.1.4. Validation of the context assessment in the fresh produce chain

Indicators and grids for the factors affecting FSMS in the (fresh) produce chain (Figure 3.1) are established in this study. We have tailored these indicators and grids to address factors that affect decisions in the FSMS activities that occur at each stage of the supply chain (primary production, processing, trade), including fresh produce and derived food products. Each stage of the supply chain was considered in view of the activities that take place in companies. The identification of indicators was based on comprehensive literature study and semi-structured in-depth interviews with experts in fields, pertinent to food safety risks and their management (i.e. microbiological and chemical hazards, production process technology, cultivation practices, pre- and post-harvest technology, water treatment technology, food quality management) in fresh produce chains. Moreover, an expert validation was conducted to validate the whole set of indicators for assessing context of FSMS in fresh produce chain. The validation was aimed at evaluating the relevance – does the indicator add to the understanding of context riskiness to decision-making in the FSMS, reliability – are the indicators and grids clear and unambiguous, and validity – does the question measure what we want to measure *(96)*. The participating experts (n=14) were different than those involved in the identification of indicators. They were from universities (n=5), institutes/laboratories (n=4) and industry organisations (n=5), from Belgium, Brazil, Egypt, The Netherlands, Norway, Serbia, and Spain. The experts were asked to evaluate the relevance and importance of the indicators and the underlying assumptions. They assessed each indicator for primary production, processing and trade companies. The experts were also given the opportunity to suggest new and more relevant indicators. The indicators that were supported by fewer than 50% (n=7) of the experts were considered for deletion. The experts were also requested to judge the importance of each context indicator in terms of its impact on FSMS activities, by using an interval ranking *(218)*, with a four-point Likert scale (not important, somewhat important, important, and very important; 0→3). The median and the interquartile range have been calculated.

3.2. Assessment of the context riskiness at primary production

The tool for the primary production includes the assessment of four types of context factors: product, production, organisation, and chain characteristics (Figure 3.1). The primary production stage incorporates pre- and post-harvest, and includes activities, such as storage and packaging, which are common for many farms *(179, 374)*.

3.2.1. Product characteristics

The context factor *'product characteristics'* is represented in the diagnostic tool by five indicators to assess risk of initial materials and final products (Figure 3.1). *'Microbiological risk of initial materials'* (Table 3.1) reflects the likelihood of high microbiological contamination levels. The initial materials at primary production are the planting materials (such as seeds, seedlings, bulbs, shrubs, trees). Initial materials that are more prone to microbial contamination, growth, and survival, due to their natural characteristics and/or their prior cultivation, production or handling practices, increase the chance on lower food safety, when inadequate decisions are taken in the FSMS. Studies have demonstrated no association with contamination when seeds with applied dedicated treatments to prevent contamination are used *(408, 451)*, and this is typically considered low- risk initial material in our tool. The situation is considered moderate or high risk when materials are susceptible to microbiological contamination. Crucial for the high-risk situation is the use of highly susceptible planting materials, such as seedlings. Studies have shown that enteric food-borne pathogenic bacteria like E. coli O157:H7 and Salmonella spp. may contaminate and even internalise in the seedlings of vegetable crops through the cultivation practices *(29, 154, 243, 299, 349, 416, 467)*. Such materials require special considerations in respect to manure management and irrigation control in the FSMS. When using these materials then inadequate decisions in control strategies imply higher risks of safety problems.

The indicator *'risk of initial materials due to pesticide residues'* gives an impression about the likelihood of high contamination with chemical pesticide residues (Table 3.1). The assumption is that initial materials, which are more prone to contamination with pesticide residues, due to their cultivation or handling practices, increase the chance on lower food safety. Pesticides can be utilised during primary production, but also during storage, at any of the subsequent stages, to keep the products free from moulds, insects, etc. *(175,* *246)*. Moreover, once on the product pesticide residues could only be reduced, but not fully eliminated *(250)*. Therefore, we included this indicator for all actors in the production chain. No use of pesticides (e.g. organic production) represents low risk of presence of pesticide residues. The risk is increasing and considered moderate or high when materials are associated with the use of chemical pesticides in pre or post-harvesting (Table 3.1). A crucial factor for the high-risk situation is that initial materials may contain also unapproved chemicals. Lack of information creates uncertainty in decision-making, which increases the chance of (unexpected) safety problems. Studies have indeed reported that when no information is available on the pesticides, and chemicals with unknown application, unknown origin and or of dubious quality are utilised, the chance of food safety problems increases *(6, 99)*. In such cases inadequate e.g. residues detection or supplier control, result in a higher risk of safety problems.

The indicator *'risk of initial materials to mycotoxins'* represents the likelihood of mycotoxin production (Table 3.1). Crops are mostly contaminated with fungi during cultivation, but improper storage conditions may lead to mycotoxin production or its increase at post-harvest, mainly during storage (27, 244). Therefore, we preserved this indicator for all companies in the production chain. Certain varieties are fungi resistant and or no mycotoxin formation was ever reported, and such materials are considered as low risk ones. The risk is increasing when initial materials are susceptible to fungi development. When little information is available about mycotoxins occurrence in fruit and vegetables, potential risk still exists and as a consequence we define it as a moderate risk. For example, toxigenic moulds have been previously found on carrots and peppers, but (so far) no mycotoxins have been detected (52, 57, 77, 253). Crucial for the high-risk situation is the scientifically established association with mycotoxin production for this type of produce. For instance, scientific evidence exists for the association of apples, tomatoes, grapes and olives with mycotoxins (18, 19, 23, 27, 59, 78, 182).

'Microbial risk of final products' (Table 3.1) gives an indication about the susceptibility of final products to growth and survival of pathogenic microorganisms, due to their inherent characteristics. Some fruit and vegetables have natural protection from microorganisms, they have surface properties that completely protect the edible part that will be removed or peeled before eating (for example, citrus fruits, bananas). Crucial for the high-risk situation is the total lack of protection or having surface properties (e.g.

complex surface, porosity, downy skin), that create good conditions for microorganisms (for instance, berries, spinach, lettuce, fresh herbs, seed sprouts). Studies have shown that whole fruits and vegetables, having complex surface and porosity, such as spinach, broccoli, melon, berries, are prone to microbial contamination, biofilm formation (14, 28, 163, 221, 275), viruses (20) and protozoa survival (126). For example, downy produce such as kiwis, apricots, and peaches are more easily contaminated with bacteria, viruses or parasites and more difficult to be effectively disinfected, than smooth waxy skinned produce such apples, tomatoes, and pears (63, 321). Such types of fruits and vegetables imply a higher risk of safety problems when FSMS activities are not well performed. *'Risk of final products due to pesticide residues'* reveals the likelihood of high levels of chemical pesticide residues in the final food product (Table 3.1). Similarly to the initial materials, no use of pesticides (e.g. organic production) represents the low risk of presence of pesticide residues, and the risk is increasing when chemical pesticides are used. Crucial for the high-risk situation is the lack of possibility for pesticide residues reduction before eating. The risk is inherent to the type and intended use of the product, which made us preserve this indicator for all companies in the production chain. Studies have demonstrated that the processes of washing, canning, and especially cooking, steaming, and peeling reduce the amount of pesticide residues in the final product (55, 103, 157). Products associated with pesticide use and no possibility of their reduction before eating require more focus on pesticide management and monitoring of pesticide residues (102, 148), and therefore are considered as high risk.

3.2.2. Production characteristics

The context factor *'production characteristics'* consists of the indicators: *'susceptibility of production system'*, '*risk of climate conditions of production environment*', '*susceptibility of water supply*', *'susceptibility to flooding'* and *'risk of cultivation site location'* (Table 3.1). The first indicator is assessing the vulnerability to microbial contamination, due to the cultivation system. Cultivation systems, having more contact with soil and environment are more susceptible to microbial contamination, and more parameters and activities need to be controlled to avoid it. Cultivation systems can be distinguished in two main categories: open field and protected cultivation systems *(135)*. In addition, cultivation systems can be further divided into soil and soilless *(137, 244)*. Greenhouses provide defence for the crops grown inside and soilless cultures are aimed at strict control to avoid contamination *(337)*, and these are considered low risk in (Table 3.1). However, risk increases and is considered moderate and high when less control is possible and there is potential for contamination (i.e. greehouses with soil and open field soilless cultivation). Crucial for the high-risk situation are the many opportunities for contamination from the environment such as wild animals or adverse weather conditions, which is the case in open field *(337)*.

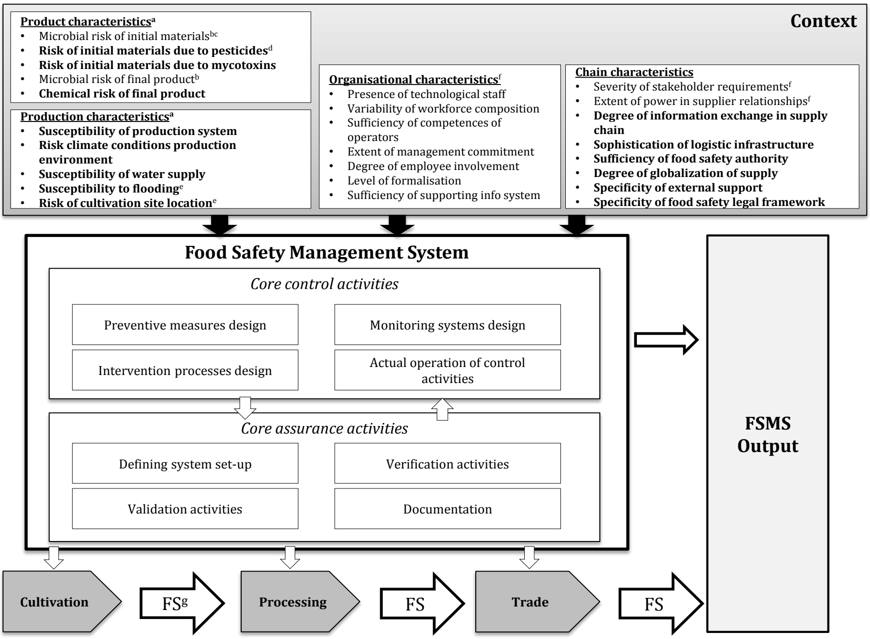

Figure 3.1: Structure of the instrument to diagnose context of FSMS in fresh produce chains

[a] *Context factor*
[b] *Indicator retained from the principles for assessment of FSMS context, but with modified situation descriptions to address the specifics of fresh produce*
[c] *Indicators for assessing the context factor*
[d] *In bold – new indicators*
[e] *Indicators added after the validation and applicable only at primary production*
[f] *Indicators retained as it is from the principles for assessment of FSMS context (294)*
[g] *Output of FSMS*

Table 3.1: Established indicators to assess riskiness of product and process characteristics at primary production

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
PRODUCT CHARACTERISTICS			
Microbiological risk of initial materials			
Initial materials that are more prone to microbial contamination, growth and or survival of microorganisms, due to their natural characteristics and/or cultivation practices, increase chance of lower food safety performance, and put higher requirements on FSMS	Initial materials are not associated with contamination with microorganisms and/or pathogens; dedicated treatment is applied to prevent contamination of initial materials (e.g. chemical/heat treated seeds)	Initial materials are occasionally associated with contamination with microorganisms and/or pathogens. Initial materials have natural protection (e.g. edible part is grown above the ground, covered with hard tissue)	Initial materials are commonly associated with contamination with microorganisms and/or pathogens. Initial materials are prone to contamination due to natural characteristics and growing conditions (e.g. contact with soil, irrigation water)
Risk of initial materials to pesticide residues			
Initial materials that are associated with pesticides contamination, increase chance of lower food safety performance, and put higher requirements on FSMS	Initial materials are not associated with pesticide contamination; no pesticides are used during cultivation/ preparation of initial materials	Initial materials are associated with pesticides. Only officially approved pesticides	Initial materials are associated with pesticides; likely to contain also unapproved pesticides
Risk of initial materials to mycotoxins			
Initial materials that are susceptible to fungal development leading to mycotoxin formation during cultivation, increase chance of lower food safety performance, and put higher requirements on FSMS	No association of initial materials with mycotoxins; resistant to fungi development during cultivation (e.g. disease resistant cultivars)	Occasional association of initial materials with mycotoxins. Initial materials are susceptible to fungi development during cultivation, which are rarely or not (so far) associated with mycotoxin production (e.g. carrots, peppers, melons, mangoes, beans, stone fruits, citrus fruits)	Common association of initial materials with mycotoxins; susceptible to fungi development, which are associated with mycotoxin production (e.g. apples, pears, tomatoes, grapes)
Microbiological risk of final product			
Products which are susceptible to pathogen or fungal growth due to their natural characteristics / surface properties increase chance of lower	No association of final products with microorganisms and pathogen contamination, surface properties completely protect the edible part	Occasional association of final products with microorganisms and pathogen contamination. Product has natural protection that hinders	Common association of final products with microorganisms and pathogen contamination, lack of protective skin or surface properties (e.g. complex

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
food safety performance and put higher requirements on FSMS	and/or will be removed/peeled before eating (e.g. citrus fruits, bananas)	microorganisms (e.g. waxy skin of apples, tomatoes, cucumbers, zucchini)	surface, porosity, downy skin) that create good conditions for microorganisms (e.g. berries, spinach, lettuce, fresh herbs, seed sprouts)
Risk of final product to pesticide residues			
When pesticides are used during cultivation and there is a limited possibility of pesticide removal during processing and/or handling, increase chance of lower food safety performance and put higher demands on FSMS	No association of final products with pesticides, no pesticides are used during production	Occasional association of final products with pesticides due to possibility of pesticides reduction during processing and/or handling (e.g. peeling)	Common association of final produce with pesticides, lack of possibility to reduce pesticides during processing and/or handling
PRODUCTION CHARACTERISTICS			
Susceptibility of production system			
Production/cultivation systems that are more susceptible to microbial contamination due to their contact with the soil and the environment, increase chance of lower food safety performance and put higher demands on FSMS	Soilless protected (greenhouse) cultivation system	Open but soilless cultivation systems, or no contact with soil, or protected cultivation (greenhouse, plastic tunnel) with soil	Open cultivation systems with soil (open field)
Risk of climate conditions of production environment			
Climate conditions of production environment that favour growth of microorganisms and/or occurrence of pests, increase chance of lower food safety performance and put higher demands on FSMS	Climatic conditions at the production site are not (very rarely) promoting the growth of undesirable microorganisms and/or pests. Production/ cultivation in controlled or climatized conditions that do not favour microorganisms survival and growth, and/or pest occurrence	Production/cultivation that occasionally (e.g. during summer) favour microorganisms survival and growth, occurrence of pests and/or mycotoxin production (e.g. open field cultivation in a continental climate)	Production/cultivation favour growth of microorganisms, occurrence of pests and/or mycotoxin production (e.g. subtropical and tropical climate zones; or sprouted seeds cultivation in high temperature and humidity conditions)
Susceptibility of water supply			
Water supply for direct contact with	No association of water supply with	Occasional association of water	Common association of water supply

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
product, which is having high likelihood of contamination with microorganisms (i.e. uncontrolled surface water), increases the chance of lower food safety performance, and puts higher demands on FSMS	contamination; potable water supply, coming from approved sources (e.g. municipal water, artesian well water, water from drilled deep wells)	supply with contamination; water controlled at the company/farm (e.g. recycled/re-used water, water stored in open reservoirs, water from dug or driven wells, rain water)	with contamination; uncontrolled surface water (e.g. from rivers, canals, ponds, lakes, creeks, etc.)
Susceptibility to flooding[b] Production/cultivation site that is more susceptible to flooding, and thus to unexpected contamination from the environment, increases the chance of lower food safety performance and put higher demands on FSMS	No risk of flooding; flooding has never occurred	Occasional occurrence of flooding; in case of extreme rainfall or storm	Common occurrence of flooding; production site is located close to a river, lake, pond, sea, etc.
Risk of cultivation site location[b] Production/cultivation site that is located next or near-by a contamination source or that has history of animal or industrial production, increase the chance of lower food safety performance and put higher demands on FSMS	The cultivation site is located far from any animal or industrial production, wild life reserves, highways/roads, sewage system, emerging urbanisation, etc. No previous use of the cultivation site for animal or industrial production	No information about located near-by possible sources of contamination. No information about the previous use of the production/cultivation site	The cultivation site is located next to possible source of contamination (e.g. wild life reserves, animal or industrial production, highways/roads, sewage system, emerging urbanisation, etc.) or the production/cultivation site has been use previously for animal or industrial production (e.g. animal farm, gas works; tanneries; petrol stations; landfill sites; scrap yards, etc.)

[a] Low, medium and high risk levels for product characteristics correspond to low, potential and high chance of microbiological or chemical contamination (294)
[b] The indicator has been added after the expert validation

'Climate conditions of production environment' (Table 3.1) is representing the risk, associated with environmental conditions that contribute to survival of microorganisms and lead to increased contamination and or growth in food, favour fungal development and mycotoxin production. Climatised conditions with controlled temperature and humidity provide for less risk to mycotoxin contamination *(26)* or growth of enteric pathogens *(311)*, and they are regarded as low-risk situation in our tool. Risk is increasing and considered moderate and high in situations with uncontrolled conditions. Crucial for the high risk are the high temperature and humidity. High relative humidity at harvest can lead to condensation of water vapour during storage; similarly, high temperature and humidity during postharvest handling and or storage provide ideal conditions for proliferation of microorganisms *(150)*. Therefore, this indicator is included for all companies in the chain. It is well documented that warmer temperatures contribute to the survival of microorganisms in the environment, leading to increased contamination and or growth in foods, and thereof higher number of food safety illnesses *(37, 90, 393)*. Mycotoxicogenic fungi are also affected, with ideal conditions for mould growth and mycotoxin production at temperatures between 20-30°C, and high water availability (RH above 0.70) *(398)*. Important mycotoxins such as ochratoxin A and patulin are more prevalent in warmer (Mediterranean, sub-tropical and tropical) climates *(111, 134, 282, 354, 404)*. In the case of sprouted seeds the production environment is of high temperature and humidity, which supports the proliferation of microorganisms and is showed to be a food safety risk *(123, 143, 144)*. Increases of temperature and humidity can also effect pests and plant diseases, which may lead to shift in pesticide application *(80, 133, 183)*.

'Susceptibility of water supply' (Table 3.1) gives an impression of the likelihood of contamination of produce with microorganisms due to the water source used for irrigation at primary production or for processing at the next chain stages (e.g. washing). Water supply for direct product contact, which is having high likelihood of contamination with microorganisms, increases the chance of lower food safety. Potable water sources (like, municipal water, artesian well water, water from drilled deep wells) are least associated with contamination, and they are prescribed for use in the EU when in contact with food *(107, 113)*. Therefore, potable water is typified as low risk in our tool. Crucial for the high risk is the use of uncontrolled surface water (for example, water from rivers, canals, ponds, lakes, creeks, etc.). Surface waters are more susceptible to contamination than groundwater because of direct discharge of sewage, runoff from rainfall, etc. *(172, 430)*. Studies have reported safety problems in

agriculture related to unapproved and untested waters, because such waters are often used in water-scarce areas, despite the fact that it may get into contact with edible part of produce that is commonly eaten raw *(129, 169, 254, 402)*.

'Susceptibility to flooding' indicates the likelihood of microbial and or chemical contamination, due to floods. Cultivation sites that are located in flood prone areas, such as alluvial plains, next to a river, pond, or lake, have shown to be at risk for contamination with heavy metals, pesticides or pathogenic microorganisms *(73, 320, 371, 413, 426, 457)*. Moreover, the risk is expected to increase as a result of climate change *(281, 443)*.

'Risk of cultivation site location' represents the microbiological or chemical risk associated with the previous use of the land linked to industrial production or animal breeding, or located nearby sources of potential contamination (such as, highways, wild life parks, urbanisation). Studies have demonstrated that waste plants, mines, sewage systems, wild life, roads, and urban areas can lead to contamination of the growing fields *(247, 252, 277, 351, 395, 453, 455, 493)*.

3.2.3. Organisational characteristics

The context factor *'organizational characteristics'* refers to the administrative conditions in the company, and the relevant indicators evolve around people (e.g. competences), and organizational structure (e.g. procedures, division of tasks) and information systems. The indicators *'presence of technological staff'*, *'variability of workforce composition'*, *'sufficiency of competences of operators'*, *'extent of management commitment'*, *'degree of employee involvement'*, *'level of formalization'*, and *'sufficiency of supporting information system'* (Figure 3.1) have been found relevant for the fresh produce sector and retained from the main principles for assessment of FSMS context *(294)*. Studies evaluating the food safety practices of workers in fruit and vegetables production highlighted that insufficiencies in technological expertise, formalization, operators' knowledge, and involvement lead to lower food safety levels of implemented FSMS *(240, 338)*. Large turnover of workers that often do not even speak the language of the country, and poor motivation, due to low attractiveness of the work, require additional efforts in the FSMS, for example by translating the procedures, additional training in other languages and by using different approaches for instruction *(34, 287, 474)*. Management commitment to food safety is another important factor for the successful implementation of FSMS *(329, 358, 474, 481)*. Lack of attention and support for food safety from the management may lead to a shift of priorities, and building of low awareness among workers *(294, 370)*.

3.2.4. Chain characteristics

Indicators of *'chain characteristics'* are addressing the inter-organizational set-up of the supply chain environment and relationships between actors and stakeholders involved. They are influencing the decision making of the food business operators in the supply chain, and hereof several indicators have been included. The indicator *'severity of stakeholder requirements'* was previously developed to represent the differences and conflict between the requirements of stakeholders through various standards and legislation, which are also relevant to companies in the fresh produce chain. The assumption for this indicator is that strict and differing requirements for FSMS by governments, client companies, etc. put demands on the FSMS *(294)*. Low risk is linked to general legislative requirements, such as good agricultural practices (GAP) or HACCP, while higher risks are associated with additional and even conflicting quality assurance requirements for major stakeholders. Studies have indeed highlighted the relevance of this issue in fresh produce, where differences in requirements have resulted in import and export ambiguities, and difficulties for fresh produce companies to implement requirements into their own FSMS and meet the safety limits *(63, 99, 459, 483)*.

'Extent of power in supplier relationships' (Figure 3.1) was previously used to provide information about the possibility of the company to affect suppliers. The assumption for this indicator is that companies which lack power to influence suppliers, may result in unpredictable safety levels of incoming materials *(294)*. Fresh produce companies that are able to closely integrate food safety controls and assure compliance with specifications by the suppliers, have demonstrated to be more capable of assuring food safety *(e.g. 165, 234, 428)*, and represent the low risk situation. Risk is increasing when company has less influence on its suppliers *(e.g. 373, 392)*.

Several new indicators have been established to address important issues for the fresh produce chain (Table 3.2). The indicator *'degree of information exchange in supply chain'* reflects how the chain members are collaborative in their efforts to secure food safety. Systematic and complete sharing of information, which is typical for long-term relationships with (preferred) suppliers represents the low-risk situation. The risk is increasing when information is less and when it is received unsystematically. Crucial for the high risk is the information exchange that is ad-hoc (upon problems), which is typical of spot market relationships *(e.g. 38, 373)*. Studies have shown that indeed the performance of an FSMS is strongly influenced by the level of coordination within the production chain *(274, 333)*. Coordination of functions at different stages of the supply chain is manifested by shared information, systems compatibility, risk sharing *(494)*, and use of both quality/safety and logistics information to improve chain performance *(471)*. However, companies lacking systematic information from suppliers have to deal with less predictable initial safety levels, which is often leading to food safety failures *(*e.g. *165)*. In such cases, inadequate decisions in control activities imply higher risks of safety problems.

Moreover, *'sophistication of logistic facilities'* indicates the risk, related to inadequate transport and storage until products reach the next company in the chain (Table 3.2). Strictly controlled conditions, modified and/or adapted for specific type of produce are considered as low risk. The risk is increasing when conditions are not controlled uninterruptedly along the chain. Uncontrolled transport and storage, typically ambient conditions, are typical of the high risk. Various studies showed that temperature abuse, inadequate facilities, handling times, and conditions can have a negative impact on food safety of fresh produce *(4, 60, 380, 461)*.

'Supportiveness of food safety authority' gives an impression about the functioning of the official control bodies in the country of operation (Table 3.2). The ideas behind this indicator is that lack of systematic procedure-driven inspections and adequate feedback by acknowledged food safety authorities will lead to less reliable feedback information to companies about their FSMS. This is especially an issue in countries without established food regulations and food safety authorities *(332)*. The low risk is defined as systematic procedure-driven inspections using risk-based sampling, providing systematic feedback, and follow-up *(10, 185, 306)*. Studies showed that when the national inspection system is not complying with international recommendations and there is a lack of adequate and reliable feedback information, more burden is put on companies to be able to guarantee the safety of their food products *(e.g. 3, 165, 234)*. Many private standards have been introduced in numerous agri-food chains, however, the lack of a dedicated agency and shortcomings in the inspection system in many (export) countries remain important factors in creating better FSMS and especially important for SMEs *(28, 318)*. The lack of feedback information from a food safety agency and inadequate decisions in

control and assurance activities in the FSMS imply a higher risk of food safety problems.

The indicator *'degree of globalization of supply'* reflects on the diversity of supply of initial materials (Table 3.2). Companies have an increased chance of unknown hazards and unexpected contamination when purchasing initial materials from suppliers with variable food regulations that do not comply with internationally acknowledged requirements. Low risk is assigned to suppliers that comply with same food regulation (*e.g.* only national suppliers). Crucial for the high-risk situation is when suppliers comply with different food regulations or they have no internationally acknowledged or benchmarked requirements. Companies that deal with suppliers from many different locations may face untypical risks, i.e. hazards that are uncommon and or unrecognized in the geographical area, not addressed in the existing legislation, etc. *(262, 342)*. An example is the case of *cyclosporiasis*, which has been introduced via trade from areas of endemicity; it was untypical hazard to temperature climates, and no specific preventive measures or legislation existed *(103, 205, 208)*. Moreover, supply often varies (*e.g.* seasonally), which requires FSMS to repeatedly adapt to new sources with their specific contexts and practices *(192, 326, 450)*.

Another two indicators reflect on issues related to the existing institutions and resources in the country of operation. The indicator *'specificity of external support'* refers to the assistance provided by governmental and non-governmental organizations, or private parties (*e.g.* consultancy agencies) to the fresh produce companies in designing their FSMS (for instance, by providing sector guidelines, training, etc.) (Table 3.2). Support that is product and production system specific, science based and well established, represents the low risk situation *(105, 159)*. Crucial for the high risk is external support that is general for the whole food sector (for example, general information from various internet sources). Growers in many (developing) countries often have limited access to information regarding safety and quality of food, which creates difficulties for FSMS implementation and operation on farm and in companies *(21, 192, 203, 242, 332, 456)*. In cases of limited external support companies need to be more proactive in their internal efforts *(201)*. In addition, *'specificity of food safety legal framework'* gives an indication about how well established and detailed is the national food policy (Table 3.2). Policy with detailed specific legislative acts on food safety (such as, microbiological criteria, maximum residue limits for pesticides), harmonized with internationally acknowledged recommendations (*e.g.* Codex Alimentarius) is defined as low risk. Crucial for the high-risk level is the general national food policy, with no food safety legislative acts (*e.g.* not yet defined). Studies have demonstrated that lack of strict legislative framework of food safety controls is hindering food safety *(e.g. 232, 456)*.

3.3. Assessment of the context riskiness at processing & trade

The tool was adapted and new grid descriptions have been added where necessary to address the context at processing (Table 3.3) and trade (Table 3.4). The processing stage includes companies manufacturing fresh products (such as fresh-cut vegetable salads and mixes, fruit salads), but also commodities that are derived from fresh produce (such as juices, purees, ketchup). The traders are all commercial companies that perform the activities of storing, sorting, packing, re-packing, etc.

Over the supply chain, the output of cultivation is the input for processing and or trade, and the output of processing is the input for trade. The initial materials at processing and trade are the whole fruits and vegetables, received from primary production. Initial materials at trade could also be processed products. Therefore, the indicator 'microbial risk of final product' at primary production is the same as the indicator 'microbial risk of initial materials' at processing (Table 3.3) and trade (in case of a supply chain for whole fruits and vegetables) (Table 3.4). Similarly, the indicator *'microbial risk of final product'* at processing is also the same as the indicator *'microbial risk of initial materials'* at trade (in case of a supply chain for processed products) (Table 3.4).

The *'microbial risk of final materials'* is determined by the inherent properties of the fruits or vegetables, in combination with their production history. Final products at processing are considered moderate to high-risk when no full intervention process is applied (like pasteurisation, or sterilisation of e.g. canned products). Inactivating heat treatments are possible for certain types of production, for instance, fruit juices, purees, jams, canned fruits and vegetables *(14, 18, 30, 328, 442)*. However, in many cases no or only partial reduction is possible. For example, only partial reduction of microbiological load can be achieved through washing in combination with disinfection of *e.g.* salad vegetables *(131, 174, 283)*. Typical for the high risk situation is the lack of any intervention step, thus no possibility for elimination of microorganisms (*e.g.* fresh-cut products), which increases the chance of high initial microbiological load *(248, 296, 357)*. Studies have indeed shown that such kind of products are susceptible to food safety problems *(1, 25, 280)*.

The susceptibility of final products at trade is determined by the handling of fruits and vegetables. Certain products have natural (e.g. peel) or not (*e.g.* packaged whole fruits/vegetables) protective characteristics that will be removed before consumption, and they are not handled manually, or very little. However, risk increases and is considered moderate and high when surface protection is limited, lacking or removed and or products are handled manually at trade *(1, 492)*. Crucial for the high-risk situation is sensitive surface properties, handled manually in packhouses, retailer shops, warehouses, etc. Various studies stated that inadequate personal hygiene of food handlers is the most important factor during trade operations and has been implicated in outbreaks of norovirus and hepatitis A *(e.g. 45, 46, 209, 444, 445)*.

The indicator *'susceptibility of production system'* was also modified for each chain stage. At processing it addresses the susceptibility to survival of undesired microorganisms, due to applied (or not) intervention processes. Production systems that have few possibilities to inactivate hazards increase the change on lower food safety. The possibility to apply intervention in produce is often limited, since many products are marketed fresh or minimally processed. Systems having full intervention to reduce microorganisms to acceptable levels (such as pasteurization, application of preservatives, etc.) are associated with a low risk *(e.g. 35, 309, 375)*. Crucial for the high risk is the lack of intervention steps to fully or partially reduce microorganisms (rely only on preventive measures) (Table 3.3). Studies have indeed shown that production systems, which lack the opportunity to apply intervention, are more prone to contamination and growth of microorganisms, e.g. fresh-cut vegetables *(275, 401)*.

Unlike the microbial hazards, there is no or very little possibility for reduction or elimination of the chemical hazards, once they are in the product. Thus, the mechanisms that create riskiness to decision-making in the FSMS remain the same, and the indicators concerning risk of initial materials and final products to pesticide residues, and mycotoxins have not been modified for processing and trade.

The indicator *'susceptibility of production system'* at trade reveals to which degree a storage concept (or packaging conditions at storage) is designed to contribute to food safety. Certain storage systems have conditions that are not aimed at influencing growth of microorganisms (these are, ambient conditions, bulk storage, in containers, or packaged in crates, plastic bags) and are not controlled, thus representing low risk to decision making in FSMS. Risk is increasing and considered moderate and high when specific conditions need to be controlled (for instance, maintaining specific temperature, minimizing water loss, reduction of ethylene effects/ respiration through reduced O_2 and elevated CO_2) to directly or indirectly limit microbial and fungal growth. A crucial factor for the high risk is when conditions are aimed at preventing growth and contamination of microorganisms and fungi (for example, controlled atmosphere (CA) storage, active packaging, modified atmosphere packaging) and many parameters need to be controlled in the FSMS (Table 3.4). Studies have shown that if environment and or packaging conditions are not properly controlled, food safety problems may occur *(84, 226, 492)*.

The indicators *'risk of climate conditions'* and *'susceptibility of water supply'*, as well as the indicators for organisational and chain characteristics remained the same for processing and trade. They have been only modified in the examples and grids to reflect the specifics of the chain stages. No major changes were necessary, because the risk that is created to decision-making follows the same mechanisms, only the way companies respond with their FSMS will be different for primary production, processing, and trade.

Table 3.2: Established indicators to assess riskiness of **chain characteristics** for primary production, processing and trade in the supply chain

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
Degree of information exchange in supply chain			
Companies that lack systematic information sharing with their suppliers have to deal with less predictable safety levels, which put demands on FSMS (e.g. requiring advanced control measures)	Systematic and complete sharing of information on food safety issues (e.g. distributed database approach); (typical for long-term relationships with (preferred) suppliers)	Specific information exchange upon request (e.g. for pesticides only); (typical for short-term contract relationships)	Information exchange on food safety issues is ad-hoc (upon problems); (typical for spot market relationships)
Sophistication of logistic facilities			
Lack of adequate and strictly controlled environmental conditions of logistic facilities, increases chance of undesired growth of microorganisms or contamination, which put demands on FSMS (e.g. requiring advanced monitoring, validation, verification)	Environmental conditions of all logistic facilities (till products reach client) are modified and/or adapted for specific type of produce and strictly controlled	Environmental conditions of some of the logistic facilities (till products reach client) are not modified/adapted and/or not strictly controlled	Environmental conditions of logistic facilities non-controlled, typically ambient conditions (e.g. harvested produce stored in ambient temperature & transported in (open) truck at uncontrolled conditions)
Supportiveness of food safety authority			
Lack of systematic procedure-driven inspections and adequate feedback by acknowledged food safety authorities will lead to less reliable feedback information about the FSMS performance to companies, which is putting demands on FSMS by requiring more advanced assurance activities (e.g. verification and validation)	Systematic procedure-driven inspections using risk-based sampling; providing systematic feedback and follow-up; performed by accredited agency, following international guidelines (Codex Alimentarius)	Inspections according to national legislation; no risk based sampling. No/variable feedback or follow up activities. Performed by an agency that complies with national requirements	No inspections or on ad-hoc basis (upon serious safety problems); performed by general authorities, lack of specific food safety agency or service
Degree of globalization of supply			
Companies purchasing initial materials from suppliers with variable food regulations that do not comply with internationally acknowledged QA requirements, have an increased chance of unknown hazards and	Company purchases from same or different suppliers of major initial materials and/or ingredients; all comply with the internationally acknowledged requirements, or only national suppliers of major initial	Both national and international suppliers, but all comply with same internationally acknowledged requirements or regulation (e.g. EU food law), or same or different suppliers but some comply with	Different (e.g. varying seasonally) suppliers of major initial materials and/or ingredients; suppliers comply with different food regulations or they have no internationally acknowledged or benchmarked

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
unexpected contamination, which is putting demands on FSMS by requiring more advanced control and assurance activities (e.g. incoming materials control, verification)	materials and/or ingredients	internationally acknowledged and others with nationally benchmarked QA requirements (e.g. KenyaGap, ChinaGap, etc.)	requirements (e.g. only comply to local requirements)
Specificity of external support			
Lack of specific product or production system external support will increase the chance on inadequate safety decisions which may lead to food safety problems hence putting more requirements on FSMS (e.g. by requiring more testing of actual situations, advanced validation)	External support on food safety is production system specific, science based and well established. Documents are easy to access and understand i.e. available in native languages (e.g. free online access, weekly magazines, newsletters)	External support on food safety is sector specific and restricted. Information is difficult to access and understand (e.g. upon payment, not in native language and need expert to use)	External support on food safety is general for the whole food sector (e.g. general information from various internet sources)
Specificity of food safety legal framework			
Lack of a well-established and detailed national food policy with specifically defined legislative acts on food safety will increase chances for inadequate safety decisions, which puts demands on FSMS (e.g. requiring advanced control measures).	National food policy is well established with detailed specific defined legislative acts on food safety (e.g. microbiological criteria, MRLs). National food safety legislative acts are harmonized with internationally acknowledged recommendations (e.g. Codex Alimentarius)	National food policy with generally defined food safety legislative acts (lacks information on e.g. authorized pesticides, MRLs, microbiological criteria). National food safety legislative acts are not (yet) harmonized with internationally acknowledged recommendations (e.g. Codex Alimentarius)	Only general national food policy available with no food safety legislative acts. i.e. either not (yet) defined or still incomplete (e.g. in draft state)

[a] Low, medium and high risk levels for organisational and chain characteristics correspond to supportive, constrained or lacking administrative chain conditions or low, restricted and high dependence on other chain actors (294)

Table 3.3: Established indicators to assess riskiness of **product** and **production characteristics** at **processing**

Assumed mechanism	Low risk[a]	Moderate risk[a]	High risk[a]
		PRODUCT CHARACTERISTICS	
Microbiological risk of initial materials – **same as *'microbiological risk of final product'* at primary production (Table 3.1)**			
Risk of initial materials to pesticide residues – **Same as for primary production (Table 3.1)**			
Risk of initial materials to mycotoxins – **Same as for primary production (Table 3.1)**			
Microbiological risk of final products **Products which are susceptible to pathogen or fungal growth due to the lack of intervention (i.e. no intervention step or a possibility of post-contamination), increase chance on lower food safety performance.**	Products with applied full intervention and no possibility of post-contamination (e.g. irradiation, UHT), or partial physical intervention but no possibility of growth (e.g. freezing)	Products with applied partial physical intervention or full physical intervention, but post-contamination and/or growth is possible (e.g. disinfection, packaging after pasteurization)	Products with no intervention applied, growth of microorganisms is possible (e.g. fresh-cut products)
Risk of final product to pesticide residues – **Same as for primary production (Table 3.1)**			
		PRODUCTION CHARACTERISTICS	
Susceptibility of production system **Production systems that have few possibilities to inactivate hazards (i.e. rely only on preventive measures), increase chance on lower food safety performance and put higher demands on HSMS.**	Production system with full intervention to reduce microorganisms to acceptable levels (e.g. pasteurization, application of preservatives)	Production system with intervention steps, which partially reduce microorganism (e.g. washing, blanching, peeling, flash pasteurization, decontamination, removal of outer leaves)	Production system without intervention steps, which cannot fully or partially reduce microorganisms (and relies only on preventive measures)
Risk of climate conditions of production environment – **Same as for primary production (Table 3.1)**			
Susceptibility of water supply – **Same as for primary production (Table 3.1)**			

[a]*Low, medium and high risk levels for process characteristics correspond to low, potential and high chance of microbiological or chemical contamination (294)*

Table 3.4: Established indicators to assess riskiness of **product** and **production characteristics** at **trade**

Assumed mechanism	Low risk [a]	Moderate risk [a]	High risk [a]
PRODUCT CHARACTERISTICS			
Microbiological risk of initial materials			
– in case of whole fruits and vegetables - same as '*microbiological risk of final product'* at primary production (Table 3.1)			
– in case of processed products - same as '*microbiological risk of final product'* at processing (Table 3.2)			
Risk of initial materials to pesticide residues			
– Same as for primary production (Table 3.1)			
Risk of initial materials to mycotoxins			
– Same as for primary production (Table 3.1)			
Microbiological risk of final product			
Final products that are more prone to microbial contamination, growth and survival, due to their natural properties and manual handling practices, increase chance on lower food safety performance, and put higher requirements on FSMS.	No association of final products with contamination with microorganisms and/or pathogens. Typically products with natural (e.g. peel) protective characteristics that will be removed before consumption or packed whole fruits or vegetables. No or very limited manual handling (e.g. citrus fruits, bananas)	Only occasional association of final products with contamination with microorganisms and/or pathogens. Typically products that have natural protective surface properties that hinder microorganisms (e.g. waxy skin). Packaged products where protective surface properties are removed by processing (cut, peeled)	Common association of final products with contamination with microorganisms and/or pathogens. Typically products sensitive surface properties. Handled manually at trade (e.g. berries, cherries)
Risk of final product to pesticide residues			
– Same as for primary production (Table 3.1)			
PRODUCTION CHARACTERISTICS			
Susceptibility of production system			
Storage and/or packaging conditions that crucially contribute to limiting microbial growth or contamination put higher demands on the FSMS by requiring advanced control & assurance	Storage and/or packaging conditions not aimed at influencing growth of microorganisms (e.g. ambient conditions, bulk storage, containers, or packaged in crates, plastic bags)	Storage at adapted temperature conditions for type of produce (e.g. cold storage)	Storage and/or packaging conditions aimed at preventing growth and contamination of microorganisms and fungi (e.g. controlled atmosphere (CA) storage, active packaging, EMAP)
Risk of climate conditions of production environment			
– Same as for primary production (Table 3.1)			
Susceptibility of water supply			
– Same as for primary production (Table 3.1)			

[a] *Low, medium and high risk levels for process characteristics correspond to low, potential and high chance of microbiological or chemical contamination (294)*

3.4. Expert validation of the context indicators

Table 3.5 lists the results from the expert evaluation on the relevance of the entire set of indicators and the importance scores (median) of each indicator per context factor. All indicators were supported on relevance by more than seven experts (out of 14), which led to keeping all indicators in the tool. Moreover, the majority of the indicators received an importance rating above 2 (scale 0-3), which indicated the validity of the tool.

At primary production, the experts gave unanimously high scores for the indicator of the water source, stressing the important role of water used for irrigation in contamination of produce with pathogenic microorganisms. Low score was attributed to the risk of mycotoxins (1, somewhat important), and the risk of pesticides in initial materials (*e.g.* seedlings). The experts noted that the risk of contamination with mycotoxins of fruits, vegetables, and their products is relatively low as compared to other food groups, such as cereals and dried fruit. High scores (3.0) were attributed to technological staff, workforce composition and management commitment. For chain characteristics, most importance was given to the 'specificity of food safety legal framework' (3.0), followed by 'supportiveness of food safety authority' and 'specificity of external support' (2.5). These results were in line with a recent study, showing that the most important information sources, used by the industry for setting and maintaining their FSMS, are the legislation and guidelines, developed by industry associations *(464)*. Moreover, the experts stressed that hired advisors and consultants also play an important role.

The experts gave higher importance scores for all the indicators at processing and trade, compared to primary production, with even higher scores at processing. The indicator for the water sources scored 3.0 for processing, and the experts highlighted the possibilities for contamination during washing. The same indicator at trade received a score of 1.5, because water is used only for certain types of products, for example, in water flumes for conveyance. Again relatively low scores were attributed to the risk of mycotoxins at processing and trade (2.0), but higher than at primary production. The experts acknowledged the importance of this indicators, and explained that at processing and trade the produce is often received in bulk, which increases the risk of moulded initial materials. Management commitment again scored high (3.0), and experts stated that it is the most important basis for a good working FSMS. The indicators for chain characteristics received high scores at processing (2.5-3.0). Experts explained that at processing products from different primary producers are mixed, which may lead to cross-contamination affecting the entire production. Thus, relationships within the supply chain are of key importance. At trade the experts stressed the importance of logistic facilities, globalization of supply, and food safety legal framework. Trade of fruits and vegetables is increasingly global, and companies have to deal with long transit times, and different production practices and legislation.

The expert validation was a starting point for further validation in companies. The tool has been translated (Dutch, Serbian, Spanish, Portuguese), and tested in various companies in the supply chain in 10 countries. Some minor changes were made to improve understanding, and examples were introduced in the description of grids to support the context assessment. The general impression of the users was that the terms were comprehensible and clear. Two new indicators have been suggested by the experts, and added after the validation and the first tests in companies (Table 3.1).

Table 3.5: Expert validation of indicators for **P**rimary **P**roduction, **P**rocessing and **T**rading companies: relevance points and importance rating (median and interquartile range)

Context factors and indicators	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
	PP	P	T	PP	P	T
Product characteristics						
Microbiological risk of initial materials [a]	11	14	10	2.0 (1.0)	**3.0** (0.0)	2.0 (1.3)
Risk of initial materials to pesticide residues[b]	9	14	11	1.0 (1.0)	**3.0** (0.0)	**3.0** (1.0)
Risk of initial materials due to mycotoxins	9	14	11	1.0 (0.0)	2.0 (2.0)	2.0 (1.0)
Microbiological risk of final product[a]	12	14	12	2.0 (1.0)	**3.0** (0.0)	**3.0** (1.0)
Risk of final product to pesticide residues	13	13	12	2.0 (1.0)	**3.0** (0.0)	**3.0** (0.3)
Production characteristics						
Susceptibility of production system	12	14	12	2.5 (0.5)	2.5 (1.0)	2.0 (2.0)
Risk of climate conditions of production environment	13	9	9	2.5 (0.5)	2.0 (2.0)	2.0 (2.0)
Susceptibility of water supply	14	13	8	**3.0** (0.0)	**3.0** (0.0)	1.5 (2.0)
Organisational characteristics [c]						
Presence of technological staff	12	12	13	**3.0** (0.0)	**3.0** (1.0)	2.0 (1.0)
Variability of workforce composition	12	13	11	**3.0** (0.0)	2.5 (1.3)	2.0 (1.0)
Sufficiency competences of operators	12	14	12	2.0 (1.0)	**3.0** (1.0)	2.0 (1.3)

Context factors and indicators	Relevance (n=14)			Importance rating (0 → 3, not to very important)		
	PP	P	T	PP	P	T
Extent of management commitment	13	14	14	**3.0** (0.0)	**3.0** (0.0)	**3.0** (1.0)
Degree of employee involvement	12	14	12	2.5 (0.5)	2.5 (1.0)	2.0 (0.3)
Level of formalization	11	14	12	2.0 (1.0)	2.5 (1.0)	2.0 (0.3)
Sufficiency of supporting information system	12	14	13	2.0 (1.0)	**3.0** (1.0)	2.0 (1.0)
Chain environment characteristics						
Severity of stakeholder requirements[c]	13	14	12	2.0 (1.0)	**3.0** (1.0)	2.0 (1.3)
Extent of power in supplier relationships[c]	10	14	11	2.0 (1.0)	**3.0** (1.0)	2.0 (2.0)
Degree of information exchange in supply chain	14	13	11	2.0 (1.0)	2.5 (1.0)	2.0 (1.0)
Sophistication of logistic facilities	11	13	14	2.0 (1.0)	2.5 (1.0)	**3.0** (1.0)
Supportiveness of food safety authority	13	14	12	2.5 (0.5)	**3.0** (0.3)	2.5 (1.0)
Degree of globalization of supply	12	14	13	2.0 (1.0)	**3.0** (0.0)	**3.0** (1.0)
Specificity of external support	13	14	13	2.5 (0.5)	**3.0** (1.0)	2.0 (1.0)
Specificity of food safety legal framework	13	14	14	**3.0** (0.0)	**3.0** (0.0)	**3.0** (1.0)

[a] *Modified from the original concept for assessment of FSMS context*
[b] *In bold – new indicators*
[c] *Indicators retained from the original concept for assessment of FSMS context (Luning et al., 2011)*

3.5. Implications of the context assessment

In this paper, we described a tool that allows assessment of context riskiness affecting decision-making in FSMS in the fresh produce chain. The tool is aimed at studying how the inherent characteristics of the company environment can put demands on the FSMS to be effective. Riskiness refers to the context characteristics that create ambiguity (lack of knowledge about underlying mechanisms), uncertainty (due to lack of information), and or vulnerability (due to high likelihood of contamination, while decisions need to be taken) in the decision-making activities in the FSMS. In other words, systems need be adapted to its context to be effective, and in our study we focused only on context characteristics that may impact the food safety management system. Compared to the diagnostic instrument developed by Luning, Marcelis, et al. *(294)*, which is focused on microbiological safety and assessing the context of FSMS in meat and dairy production, our tool is specifically designed to address microbiological and chemical safety of fresh produce from a chain perspective. The purpose of our tool is neither to identify causes of quality problems, like for example the Ishikawa diagram *(e.g., 20, 268)*, nor to investigate the likelihood of occurrence *(419)*.

The differentiation of context characteristics into descriptions of low, moderate, and high risk enables a nuanced assessment of the context, wherein an FSMS has to operate. A more risky context requires a more advanced FSMS in terms of control and assurance activities being based on scientific evidence, specific information, stable, predictable, and tailored for the specific food production situation. Such systems are better able to deal with ambiguity, uncertainty, and vulnerability in the systems' context *(288, 294)*. The tool is applicable at primary production, processing, and trade, and can thus provide insights into the changes in context riskiness over the whole supply chain. Moreover, specific indicators for the chain environment (for instance, 'specificity of food safety legal framework' and 'sufficiency of food safety authority') allow for comparison between international supply chains, which can be used by companies in emerging or developing economies to get better insight in their context.

The tool is currently being used together with a similarly structured tool for assessment of FSMS activities *(256)*, to analyse the status of FSMS at primary production alone and along whole supply chains, in Europe and beyond. Data from these quantitative studies will be presented in the near future. Further studies will combine microbiological and system analysis to enable risk profiling for a chain stage, product group, or country. These studies will be the basis for development of quality assurance requirements/recommendations in fresh produce chains, tailored for different climate zones, countries (EU and non-EU), chain actors, and product groups *(229)*.

3.6. Acknowledgements

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Chapter 4: Exploring the influence of context on food safety management: Case studies of leafy greens production in Europe

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Abstract

Fresh produce companies operate their food safety management systems (FSMS) in a complex context. On the one hand, during setting and operating their FSMS activities, companies need to consider the riskiness of the 'FSMS context' of the company, including the risk of product and production, and the limitations and opportunities of the organisational and chain characteristics. On the other hand, companies with their narrow 'FSMS context' and actual FSMS, can be influenced by the 'broad context' in a country and sector.

This paper presents an analytical framework with operational tools that enable assessment of the status of FSMS in view of the context riskiness at company level, and exploration of the influence of the 'broad context' in a country and sector. The latter was defined to include: food safety governance, agro-climatic, market, and public policy environment. Empirical data from three case studies of leafy greens production, intentionally chosen to represent three European regions with their specific contexts, was used to validate the analytical framework. As a conclusion, we postulate that the FSMS output is a function of the broad context in a country and sector, the 'FSMS context' in a company, and implemented food safety management system. The model is a first step towards conceptualisation of the complex systems influencing FSMS implementation and operation in companies.

4.1. Introduction

Many efforts have been put into implementing food safety management systems (FSMS) in companies in the food production chain *(152, 265, 315)*. In scientific research the focus was largely on investigating the status and effectiveness of FSMS in the animal sector (i.e. dairy and meat) *(228, 229, 289, 397)*. More recently, incidences of foodborne illnesses have triggered the attention of the public to safety of fresh produce such as leafy greens *(15, 27, 297)*. These outbreaks have been occurring worldwide and due to the large volume of international trade with these commodities, several of them involved multiple countries *(e.g. 160, 184, 297)*. Furthermore, pesticide residues are still an important issue *(81, 207)*, and the risk is perceived as high by consumers *(76, 464)*.

To mitigate the risks to food safety, companies have put efforts into upgrading their food safety management systems (FSMS). These systems at primary production are commonly based on good agriculture and good hygiene practices, however, no special provisions or guidelines are yet elaborated regarding their actual implementation within the European Union (EU). The EU policies are following the principles of subsidiarity and multi-level governance, which aim at distributing the policy responsibility among different governmental levels, and among the public and private sector, as decision-making takes place at the lowest possible level *(42)*. These principles are enforced differently in each member state by following different public strategies to induce compliance and often leaving a lot of room for industrial self-regulation *(69, 194)*. This niche is covered by various private standards (e.g. GlobalGAP, IFS, Marks & Spencer's Field-to-Fork, Tesco Nature's Choice), commonly imposed by the retailers. *De jure* they are voluntary, but *de facto* food business operators need to conform with them to gain market access *(158, 199, 216)*. This whole set of legislation and standards, organisations (public and private) and processes involved in their enforcement, are described by the term food safety governance *(382)*.

Food safety governance is part of the broader context of a sector and country that can have an influence on FSMS. Primary production of fresh produce is particularly vulnerable to contextual influences such as contamination from people and environment, including agricultural workers, irrigation water, manure, surroundings, wild life, etc. *(40, 135)*. Furthermore, fresh produce and leafy greens are increasingly traded globally, grown and processed under diverse conditions, following different legislation and standards *(369)*. They are mostly consumed raw, and there is limited possibility to apply intervention for elimination of any contamination, even further down in the chain for derived products, such as fresh-cut salads. Moreover, fresh produce is susceptible to climate change impacts *(257, 281)*.

Previous research described the relationships between the context and quality and food safety management systems and their output *(259, 294, 424)*. Empirical studies showed that companies working in a high risk context need more advanced FSMS activities to be able to achieve a good output *(288, 289, 352, 396)*. However, these studies focused on the context of FSMS on a company level and the broad environment of the country and sector was not taken into account. The latter has been partly addressed in political economy research investigating the food safety governance and the mechanisms behind public and private enforcement *(e.g. 383, 391, 435)*. These studies, however, do no investigate the effect of food safety governance on FSMS implemented in companies. The study of *(227)* investigates the influence of a public standard on food safety management systems on a company level, but without analysing the underlying governance mechanisms. No research yet explores the elements of the broad context in a country and a sector that can affect the actual implementation of FSMS in companies. No research yet explores the elements of the broad context in a country and a sector that can affect the actual implementation of FSMS in companies.

Therefore, the objective of the study was twofold: 1) to assess the status of FSMS in the leafy greens sector; 2) to explore the 'broad context' and the mechanisms through which it can influence the 'FSMS context' in a company, FSMS activities and the system output. This paper presents an analytical framework with operational tools that enables assessment of the status of food safety management systems in view of the context riskiness at company level, and exploration of the possible influence of the 'broad context' in a country and sector. The latter included food safety governance, agro-climatic, market, and public policy environment. The model is a first step towards conceptualisation of the complex systems influencing FSMS implementation and operation in companies. It builds on previously developed theories about status of FSMS in fresh produce companies in view of their company specific FSMS context *(256, 259)*.

4.2. Analytical framework

The analytical framework (Figure 4.1) shows a schematic representation of the FSMS as influenced by their narrow and broad context. The analytical framework is grounded on the systems thinking approach aimed to study how systems behave, interact with their context and influence each other *(470)*. The general systems theory describes that all systems constitute of elements, have a structure of sub-systems and participate in bigger hierarchy of systems *(415)*. In the analytical framework were considered hierarchical system levels: 1) the companies with their unique FSMS and context, and 2) the broad context in which they operate with its sub-systems including food safety governance, agro-climatic, market and public policy environment. To assess the FSMS and their context, we used a previously developed diagnostic tool *(256, 259)*. This tool was embedded in the analytical framework aimed to explore the broad context with its sub-systems, and their possible influence on the FSMS.

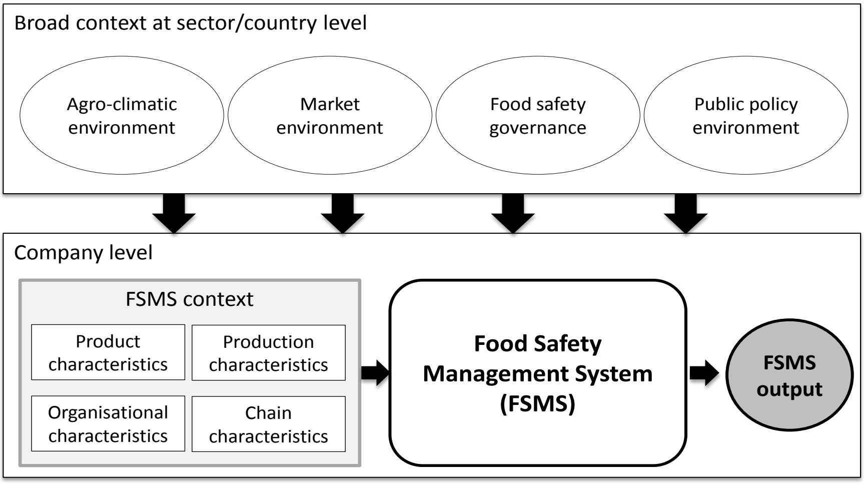

Fig. 4.1: Analytical framework showing the hierarchy of the national and company level and relationships between the broad context, narrow FSMS context, FSMS and FSMS output (elaborated by the authors)

4.2.1. Diagnostic tool for assessing status of FSMS in fresh produce

In the lower level of our hierarchy we have considered the food companies with their FSMS. To collect information we have used a diagnostic tool which allows assessment of the 'FSMS context', FSMS activities and the FSMS output *(256, 259)*. The 'FSMS context' consist of the product, production, organisation and chain characteristics of the company that can create riskiness to the decision-making process during the set-up and operation of the FSMS with its control and assurance activities, and thus their final FSMS output. Riskiness is created by the vulnerability of the products, uncertainty due to lack of information and ambiguity due to lack of understanding *(294)*. Companies can reduce the riskiness of the 'FSMS context' by addressing it in the FSMS activities with systematic methods and independent positions, adequate and science-based information *(294)*.

To allow for measurement, indicators with corresponding stereotypical situation descriptions, in which companies have to position themselves, were defined in the diagnostic tool. For each context indicator three situational descriptions represent low (situation 1), moderate (situation 2), and high risk (situation 3) to decision-making during setting and operating the FSMS activities. For the context factors product and production characteristics, the low, moderate, and high risk situation represent, low, potential, and high chance of microbial or chemical contamination, growth, and or survival of pathogens, and other undesired microorganisms. The low, moderate, and high risk situations for organisational characteristics respectively correspond with supportive, constrained (restricted), and lack of administrative conditions for appropriate decision-making during set-up and operation of FSMS. For the chain characteristics, the descriptions for low, moderate, and high risk situation correspond to low, restricted, and high vulnerability to safety problems or dependability on other chain actors *(259, 294)*.

For each control and assurance activity indicator three stereotypical descriptions represent basic (situation 2), average (situation 3), and advanced situation (situation 4) *(256, 286, 295)*. Situation 1 is given when an activity is not possible in the given production circumstances, it is not applied, although it is possible, or no information is available. The basic situation (2) for control activities represents standard equipment, unknown capability, use of own experience/general knowledge, incomplete methods, restricted information, lack of critical analysis, and non-procedure-driven activities. For assurance, the basic (2) is typified by problem driven, only checking, scarcely reported, not independent positions. The average situation (3) for control activities represents activities that are based on the following aspects: expert (supplier) knowledge, use of (sector, governmental) guidelines, best practices, standardised, generic information and sometimes problems. The average situation for assurance activities represents active translation of requirements, additional analysis, regular reporting, and experts support. The advanced situation (4) for control and assurance activities represents the use of specific information, scientific knowledge, critical analysis, procedural methods, systematic activities, and independent positions.

The output of the activities is measured through performance indicators, and the situations represent no information (situation 1), poor (situation 2), moderate (situation 3), and good output (situation 4) *(230, 256)*. Poor output represents situations with ad-hoc sampling, minimal criteria used for evaluation, and having various food safety problems or remarks during inspections/audits. Moderate output represents regular sampling, several criteria used for evaluation, and having restricted food safety problems mainly due to one (restricted) type of problem. The good output represents systematic evaluation, using specific tailored criteria, and having no safety problems or important remarks during inspections/audits.

The overall assumption behind the diagnosis is that companies operating in a high risk context need more advanced FSMS to achieve a good output *(294)*.

4.2.2. Tool to analyse the broad context

On the higher level of our hierarchy we have considered the so-called 'broad context' of a country and sector. Based on a literature study four main sub-systems were defined: food safety governance, agro-climatic, market and public policy environment (Fig. 4.1). The criteria used to select these sub-systems was their possible influence on food safety of fresh produce, through FSMS or its narrow FSMS context. Under agro-climatic environment were considered climate zone and production season; under market environment - structure of the market and supply chain; under public policy environment - subsidies and other policy measures aimed at influencing the market, quality and safety of food products. Food safety governance was analysed separately, which is explained in the next section. The overall hypothesis was that the broad context affects both the FSMS and their output, and the FSMS context consisting of product, production, organisational and chain characteristics *(259)*.

The agro-climatic environment can influence the occurrence of pests and plant diseases *(133)*, occurrence and survival of fungi, bacteria, protozoa *(87, 131, 168, 361)*, which are part of the product and production characteristics of the narrow 'FSMS context'. The agro-climatic environment can also directly affect the effectiveness of pesticides (2), which puts requirements about selection type of pesticides and time of application in the FSMS activities. Requirements of the market and food safety governance can directly influence the choice of pesticides and production methods by the farmers *(161, 163)*, which might be reflected in the FSMS activities and the system output (e.g. pesticide residues in final product). Market and food safety governance may also determine the microbiological limits and allowed control strategies, such as irradiation, disinfection, etc. *(19)*. Change of the public policy interventions, such as subsidies and tariff measures, can also affect the choice and amount of pesticides used by the producers *(405)*.

4.2.3. Tool to analyse food safety governance

Food safety governance is one of the sub-systems of the 'broad context', aimed influencing the FSMS implemented in companies. Governance has been described previously as the institutions, structures of authority and collaboration between stakeholders, aimed at allocating resources and controlling or coordinating an activity *(431)*. In the case of food safety, it is aimed at assuring compliance of food companies to the food safety standards and regulations *(391)*. Food safety governance, as any other governance, is the result of public and or private enforcement. Therefore, in the analysis of food safety governance, we have used a theoretical framework for investigating the existing enforcement practices and strategies (Fig. 2), based on May and Burby *(308)*, Unnevehr and Jensen *(460)*, Garcia Martinez et al. *(164)* and Rouvière and Caswell *(391)*. The framework allows identification of the strategy and the underlying philosophy applied in the enforcement, by studying the enforcement practices (Fig. 4.2).

Philosophies can be systematic and facilitative *(308)*. The systematic approach aims at identifying food business operators that do not comply with legislation and penalise them, while the facilitative seeks to avoid such non-compliances *(391)*. Different strategies can be employed, and they can have varying degree of public involvement: from direct command and control by the governmental agencies, to self-regulation, which relies on market solutions *(164)*. In-between is the co-regulation, which integrates the use of primary regulation and market self-regulation, and involves public-private initiatives *(127)*. The enforcement strategy consists of different practices; commonly used ones for the enforcement of food safety are: audits and inspections, incentives (sanctions and stimuli), information and education, and sampling/monitoring *(141, 164, 391, 487)*.

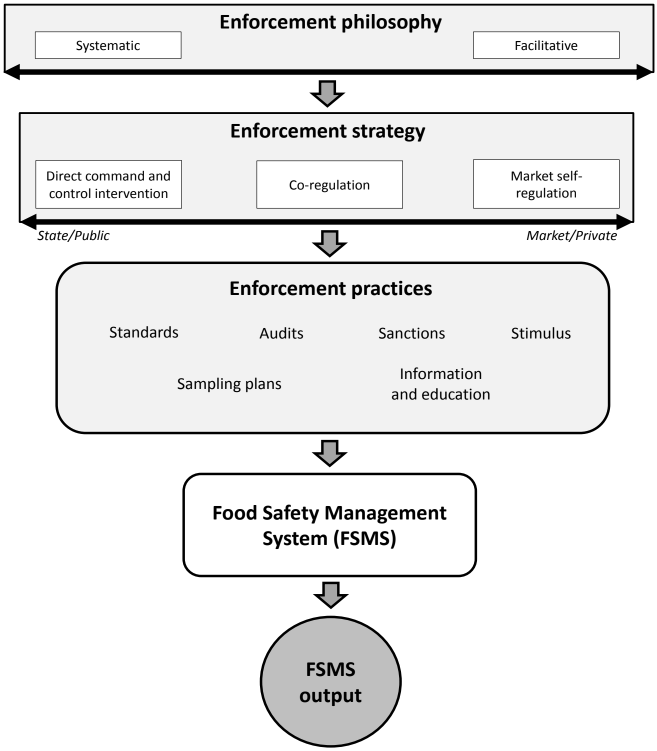

Fig. 4.2: Tool to analyse food safety governance. Developed by the authors based on: *(164, 308, 391, 460)*

Quality assurance standards are usually used to induce compliance by the companies. They are enforced through audits. They can be direct - visits, random or scheduled, but they can be also indirect - through monitoring companies' records or through (third-party) audits *(391)*. Besides, monitoring and sampling of the (final) product can also be done. It can be focused on either microbial or chemical safety. Incentives can be applied to stimulate compliance, which may be coercive or rewarding. Sanctions can be imposed upon non-compliance. They can be repressive (e.g., fines, prosecution, recall, closure of facilities, seizure of products, disqualification from market), informative - requiring corrective actions, and 'naming and shaming' - providing negative information to the consumers *(391)*. Stimuli such as awards, labels, tax reduction, can also be employed to encourage compliance *(190, 227)*. Furthermore, information and education (such as guidelines, training, advice) are used to support companies, especially in the case of small and medium enterprises *(164, 487, 488)*.

4.3. Results

4.3.1. Application of the analytical framework

Three exploratory case studies have been used to apply the analytical framework and to represent differences in assumed conceptual elements of the 'broad context', as suggested by Pettigrew *(365)* for theory building. The three main sub-systems of the 'broad context' were analysed as follows: Initially, the 'broad context' was considered during the design of the case studies by studying three different growing regions of leafy greens in Europe: Murcia (Spain), Lier (Norway) and Flanders (Belgium) with different agro-climatic (typical climate and ways of production). The leafy greens companies were selected to represent different market environment with its typical producers and supply chain. The public policy was addressed by reviewing the main agricultural policy interventions utilized in the sector, such as subsidies and imports tariffs. Moreover, information about the broad context was collected by literature review and interviews with experts in these three regions.

Food safety governance was defined by reviewing literature, reports and information bulletins of the national food safety agencies (FASFC in Belgium; Mattilsynet in Norway; AESAN in Spain) and produce organisations involved in the enforcement (Vegaplan in Belgium; Matmerk in Norway; Proexport in Spain), and by interviewing twenty-seven (27) experts (nine per case study). Two experts for the Spanish case were from a research institute (S01 and S02), one from a produce organisation (S03), and six from companies (S04-S09). One expert for the Norwegian case was from the national food safety authority (N10), two from a produce organisation (N11-N12), and six from companies (N13-N18). Two experts for the Belgian case were from sector organisations (B19 and B20), one from the organisation of the auctions (B21), and six from companies (B22-B27).

Data about the FSMS was collected with the diagnostic tool at twenty-seven (27) leafy greens production companies. The producers have been approached randomly to represent typical companies in characteristic supply chains in each of the regions: eleven (11) in Spain, and eight (8) in Belgium and Norway each. Twenty-three (23) companies in the primary production sector of leafy greens responded and participated in our study (Table 4.1). The response rates per country case were as follows: 11/11 in Spain, 6/8 in Norway, and 6/8 in Belgium. We have ceased approaching new companies because the incremental learning between theory development and data analysis showed to be minimal

(128) due to the high recurrence in the data collected with the diagnostic instrument. Data from the primary production companies was collected by using the diagnostic tool in two ways: interviews with the quality assurance manager or company owner for about 1½ hour, and a workshop with companies in Spain in February 2012. Interviews were combined with on-site visit, while the workshop allowed for discussion with the companies about the real-life situation.

4.3.2. Characteristics of the broad context: agro-climatic, market and public policy environments

Details about the agro-climatic (climate zone and way of production) and market environment (size of companies, type of supply chain) of the companies that participated in our study are presented in Table 4.1. The companies in Spain have been producing open field in cold semi-arid (Mediterranean) climate. They have been mostly big, export-oriented and certified against many private quality standards. Production in Norway was both open field and in greenhouses, in humid continental climate. Primary producers have been mostly small, producing only for the local market (both supermarkets and processing companies) and they have applied public national standards such as Quality System for Agriculture (KSL), Nyt Norge and Debio. The local producers have been protected by the public policy in Norway through direct subsidy transfers and seasonal import tariffs *(334, 439)*. Companies in Belgium have been producing open field and in greenhouses, in maritime temperate climate. They were micro family-owned farms, supplying to the local market and exporting to the neighbouring countries via an auction. They have been certified against the national self-checking system (SCS), the industrial national standard Integral Chain Quality Control (ICQC), as well as for GlobalGAP. Companies in both Spain and Belgium have been operating under the public policy environment of the EU, which subsidises primary production *(182)* and puts tariffs on products imported to the EU *(120)*. The subsidies are linked to size of land and cross-compliance to standards for environmental protection and food safety, although, no criteria is given for measuring the latter *(17)*. The subsidies are granted according to the historical references of a country and farm, which with time led to more benefit for the bigger land owners and certain groups of producers *(182)*.

Table 4.1: Agro-climatic and market characteristics of the companies that participated in the case studies

Company code	Climate	Production	Size	Supply chain	Enforced standards
Spain					
S01	cold semi-arid	open field	big [b]	integrated export-	GlobalGAP
S02	climate [a]	open field	big	oriented supply	GlobalGAP, BRC, IFS, ISO 9000, Producción Integrada
S03		open field	big	chain [c]	GlobalGAP, UNE 155000
S04		open field	big		GlobalGAP, ISO 9000, ISO 14001, TESCO Nurture
S05		open field	big		GlobalGAP, ISO 9000
S06		open field	big		GlobalGAP, ISO 9000, BRC, IFS, TESCO Nurture, Leaf Marque
S07		open field	medium		GlobalGAP, TESCO Nurture
S08		open field	medium		GlobalGAP, ISO 9001, Leaf Marque
S09		open field	medium		GlobalGAP, BRC, IFS, QS
S10		open field	big		GlobalGAP, IFS
S11		open field	medium		GlobalGAP, BRC, IFS, QS, Tesco Nurture, Leaf Marque, McDonalds' GAP, Marks & Spencer's Field-to-Fork
Norway					
N12	humid	greenhouse with soil	small	integrated supply	KSL, Nyt Norge
N13	continental	greenhouse without soil	micro	chain for local	KSL, Nyt Norge, Debio
N14	climate	open field	small	market	KSL, Nyt Norge
N15		open field	small		KSL
N16		open field	small		KSL, GlobalGAP
N17		open field	small		KSL, Nyt Norge, Debio
Belgium					
B18	maritime	open field	micro	fragmented supply	SCS, GlobalGAP
B19	temperate	greenhouse with soil	micro	chain via auction	SCS, GlobalGAP
B20	climate	greenhouse with soil	micro	for local and export	SCS, GlobalGAP, ICQC
B21		greenhouse with soil	micro	market	SCS, GlobalGAP, ICQC
B22		open field	micro		SCS, GlobalGAP, ICQC
B23		open field	micro		SCS, GlobalGAP, ICQC

[a] Climate zones are indicated according to the Köppen-Geiger climate classification (362)
b The classification is according to European Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (109): few than 10 people (including seasonal workers) – micro; 10-50 people – small; 50-250 – medium sized; above 250 – big
c Characterization of the supply chain

4.3.3. Characteristics of the broad context: food safety governance

Table 4.2 shows the results from the analysis of the food safety governance, as a result from public and private enforcement, which makes it also a part of the 'broad context' in which companies operate.

In Spain the enforcement strategy has been based on market self-regulation, as the companies have been following many voluntary private standards and retailer's quality assurance schemes (Tables 4.1 and 4.2). On-site audits have been performed by different third-parties, both random and scheduled, but a national standard has not been introduced.

The enforcement strategy in Norway has been identified as generally following the traditional approach of direct command and control intervention by the state, because companies have been following the national public standards (Tables 4.1 and 4.2). Still, a sign of co-regulation has been observed in the joint management of the standards by state and industry. The national food safety authority (Mattilsynet) has been responsible for regulating food safety, including legislation related to the production and distribution of food. A government-owned food safety standard called KSL Matmerk (Quality Systems in Farming – Quality Mark) has been set for the primary production sector. The standard has been managed by an independent, publicly supported organisation, founded by the government, and governed by a board of representatives of primary producers, retailers and processors. KSL is a baseline standard, meaning that it is based on legislation. It is also a pre-requisite for the Nyt Norge label, which claims that only Norwegian ingredients have been used in the product. Audits have been based on yearly self-reporting, and on-site visits on a risk-based principle *(305)*. Negative information has been provided to the consumers through 'naming and shaming' of the companies which have exceeded the maximum residue limits (MRLs) *(386)*. The product sampling for pesticides has been done in a risk-based principle by the retailers or by the processing companies, and as a result the focus has been mostly on imported produce rather than on the locally grown one (Norwegian expert from produce organisation). Microbiological sampling of the water source has been foreseen in the KSL standard.

Due to the use of public and private standards, and their joint management by the sector organisation, we have typified the enforcement strategy in Belgium as following the principles of co-regulation (Tables 4.1 and 4.2). Primary production companies in Belgium have to comply with the law for self-regulation and implement a self-checking system *(139)*. Sector associations have prepared guidelines for the implementation of the self-checking system (SCS), and companies have been stimulated to get certification to the SCS, as this leads to reduction of the annual fee to the agency and the number of inspections *(227)*. Furthermore, a chain-wide industrial standard called ICQC (Integral Chain Quality Control) with enhanced requirements have been initiated by several leading producers and processors *(326)*. SCS and ICQC have been jointly managed by a sector association, which is responsible for updating and training the auditors *(468)*. Next to these national standards, GlobalGAP has been also widely implemented by the companies, as a certification has been required for export (Belgian experts from industry). The audits against GlobalGAP may be combined with those against SCS and ICQC, and have been done by third-party accredited auditors.

Table 4.2: Characteristics of the food safety governance for the case studies in Spain, Norway and Belgium

Enforcement practice/strategy	Spanish case: market self-regulation	Norwegian case: direct command and control	Belgian case: co-regulation
Standards	GlobalGAP and other private quality assurance standards for specific retailers (Lario et al, 2006). No sector guidelines or national guidelines are applied by these companies apart from legislative documents (S03-S09[a]).	State-owned voluntary standard for primary production (KSL) is in place. The KSL Matmerk is the basis and pre-requisite for the Nyt Norge standard (Matmerk, 2013; Richards et al., 2013). The standard is managed by an independent, publicly supported organisation (Matmerk), founded by the Ministry of Agriculture, and managed by a board of representatives from the agricultural food producers, retailers and consumers (Matmerk, 2013; Richards et al., 2013).	Nationally agreed voluntary self-checking guideline per sector, approved by the competent authority (Federal Agency for the Safety of the Food Chain (FASFC)), and an industrial chain-wide industrial standard (ICQC) are in place. The private standard GlobalGAP is also widely implemented. A sector association (Vegaplan) is managing both the public self-checking system and the industrial standard ICQC (e.g. updating, organising trainings). In Vegaplan are represented the cultivators' associations, auctions, produce trading and processing industry (FASFC, 2003; Vanhaverbeke, Larosse, & Winnen, 2008; Mondelaers & Van Huylenbroeck, 2008; Vegaplan, 2013; B19-B21).
Audits	Audits against the private standards by third-party accredited auditing bodies (Lario et al, 2006; S03-S09).	Risk-based inspections performed by the regional offices of the food safety authority, and reduced number of the on-site audits in fresh produce cultivation (low risk). Every year each company performs a self-audit against KSL. On-site visits are also foreseen, based on the risk-based principles (approx. every 3 years) (Matmerk, 2013). The results from the self-audit are communicated via a web-based system to Matmerk. The information from the web-based system is available to auditors of the KSL standards, and to the national food safety authority (Halkier and Holm, 2006; Riksrevisjonen, 2012).	1) The voluntary self-checking system in place: audits conducted by either the FASFC or by a commercial accredited certification body, approved by the agency. Certificate is given, and valid for 3 years. The audit may be combined with an audit of voluntary quality assurance standards (e.g. Global GAP, ICQC). 2) No self-checking system: unannounced random inspections on hygiene and traceability from the FASFC (FASFC, 2003; Jacxsens et al., 2013; B19-B21).
Sampling plans	Regular sampling for pesticide residues and micro-organisms is performed by the producing	Regular sampling of pesticide residues from the wholesalers or processing companies, but mainly focused on	Sampling can be done as sectorial residue monitoring plan (coordinated by Vegaplan) or as an own plan of the auction or another trader in fresh produce. In case of the

Enforcement practice/strategy	Spanish case: market self-regulation	Norwegian case: direct command and control	Belgian case: co-regulation
	companies, as demanded by the customer companies (mainly retailers) (S03-S09).	imported produce (N12) and not communicated to the farmers. Lack of structured sampling on a sector or company level for micro-organisms at cultivation (N11-N18). Sampling only of the water source.	sectorial residue monitoring plan every three months anonymously all data from the residue analysis is sent to the sector association Vegaplan. No organised microbial sampling is done so far. Some auctions recently started performing analysis of Salmonella, Listeria, E. coli EHEC and E. coli as hygiene indicator (FASCF, 2003; Vegaplan, 2013; B19-B27).
Sanctions	Exclusion of market (S03-S09).	Industrial self-regulation upon discrepancies in the KSL by financial sanctions in the form of price reductions. Listing and thus 'naming and shaming' of the companies who exceed the MRLs on the web site of the national food safety authority (Matmerk, 2013; N10)	In case of an exceedance of the MRL, a risk analysis has to be performed by the auction, trader or the individual cultivator, to check if there is a risk for public health. When there is risk for the public health a notification has to be done to the FASFC will take appropriate measures (e.g. recall, checking traceability or SCS of the cultivator). The auction or trader that is responsible for the sampling is obliged to immediately inform Vegaplan, and to implement corrective actions at cultivation. In case of use of unauthorized pesticide, a notification to FASFC is always obligatory (Vegaplan, 2013; B19-B27).
Stimulus	Access to market (S03-S09).	N/A[b] (N10)	Positive incentive by certification (approval) of the self-checking system leading to reduction of the annual financial contribution legally due by a food business operator to the FASFC (i.e. certification leads to a discount), and reduction of the inspection frequency (FASCF, 2003; Jacxsens et al., 2013).
Information and education	Regular training of the cultivators by the central quality departments of the traders or processing companies about application of standards and food safety management activities (S03-S09).	Training of the cultivators by the produce organisation upon e.g. changes of requirements (N11-N18).	Vegaplan and cultivators' associations provide training to the cultivators about the application of the self-checking system and ICQC (B19). Wide use of private consultants and advisors, especially for pest management and pesticides application (Vegaplan, 2013; B19-B27).

[a] *Codes of the experts are listed in materials and methods of this article*
[b] *N/A - not applied*

4.3.4. Food safety management at companies

FSMS context

The frequency distributions in Table 4.3 show the results for the narrow 'FSMS context' indicators for all companies, and modes calculated per case study. The indicators for product and production, and some of the chain characteristics scored similarly for all the companies. This can be explained by the fact that all companies were growing the same type of product, buying their supplies locally, and following the same hygiene and food safety EU legislation.

The modes in Table 4.3 have been calculated to compare the results for the 'FSMS context' indicators between the companies in the Spanish, Norwegian and Belgian case study. The biggest differences have been observed in the organisational characteristics. **Spanish companies** had central quality departments, with a special team responsible for quality and safety at primary production (Spanish experts from industry), which was depicted in the results from the diagnostic instrument with the low risk (situation 1) for the indicators about technical personnel (CO9), management commitment (CO12) and formalization (CO14). Attention was put also on the training and involvement of the workers. Upon hiring, Spanish companies were setting requirements on previous experience and providing basic food safety training (CO11=2, moderate risk). They were also stimulating their employees to discuss and provide suggestions for improvement via their group managers (CO13=2, moderate risk).

Table 4.3: Number of companies with same scores and mode[a] for indicators of context factors of the companies in the Spanish (S), Norwegian (N) and Belgian case (B).

Indicators	Frequency			S	N	B
	1[b]	2	3	(n=11)	(n=8)	(n=8)
PRODUCT CHARACTERISTICS						
CP1: Microbiological risk of initial materials	5	2	**16**	3	3	3
CP2: Risk of initial materials due to pesticides	2	**20**	1	2	2	2
CP3: Risk of initial materials due to mycotoxins		**23**		2	2	2
CP4: Microbiological risk of final product			**23**	3	3	3
CP5: Risk of final product due to pesticides	1	7	**15**	3	3	3
PRODUCTION CHARACTERISTICS						
CP6: Susceptibility of production system	1	4	**18**	3	3	3
CP7: Risk of climate conditions		**21**	2	2	2	2
CP8: Susceptibility of water supply	5	**14**	4	2	1	2
ORGANISATIONAL CHARACTERISTICS						
CO9: Presence of technical staff	5	10	8	1	2	3
CO10: Variability of workforce composition	10	9	4	1	1	2
CO11: Sufficiency of operators' competences	2	10	11	2	1	3
CO12: Extent of management commitment	6	**16**	1	1	3	2

CO13: Degree of employee involvement	2	10	11	2	2	3
CO14: Level of formalization	7	**14**	2	1	2	2
CO15: Sufficiency supporting info system	5	**16**	2	2	2	2
CHAIN CHARACTERISTICS						
CO16: Severity of stakeholder requirements	2	**16**	5	2	2	3
CO17: Extent of power in supplier relationships	6	**14**	3	2	2	2
CO18: Degree of information exchange	6	**14**	3	2	2	2
CO19: Sophistication of logistic facilities	13	9	1	1	2	1
CO20: Supportiveness of food safety authority	5	9	9	3	3	2
CO21: Degree of globalization of supply	**14**	8	1	1	2	1
CO22: Specificity of external support	**19**	2	2	1	1	1
CO23: Specificity of food safety legal framework	**23**			1	1	1

[a] The modes represent the most frequent number among companies in the case study
[b] Low (1), medium (2) and high (3) risk situations for product and process characteristics correspond to low, potential and high chance of microbiological or chemical contamination. For organizational and chain characteristics they correspond to supportive, constrained and lacking administrative chain conditions or low, restricted and high dependence on other chain actors.

In **Norwegian companies**, a technical person was present but with no specific knowledge on food safety (CO9=2), and companies did not have special quality policy. However, workers have been stimulated to provide suggestions via their group managers (CO13=2). **Belgian companies** commonly did not have any technical person with knowledge on food safety and were relying on common cultivation practices (CO9=3, high risk), and their workers showed low involvement (CO13=3). Moreover, no requirements have been put on previous experience or education, and no training has been provided for the (seasonal) workers (CO11=3).

<u>FSMS activities</u>

Table 4.4 shows the frequency distributions of the scores for the indicators of the FSMS activities for all companies, and the modes calculated per case study. The indicators for control activities such as design of equipment and facilities (PM24), maintenance program (PM25), storage facilities (PM26), supplier control (PM31), water control (PM34), measuring equipment (MS42) and corrective actions (MS43) scored as 3 (average situation) for most of the companies. This indicated the use of best available equipment and methods, and following standards and guidelines common for the sector. However, the indicators for packaging (PM30), partial physical intervention (IM36), and analytical methods for microorganisms (MS38) and pesticide residues (MS39) showed more polarized results. They were either not applied (score 1), or at average (3) to advanced situation (4). Regarding assurance activities, most companies have been regularly using feedback information from the control activities for introducing improvements, but rarely documenting the changes (SR53=3). Majority of the companies have been keeping records (DA59=3) of the critical product and production parameters (such as, pesticide type and time of application).

The modes in Table 4.4 have been calculated to compare the results for the indicators of the FSMS activities between the companies in the Spanish, Norwegian and Belgian case study. The Spanish companies showed higher scores for their control and assurance activities (mostly 3 and 4), compared to companies in Belgium and Norway. Core control activities such as personal hygiene requirements (PM28), programs for organic fertilisers (PM32) and pesticide management (PM33), water control (PM34), irrigation method (PM35) and supplier selection (PM31) scored as 3 (average) and 4 (advanced situation), which revealed activities that have been following the 'best practices' in the sector, and have been adapted and tested for the specific production practices. Indicators of assurance activities again scored higher in Spain, where companies were actively following changes in requirements from stakeholders and implementing the necessary changes (SR52=4). The companies scored high on verification of people (VE56=4) and equipment (VE57=3), and validation (SR54, 55=3).

Norwegian companies scored lower than the Spanish - mostly scores 2 and 3 (Table 4.4). Several crucial control activities, such as personal hygiene control (PM28), storage facilities (PM26), sanitation program (PM27), incoming material control (PM29), and corrective actions (MS43) scored 3. These results represent situations when activities are designed by following standards or guidelines. Norwegian companies demonstrated good insights into actual operation of their control activities, because of the advanced and average situations for availability of procedures (OC44=4), hygiene performance of equipment (OC46=3), storage capacity (OC47=3), and measuring equipment performance (OC50=3). Assurance activities scored as basic situation due to ad-hoc validation activities (VA54, VA55=2), which have been performed by the owner or managers, based on historical knowledge.

Table 4.4: Total number of companies with same scores, and the modes[a] for the indicators of food safety management practices of the companies in the Spanish, Norwegian and Belgian case.

Indicators	Frequency				Spanish case (n=11)	Norwegian case (n=8)	Belgian case (n=8)
	1[b]	2	3	4			
PREVENTIVE MEASURES DESIGN							
PM24: Sophistication of hygienic design of equipment & facilities	1	7	**12**	3	2	3	3
PM25: Specificity of maintenance program		1	**17**	5	3	3	3
PM26: Adequacy of storage facilities	3		**14**	6	3	3	3
PM27: Specificity of sanitation program		7	11	5	3	3	2
PM28: Extent of personal hygiene requirements		7	12	4	3	3	2
PM29: Sophistication of incoming materials control	1	**13**	5	4	3	2	2
PM30: Adequacy of packaging	11	1	7	4	4	3	1
PM31: Sophistication of supplier control	2	5	**14**	2	3	2	3
PM32: Specificity of fertilizer program	7	1	9	6	4	1	3
PM33: Specificity of pesticide program	3		9	11	4	3	3
PM34: Sophistication of water control	1		**16**	6	4	3	3
PM35: Adequacy of irrigation method		10	12	1	3	2	2
INTERVENTION METHOD DESIGN							
IM36: Adequacy of partial physical intervention	8	2	11	2	1	3	1
MONITORING SYSTEM DESIGN							
MS37: Appropriateness of hazard analysis	6	5	9	3	3	2	1
MS38: Adequacy of analytical methods for microbiological hazards	12	1	1	9	4	1	1
MS39: Adequacy of analytical methods for pesticide residues	6		1	**16**	4	1	4
MS40: Specificity of microbiological sampling plan	12	3	2	6	4	1	1
MS41: Specificity of pesticides' sampling plan	6	4	7	6	4	1	4
MS42: Adequacy of measuring equipment	2	2	**15**	4	3	3	3
MS43: Extent of corrective actions	3		**17**	3	3	2	2
ACTUAL OPERATION OF CONTROL ACTIVITIES							
OC44: Availability of procedures	1	5	10	7	3	4	2
OC45: Compliance to procedures		6	**13**	4	3	3	2
OC46: Actual hygienic performance of equipment & facilities	6	2	6	9	4	3	1
OC47: Actual cooling and storage capacity	6	3	7	7	4	3	1
OC48: Actual capability of partial intervention	11	2	6	4	1	4	1
OC49: Actual capability of packaging	10	2	6	5	4	3	1
OC50: Actual measuring equipment performance	2	2	**15**	4	3	3	1

Indicators	Frequency				Spanish case (n=11)	Norwegian case (n=8)	Belgian case (n=8)
	1[b]	2	3	4			
OC51: Actual analytical equipment performance	9	1	1	12	4	1	1
ASSURANCE ACTIVITIES							
SR52: Sophistication translating external requirements		3	12	8	4	3	3
SR53: Extent of systematic use of feedback information		6	**13**	4	3	3	3
VA54: Sophistication validating preventive measures	6	8	9		3	2	1
VA55: Sophistication validating intervention strategies	8	7	7	1	3	2	1
VE56: Extent verifying people related performance		12	6	5	4	2	2
VE57: Extent verifying equipment & methods performance		10	9	4	3	2	2
DA58: Appropriateness documentation		6	10	7	4	3	2
DA59: Appropriateness record-keeping system		2	**17**	4	3	3	3

[a] The modes represent the most frequent number among companies in the case study

[b] Situations 1, 2, 3, and 4 correspond to: low situation (1) → absent, not applicable, unknown; basic situation (2) → lack of scientific evidence, use of company experience/history, variable, unknown, unpredictable, based on common materials/equipment; average situation (3) → best practice knowledge/equipment, sometimes variable, not always predictable, based on generic information/guidelines for the product sector; advanced situation (4) → scientifically underpinned (accurate, complete), stable, predictable, and tailored for the specific food production situation.

Table 4.5: Total number of companies with same scores, and the modes[a] for the indicators of the FSMS output of the companies in the Spanish, Norwegian and Belgian case.

Indicators	Frequency				Spanish case (n=11)	Norwegian case (n=8)	Belgian case (n=8)
	1[b]	2	3	4			
SA60: Comprehensiveness external evaluation		4	12	7	3	2	3
SA61: Seriousness of remarks		1	2	**20**	4	4	4
SA62: Type of microbiological complaints	1	2	5	**15**	4	4	4
SA63: Type of chemical food safety complaints	1	1	**12**	9	3	4	3
SA64: Type of visual quality complaints	1	4	**17**	1	3	3	3
SA65: Advancedness of microbiological sampling	10	2	2	9	4	1	1
SA66: Comprehensiveness of judgement criteria for microbial FS	10	1	7	5	3	1	1
SA67: Advancedness of pesticides sampling	6	2	8	7	4	1	3
SA68: Comprehensiveness of judgement criteria for chemical FS	6	2	3	12	4	1	4
SA69: Type of non-conformities	1	3	11	8	3	3	4

[a] The modes represent the most frequent number among companies in the case study

[b] Situations 1, 2, 3, and 4 correspond to: no information (1) → absent, not applied, unknown; poor output (2) → ad-hoc sampling, minimal criteria used for evaluation, various food safety problems due to different problems in the activities; moderate output (3) → regular sampling, several criteria used for evaluation, restricted food safety problems mainly due to one (restricted) type of problem in the activities;good output (4) → systematic evaluation, using specific criteria, no safety problems.

The **companies in Belgium** scored the lowest in our study (Table 4.4). Many of their core control activities, such as sanitation program (PM27), personal hygiene requirements (PM28), incoming material control (PM29), irrigation method (PM35), and corrective actions (MS43) have been designed according to own experience and knowledge (score 2). They had also limited insight into actual operation of their control activities and had to deal with regular problems, as all indicators scored 1 (low) and 2 (basic). Moreover, validation activities have been lacking (VA54, VA55=1), and verification has been basic, performed ad-hoc, not documented, only by checking the presence but not analysing (VE56, 57=2), which calls under question the effectiveness of the control activities. Documentation was unsystematic and ad-hoc (score 2), compared to the structured and easily available documentation in Norway (score 3) and Spain (score 4).

FSMS output

Table 4.5 shows the frequency distributions of the scores for the indicators of the FSMS output for all companies, and the respective modes that were calculated to compare the results between the companies in the Spanish, Norwegian and Belgian case study. Spanish companies received audits by many third parties, including audits against GlobalGAP, which is comparable to the situation in Belgium, but contrasting to the audits from only one third party in Norway (that is, Matmerk). The Spanish leafy greens companies have been able to show evidence of their good system output to the stakeholders as they have been performing structured sampling for microorganisms and pesticide residues (SA65, SA67, SA68=4; SA66=3). This was differing from the lower results in Norway, where no samples were taken (MS38, MS39, MS40, MS41=1). In Belgium, a structured sampling for pesticide residues was in place, organised on a sector level or as part of sampling plans of an auction or trader (SA67=3). Sampling for microorganisms in Belgian companies has been done only occasionally by the auctions or traders (like, in the case of a presumed outbreak in the fresh produce sector; Belgian experts).

4.4. Discussion

The objective of this explorative study was to gain insight into the 'broad context', its sub-systems and the relationships between them, and the mechanisms through which they can potentially influence the narrow 'FSMS context', FSMS activities and their system output. We have defined the 'broad context' as consisting of agro-climatic, market and public policy environment, and food safety governance. Moreover, we have observed that these sub-systems interact with each other and can also indirectly influence the 'FSMS context', FSMS activities and their output.

4.4.1. Interactions within the 'broad context'

Case studies in leafy greens production were conducted in three regions: Murcia (Spain), Lier (Norway) and Flanders (Belgium). Markets and supply chains differ in those countries. Spanish companies operate in a favourable agro-climatic environment, which also positively affected the market. Actually, about half of the lettuce in the EU is grown in Spain *(138)*, and Murcia is the biggest producing region that provides about 70% of exported lettuce *(272)*. The opportunity for year-round supply has attracted investors from the northern EU member states (i.e., companies in UK, Belgium, the Netherlands) *(272)*. The export market grew, which led to expansion of the companies. Several of the Spanish companies even invested in production fields on higher altitudes, which allowed them to produce all year around (even in the hot summer months), and thus to control the agro-climatic environment. The market also governed the food safety, as stringent private standards have been the major food safety and quality enforcement strategy applied to the companies.

In the case of Norwegian companies, however, the producers are small and these represent the majority of the farmers in the country *(383)*. The unfavourable agro-climatic environment makes the local agriculture non-competitive with the world market prices, which was the reason for the introduction of direct transfers and tariffs on import products in the public policy, in order to secure the incomes of the primary producers *(439)*. A public baseline national standard (KSL), and other national standards promoting local production (Nyt Norge, Debio) have been introduced to induce compliance by the companies to quality and safety *(57, 383)*. The Norwegian fresh produce chain is heavily concentrated in its retail part where four retailer chains have 99% of the market, which makes it among the most concentrated in Europe *(157, 238)*. The production is marketed through cooperatives, which are owned by the primary producers and serve as their joint agents *(383, 439)*. The cooperatives have dominating market position, and long-term contracts with the biggest retailers and wholesalers *(341)*. No market standards have been imposed to the farmers (such as GlobalGAP), which is linked to the strong power position of the local farm-owned cooperatives promoted by the state *(383)*.

The Belgian market is highly fragmented, with many micro family-owned companies *(468)*. A public national self-checking standard is introduced to guide food companies in setting and operating their FSMS *(139)*. The market is organised around cooperative auctions, which are common marketplaces where growers and wholesalers or retailers meet and an auction clock determines the price of goods *(326)*. From these auctions the production can be distributed to either local market or export, and thus certification against both the industrial national ICQC standard, and the international GlobalGAP is required from the farmers *(326)*. To ease the certification of all these small farmers, a sector organisation is managing both the public and the private national standard. Moreover, audit against both national standards or together with GlobalGAP can be combined.

4.4.2. Impact of the 'broad context' on the narrow 'FSMS context'

The 'broad context' can be linked to the differences in the narrow context of the FSMS, and especially the organisational characteristics of the companies. To answer to the many market requirements and standards, Spanish companies have established food quality and safety policy, and central quality departments, with technical staff to support primary production. They have invested in training of personnel and establishing of strict procedures. The pressure from the market was more lax in Norway, food safety governance was publicly led and companies have shown not to have a special quality policy and less technical staff. The small family-owned farms in Belgium experienced difficulties in acquiring technical expertise, educating and motivating the temporary workers. Nevertheless, in both Norway and Belgium, general procedures and information systems have been established, which could be associated with the wide-spread certification against the national baseline standards.

4.4.3. Impact of the 'broad context' on FSMS activities

Differences in the 'broad context' can also relate to the actual implementation of the FSMS in the three selected case studies in Spain, Norway, and Belgium. Spanish companies heavily invested in equipment and methods, and assured the continuous incorporation of technical innovations (e.g. new crop varieties, drip irrigation, harvesting methods), which was demonstrated by the advanced control activities in our study. Assurance activities, which aim at providing evidence that control activities and the FSMS as a whole are effective and working well, also showed average to advanced levels. This is in line with reports indicating that the leafy greens sector in Murcia is among the best performing in Spain and in Europe *(272)*. The sector is characterised by high supply chain integration as many primary production companies are owned by the traders, and close relations are maintained with suppliers of seeds and other inputs *(272)*. Norwegian companies, however, strictly adhere to the national standards, as the control activities in our study mostly scored as average situation. The knowledge-intensive assurance activities, however, have been mostly based on own knowledge and experience (basic situation). This is in line with a study done in Japanese dairy companies, which also strictly followed national standards but scored lower for assurance activities *(397)*. Belgian companies showed the lowest scores, with basic FSMS activities, despite the wide certification against three quality assurance standards. They also had little insight about actual operation of the control activities. Validation activities have been lacking, and verification of people and equipment has been done only ad-hoc. However, several activities for which companies received support from the sector organisation and the auctions scored as average, like for instance the translation of external requirements (SR52) and systematic use of feedback information (SR53).

4.4.4. Impact of the 'broad context' on FSMS output

Differences in the 'broad context' have been clearly reflected in the results of the FSMS output. Spanish companies have had very detailed information about all the indicators of the FSMS output. They have been audited against several quality assurance standards, because these have been required by the market. Companies have been also doing extensive sampling for microorganisms and pesticide residues, and systematically registering non-conformities and complaints. This information has been required by their clients to prove the good functioning of their FSMS.

The situation in Norwegian companies has been rather different. The audits of the companies again the national public KSL standard have been mostly based on self-auditing and self-reporting. No sampling was done for neither microorganisms nor pesticide residues. Actually the situation in Norway is unique, because the country never had a big food scandal, and the wide public believes in the safety of local produce *(188, 260)*. This trust was demonstrated also in our study by the lax inspections and lack of sampling.

The family-owned micro companies in Belgium have received support in acquiring information about their output by both market and public sector. Auctions have regularly taking and analysing samples for pesticide residues. The sampling information has been communicated to the sector organisation, which further coordinated the process of applying corrective actions upon non-conformities. However, no systematic microbiological sampling was performed yet.

4.4.5. The food safety governance

The governance of food safety, which aims at inducing compliance to food safety requirements by the companies, forms an integral part of the 'broad context'. The EU has promoted the co-regulation and shift of responsibility towards private and public-private hybrid forms *(314)*. The approaches observed in our case studies, varied between the member states, ranging between market self-regulation (Spain), co-regulation (Belgium) and state-controlled regulation (Norway). These findings feed the theories about traditions of public policy and governance *(43, 44)*. Spain has been following the Napoleonic tradition of central state and many regional organs responsible for the equal implementation of the policy across the country *(364)*. This tradition has however eroded into regionalisation with significant differences between the regions and involvement of market mechanisms *(359, 447)*. The strong role of the state has been typical for the Nordic countries, although some new ideas have been also adapted *(83)*. The latter was observed in the management board of the KSL standard, consisting of representatives from both government and industry. The Belgium tradition has been embedded in the neo-corporatist democracy, which is based on consensus, compromise, and representation by a few well-organised groups that are recognised by the state *(253)*.

The results from the three cases raise questions about independence, consistency, and transparency of the food safety audits, enforcement of the standards, and the role of the public sector. Enforcement often relies on third-party private audits, like in the Spanish and Belgian case. However, these have been criticised for their ineffectiveness and partiality, and for providing only a snap-shot picture of the food production *(10, 368)*. In some cases, less attention is paid to primary production of fresh produce because of the risk-based character of the food audits and inspections and limited time and resources. This was observed in the Norwegian case. Audits, inspections and monitoring should be independent, objective, consistent and transparent *(368)*, which provides room for the public sector to control and intervene upon doubt or breach of these principles. Education and training also face limitations due to inconsistent programs, lack of follow up and evaluation of the effectiveness to change behaviour *(125, 240, 418)*. Instead, studies have stressed the importance of establishing and reinforcing a food safety culture with shared values by the management and the workers *(187, 370)*.

4.4.6. Methodological considerations

This research explored about the role of the 'broad context' in a country and sector on the status of FSMS on a company level. It used three different case studies to extend existing theories about factors influencing design and operation FSMS in companies *(230, 286, 294, 295)*. Further studies should consider in their design the ceteris paribus condition by keeping constant some of (the elements in) the sub-systems of the 'broad environment' and thus define the direct and indirect influences and possibly their magnitude on FSMS.

Last but not least, this study was a further validation of the robustness of the developed diagnostic tool for assessing FSMS in the fresh produce sector in view of their narrow 'FSMS context' *(256, 259)*. The tool provided consistent results and demonstrated ability to detect differences between FSMS of companies in different contexts, which supported the external validity of the tool. However, the validation of the tool should address also the criterion validity, which compares with other measures or outcomes already held to be valid *(96)*. A comparison with microbial sampling data from the same companies is on-going and the results will be published in the near future. The FSMS diagnostic tool provides for assessment of FSMS by generating semi-qualitative data. This study showed its usefulness to explore the factors that affect the status of FSMS, especially when used in multi-methodology approach combining in-depth qualitative data.

4.5. Conclusion

Food companies operate their FSMS in a complex context. On the one hand, during setting and operating their FSMS activities, companies need to consider factors in the 'FSMS context', such as risk of product and production, and limitations and opportunities of their organisation and chain characteristics. On the other hand, in this paper we have demonstrated that the 'FSMS context', the implemented FSMS and their output, are likely influenced by the 'broad context' shaped by food safety governance, agro-climatic, market, and public policy environments. The latter involved both public and private actors. Although all the companies in our case studies have been operating under the same EU food legislation, the approaches to food safety governance have varied. They have ranged between market self-regulation, co-regulation, and state regulation, which implies a link to the different governance traditions in the three European countries, and explaining the shift in the role of the state.

The companies operating in favourable 'broad context', including favourable climate, big companies in integrated market, and stringent standards as a result of market self-regulation, have demonstrated advanced FSMS, good information about the output and supporting organisational characteristics. The FSMS of the companies that were operating in less favourable 'broad context', either in fragmented market with small companies or in less favourable climate, have demonstrated less mature FSMS. However, the national state intervention via public policy interventions (subsidies and import tariffs) and baseline food safety standards have supported domestically supplying companies and they realised average FSMS, based on 'best available' knowledge and experience. This was not the case with the small companies operating in fragmented market, which demonstrated basic FSMS and lack of support from organisational characteristics. These companies have been dealing with both domestic and export market, certified against both private and public standards. This mixture or standards and requirements has proved difficult for the implementation capabilities of small farmers.

As a conclusion, we postulate that the FSMS output is a function of the 'broad context', the narrow 'FSMS context', and activities in the FSMS.

FSMS output = f (Broad context; FSMS context; FSMS activities)

The combination of tools used in this study enables analysis of the food safety management in a country and sector from a systems perspective, including interactions and relationships between and within the FSMS and the context in which they operate. The outcome of the analysis contributes to understanding the effectiveness of the current systems for food safety management. The approach can be further elaborated to analyse the most important determinants of the agro-climatic, market, public policy environment, and food safety governance that influence the implementation of food safety management systems in companies.

4.6. Acknowledgements

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Chapter 5:
The role of cooperatives in food safety management of fresh produce chains

To be submitted as: Kirezieva, K., Bijman, J., Jacxsens, L., Luning, P.A. The role of cooperatives in food safety management of fresh produce chains

Abstract

Purpose: The overall objective of this article is to explore the role of cooperatives in food quality and safety management in the fresh produce chain, focussing on the food safety management systems (FSMS) implemented on the farms. More specifically, we raise the question how a more market-like or a more hierarchy-like governance of transactions via cooperatives affect the quality and safety management system members apply and thereby affect the quality and safety of produce.

Design/methodology/approach: The research employed case studies in four cooperatives in Belgium and the Netherlands, each with different size and percent of contractual sales. Data was collected with a diagnostic tool for assessment of food safety management systems on the farms, and semi-structured interviews with the quality assurance managers of the cooperative firms.

Findings: Farmers in more hierarchical cooperatives had more advanced FSMS activities, science based, adapted and tested for their effectiveness in the particular situation. This was associated with more efforts put in supply chain management and services by the cooperative firm to support collaboration and coordination in the chain.

Research limitations/implications: The research was conducted for one product group and only in cooperatives in Belgium and the Netherlands, which limits generalizability towards other parts of the world and types of products.

Originality/value: Firstly, the article defines the role of cooperatives in food safety management. Cooperatives play a double role in managing quality and safety in the supply chain. On the one hand, they are responsible for the supply chain management, including tactical decisions about collaboration and coordination of quality and safety between farmers, the cooperative firm and the customers. On the other hand, cooperative firms sell the products of their members and make strategic decisions about the governance of transactions in the supply chain, which ultimately may have an impact on the supply chain management and the implemented FSMS in the farms. Secondly, the article provides evidence that market-like governance of transactions via cooperatives is associated to less advanced FSMS on the farms, compared to hierarchy-like ones.

5.1. Introduction

Each company in the food chain needs to implement a food safety management system, and moreover it is a legal requirement in many parts of the world, for instance within the European Union *(108)*. Food safety is considered as one of the aspects of food quality, and a food safety management system is a part of the overall quality management system of the company *(292)*. Quality management systems encompass activities of companies aimed to direct, control and coordinate quality, including formulating policy, setting objectives, planning, controlling, assuring and improving *(291, 293)*. Over the last years, however, the focus of quality management is moving from intra-company to inter-company within a supply chain *(249)*. This is especially pronounced in the fresh produce chain due to the perishability of products, global sourcing and longer supply chains *(52, 388)*. Recently, studies have begun to focus on the alignment between supply chain governance structures and food quality assurance schemes *(449, 478)*. However, to our best knowledge insights are lacking about the influence of the supply chain governance on the food safety management systems implemented at farmer level.

From a transaction cost economics perspective, supply chain governance structures differ in their level of coordination, ranging from market-based (i.e. spot market), through contract-based (verbal, formal and equity-based), to hierarchy-based *(378)*. A specific type of governance structure often found in food supply chains is the farmer-owned cooperative. According to Ménard *(312, 313)*, a cooperative is a hybrid governance form, as it combines pooling of resources, coordination through contracts and combining competition and cooperation. Chaddad *(78)* has further elaborated on this conceptualization of the cooperative as a hybrid governance structure, emphasizing that cooperatives use both market-like and hierarchy-like governance mechanisms. In other words, the relationship between the farmer-member and the cooperative firm is partly market-based and partly contract based. Cooperatives, however, differ greatly in the extent to which they apply more market-based versus more contract-based transaction relationships with their members.

Cooperatives play a dominant role in fresh produce chains in Europe *(50)*. Marketing cooperatives are actually a form of supply chain integration, as they are primarily aimed at marketing the products of their member- farmers. With more than 85% market share, cooperatives in The Netherlands and Belgium are the dominant sales organisations for fruits and vegetables *(48)*. Historically the sales of fresh produce in The Netherlands and Belgium was carried out through a cooperatively organised auction, using an auction clock, which is a typical Dutch type of auction *(51)*. However, in the Netherlands the auction clock has been abolished in the 1990s, because of dissatisfaction with the prices, quality, and logistics. Instead, most produce is now sold through short- and medium-term contractual negotiations between cooperatives and buyers. In Belgium, however, most produce is still sold through the auction clock. Nevertheless, both in Belgium and The Netherlands, new cooperative structures have emerged over the last decades, mostly pursuing higher degrees of supply chain coordination *(48)*.

The impact of the cooperative governance structure on food quality and safety assurance is an on-going debate. Several studies have claimed that cooperatives provide more support services to their members and therefore deliver better and more uniform quality than investor-owned companies *(75, 210)*. Others, however, claim that members of cooperatives have the incentive to produce lower quality *(363)*. The latter studies have argued that the dispersed ownership and democratic decision-making structures of cooperatives lead to low incentives to increase quality. We are not so much interested in the ownership structure, but in the governance of the transaction between members and their cooperative. More specifically, we raise the question how a more market-like or a more hierarchy-like governance of transactions affects the quality and safety management system members apply and thereby affect the quality and safety of produce. The overall objective of this article is to explore the role of cooperatives in food quality and safety management in the fresh produce chain, focussing on the food safety management systems implemented on the farms.

5.2. Theoretical foundation

Food quality and safety management are among the most challenging functions of cooperatives, as these organisations need to work in the interests of their members as well as meet the stringent requirements of wholesalers and retailers. To achieve this, not only the cooperative firm but also the cooperative members (the farmers) need to implement quality management systems. Within such quality management system, a particular part that is aimed at assuring safety is called a food safety management system (FSMS) *(295)*. Quality and safety management systems are supporting the operational decisions on the farms or in the companies by monitoring and controlling food quality and safety and by providing assurance *(295)*. Furthermore, to answer the market requirements and to realise the demanded quantity and quality (including safety), cooperatives apply supply chain management practices to coordinate production, processing and distribution activities with other companies in the supply chain *(104, 146)*. This, for instance, involves tactical decisions about the choice of quality assurance standards in the supply chain *(478)*. Supply chain management is affected by the strategic decisions taken about the governance and types of transactional relationships of the supply chain *(384)*. Figure 5.1 represents the hypothesised interrelations among these three levels of decision-making, which are elaborated in the following sections.

5.2.1. Food quality and safety management systems

Quality management systems represent all the activities used to direct, control and coordinate quality in a company, including the organisational structure, responsibilities, processes, procedures, and resources that facilitate the achievement of quality management. These systems are the result of translating requirements from the market and regulatory environment into the specific production activities and organisational structures of the company *(293)*. These requirements can be put by public standards or recommendations (like, code of practice according to Codex Alimentarius). Furthermore, private stakeholders in the supply chain, such as retailers, can also demand certification against private standards (e.g. GlobalGAP, Tesco's Nurture).

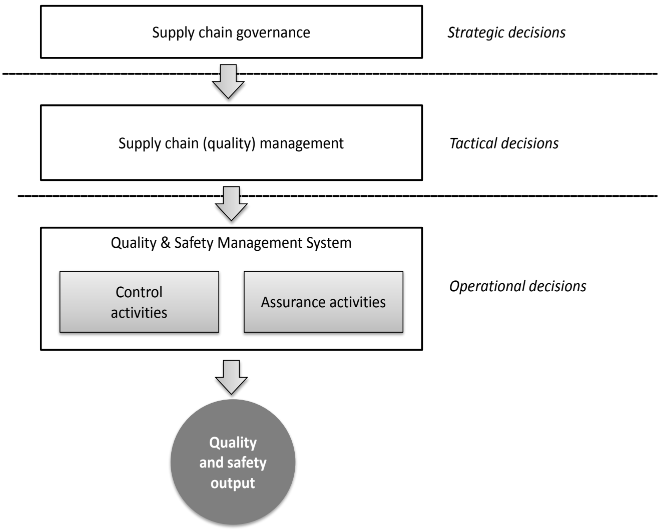

Figure 5.1: Key concepts in the study and their interrelatedness in view of the quality management decisions taken in a company

5.2.2. Supply chain management

Quality management systems can be influenced by the overall supply chain management of the company, which is aimed at coordinating activities with suppliers and customers and to achieve certain levels of quality and safety throughout the supply chain *(151)*. This is targeted through tactical decisions, such as the selection and control of suppliers (e.g. based on certification), coordination of deliveries according to harvesting time and required quality, and the organisation of logistics and inventory *(471)*. Still, the integration of quality and safety decisions into supply chain management faces difficulties as supply chain managers and quality managers have different perspectives on supply chain management activities; the first focus at reducing transaction costs, while the second focus on quality assurance *(146, 356)*. Moreover, quality and supply chain management decisions can be contradictory. For instance, research has shown that the use of quality information in food supply chain logistics positively contributes to the final quality and safety of products, but at the expense of transportation costs *(385)*.

5.2.3. Supply chain governance

Supply chain management is affected by the strategic decisions about the overall governance of transactions in the supply chain. Previous research revealed that hierarchical governance structures are used with private reputational quality assurance certifications, whereas market-based governance structures - with public standards *(378, 478)*. Still, acquiring certification is not a guarantee for quality (or safety) *(181, 194, 390)*. A question remains whether governance structures may influence food quality and safety management systems implemented in companies, and whether more hierarchical governance of transactions in the supply chains promote more advanced food quality/safety management systems. The latter is also the first hypothesis of this research.

5.2.4. Cooperatives in supply chain governance

In the fresh produce chain, supply chain management decisions are commonly taken within the cooperatives in their aim to supply large volumes of similar quality to comply with requirements of customers. In practice this means pursuing the reduction of product and production variation between different farms. To achieve these goals cooperatives provide services at the level of the cooperative firm, such as sorting, packaging, storage and transport. In addition, they facilitate the implementation of quality and safety management systems in the member-farms. These activities may differ between cooperatives, as they are governed by different transactional relationships. Traditionally cooperatives in Belgium and the Netherlands were selling their production via the auction clock, which is a spot market arrangement where the goods are exchanged immediately and the identity of the partners is irrelevant, and often unknown *(47)*. However, many cooperatives shifted to selling part of the production via contracts *(51)*. These cooperatives initiated also strategies, such as branding, global expansion and value-added activities to increase their competitiveness *(211)*. However, some empirical evidences suggest that cooperatives with complex functions may face difficulties with declining commitment of the members *(340, 353)*. Therefore, the second hypothesis of this study is that members of cooperatives with complex business operations will have less advanced food quality and safety management systems.

5.3. Methodology

5.3.2. Field study design

Cooperatives involved in the study were selected to represent different types of cooperatives in Belgium and the Netherlands – from small to big, from selling mostly via spot-market (auction) to having higher number of contractual sales (Table 5.1). COOP1 is selling 70% of the products via an auction clock, and this percentage is lower for the other three cooperatives. The rest of the production of the cooperatives is sold via contracts with retailers and wholesalers.

Table 5.1: Characteristics of the cooperatives

Characteristic	COOP1	COOP2	COOP3	COOP4
Size (number of members)[a]	300	186	354	720
Turnover (million euro)[a]	165	47	353	1,400
Voting rule	1 member 1 vote	Proportional	Proportional[b]	Proportional
Auction clock sales, %	70%	30%	25-30%	20-30%
Contract sales	30%	70%	70-75%	70-80%
Own brand	yes	yes	yes	yes
Selling also non-members products	no	no	yes	yes
Foreign alliances	no	no	Collaboration with one cooperative	Several subsidiaries
Location	Belgium	The Netherlands	The Netherlands	The Netherlands

[a] *In the end of 2012, based on the annual reports of the cooperatives*
[b] *Members are granted votes according to the number of their patronage equity shares*

To diagnose the performance of food safety management activities at primary production, seven strawberry farmers have been visited and interviewed in each of the four cooperatives. The sample selection occurred by randomly choosing berry farmers from the member list of each cooperative. Strawberries have been chosen as a case study due to their sensitivity in terms of quality and safety, and the significant trade value in Belgium and the Netherlands *(231)*. Moreover, strawberries are a seasonal product and are therefore suitable to sell via an auction system. All farmers were certified against the same quality assurance standard – GlobalGAP.

5.3.2. Diagnostic tool to assess food safety management systems' performance

A diagnostic tool has been used to collect the information about the FSMS *(256, 259)*. The tool allows assessment of the following elements: 1) the status level of FSMS (control and assurance activities) and their system output, and 2) the riskiness of the context, including product, production, organisational and chain characteristics. Context factors are defined as structural elements of a situation that can affect decision-making in the FSMS *(294)*. The assessment of the FSMS focuses on the core control and assurance activities. Core control activities are assessed on how preventive measures, intervention strategies, and monitoring activities are designed and actually operated. Assessment of assurance activities focuses on the set-up of the systems, validation, verification and documentation. A grid with three situational descriptions is designed for each indicator. The grids for context indicators represent low (score 1), moderate (score 2) and high risk (score 3) to decision making, by following the criteria of vulnerability to contamination, uncertainty due to lack of information and ambiguity due to lack of understanding. The grids for FSMS activities represent low (score 1), basic (score 2), average (score 3), and advanced level (score 4). Similarly, the grids for the system output represent no information (score 1), poor (score 2), moderate (score 3), and good output (score 4). The overall assumption behind the assessment is that advanced FSMS are required in cases of high context riskiness, so to be able to realise a good output *(294)*. Risk is reduced by systematic information, scientific methods and independent positions *(295)*.

In total, the tool encompasses sixty-nine (69) indicators with corresponding situational grid descriptions (Figure 5.2). For the context factors, a low risk level (score 1) is given when the chance of microbial or chemical contamination is low, and when the organisation characteristics support appropriate decision-making and when chain characteristics levels less dependency. A moderate risk level (score 2) is given when there is a potential risk of contamination, constrained organisational support, and restricted dependency on the other chain actors. High-risk level (score 3) is given when risk of contamination is high, organisational support is low, and chain dependency is high. For the FSMS activities, a low level is given when an activity is not implemented or not applicable. A basic level is given when activities are executed according to historical knowledge and or own experience, using common materials and or methods. An average level is given when standardised equipment and methods are used, sector standards or guidelines are followed. An advanced level is given when activities are performed systematically, modified and tested for the concrete farm situation, by following scientific knowledge and methods. For the system output, a poor output level is defined as the situation when sampling is ad-hoc, minimal criteria are used, and various complaints and remarks are received. A moderate output level is given when sampling is done regularly, several criteria are used, complaints and remarks are restricted. A good output level is given when sampling is done systematically, criteria is specific and tailored, complaints and remarks are not received. Furthermore, the tool includes an introduction part with general questions about characteristics of the farm: number of workers, standards and guidelines implemented and certified, etc.

A. Example for indicator of context: **Risk of water supply**

Situation 1 (low risk)	**Situation 2 (moderate risk)**	**Situation 3 (high risk)**
• No association of water supply with contamination • Potable water supply, coming from approved sources (e.g. municipal water, artesian well water, water from drilled deep wells)	• Occasional association of water supply with contamination • Water controlled at the company/farm (e.g. recycled/re-used water, water stored in open reservoirs, water from dug or driven wells, rain water)	• Common association of water supply with contamination • Uncontrolled surface water (e.g. from rivers, canals, ponds, lakes, creeks, etc.)

Assumption: Water supply for direct contact with product, which is having high likelihood of contamination with microorganisms and/or chemicals (i.e. uncontrolled surface water), increases the chance on lower food safety performance, and puts higher demands on FSMS.

B. Example for indicator of control activity in the FSMS: **Extent of personal hygiene requirements**

Situation 1 (low level)	**Situation 2 (basic level)**	**Situation 3 (average level)**	**Situation 4 (advanced level)**
Personal hygiene requirements are not implemented (i.e. absence of washing facilities and toilets and no emphasis on personal care and hygiene)	• Standard requirements for all employees on clothing (gloves, jacks); • Idem for personal care and health; • Common washing facilities and toilets with no washing stations • No specific hygiene instructions.	• Additional task-specific requirements on clothing (own clothing, specific storage conditions); • Idem for personal care and health; • Special hand washing facilities and toilets with washing stations; • Basic hygiene instructions;	• High and specific requirements, for all food operators, on clothing; • Idem for personal care and health; • Tailored facilities to support personal hygiene; • Specific hygiene instructions implemented in daily practice
Assumption: Higher and more specific personal hygiene requirements and specific instructions reduce chance on contamination, which will positively contribute to food safety			

C. Example for indicator of the system output: **Advancedness of sampling for pesticide residues**

Situation 1 (no info)	**Situation 2 (poor output)**	**Situation 3 (moderate output)**	**Situation 4 (good output)**
No samples are taken and no chemical analyses are performed	• Ad-hoc sampling (on demand of customers or legislation) on particular lot(s)/batch(es)	• Structured sampling (with fixed frequency) at company level	• Structured sampling, on company level, and regular monitoring on a sector level (statistically underpinned)
Assumption: Structured sampling on both company and sector level will give a more representative indication of the actual chemical performance of your FSMS			

Figure 5.2. Examples of indicators for context (A), FSMS activity (B) and output (C) from the diagnostic tool to assess food safety management systems' performance

5.3.3. Semi-structured interviews to characterise activities of cooperatives

Next to the diagnostic tool, semi-structured interviews have been conducted with the quality assurance managers of the cooperatives. These interviews aimed at collecting additional information about cooperatives' decisions about supply management activities such as logistics, supplier relationships and support services provided to the members. The interviews included questions about logistic services, investments in infrastructure and equipment, information and training of farmers on quality assurance and food safety, chemical, physical and microbiological control of the products, complaint registration and assurance activities (i.e. validation and verification). The support that the cooperative firm claimed to provide to the farmers were confirmed during the interviews with the farmers.

5.4. Findings

5.4.1. Status of FSMS in cooperative members

Figure 5.3A presents the results for the indicators of the **context factors** of product and production characteristics. Score 3 (high risk) was given for the indicators of microbial, pesticide residues and mycotoxin risk of final product, as all farmers were dealing with sensitive products in terms of food safety – strawberries. The risk for initial materials (*i.e.* growing seedlings, pesticides) was assessed as moderate for both risk of microorganisms and pesticide residues, as berries are sensitive to microbial contamination and fungi and pesticides are sprayed. Microbial risk of initial materials scored even higher in COOP1 and COOP2 (3, high risk), compared to COOP3 and COOP4 (2, moderate risk). Farmers in all cooperatives scored as moderate risk (2) for the indicators of production characteristics, due to protected cultivation, moderate climate conditions and controlled source of water. Most indicators for organisation and chain characteristics scored as moderate risk (2) (Figure 5.3B). COOP1 and COOP2 demonstrated higher risks in their organisation and chain context due to low worker competences (high risk), and logistic facilities that were not specific for fresh produce (COOP1=2) or not controlled at all (COOP2=3).

Figure 5.3C presents the results for the indicators for **control activities** to analyse the design of the preventive measures, intervention strategies, and monitoring system. Most activities were designed according to guidelines and standards (*e.g.* GlobalGAP) and by using best available equipment and methods (score 3, average level). Several activities, however, scored lower for COOP1, 2 and 4. These were hygienic design of equipment, premises and tools, which was mostly not considered (score 1, low level); sanitation program, incoming materials control and corrective actions, which were based on own knowledge and experience (score 2, basic level). All cooperatives, except COOP3 (score 3, average level), were not taking microbiological samples (score 1, low level). Only COOP1 was using organic fertilizers, applied according to guidelines (score 3, average level).

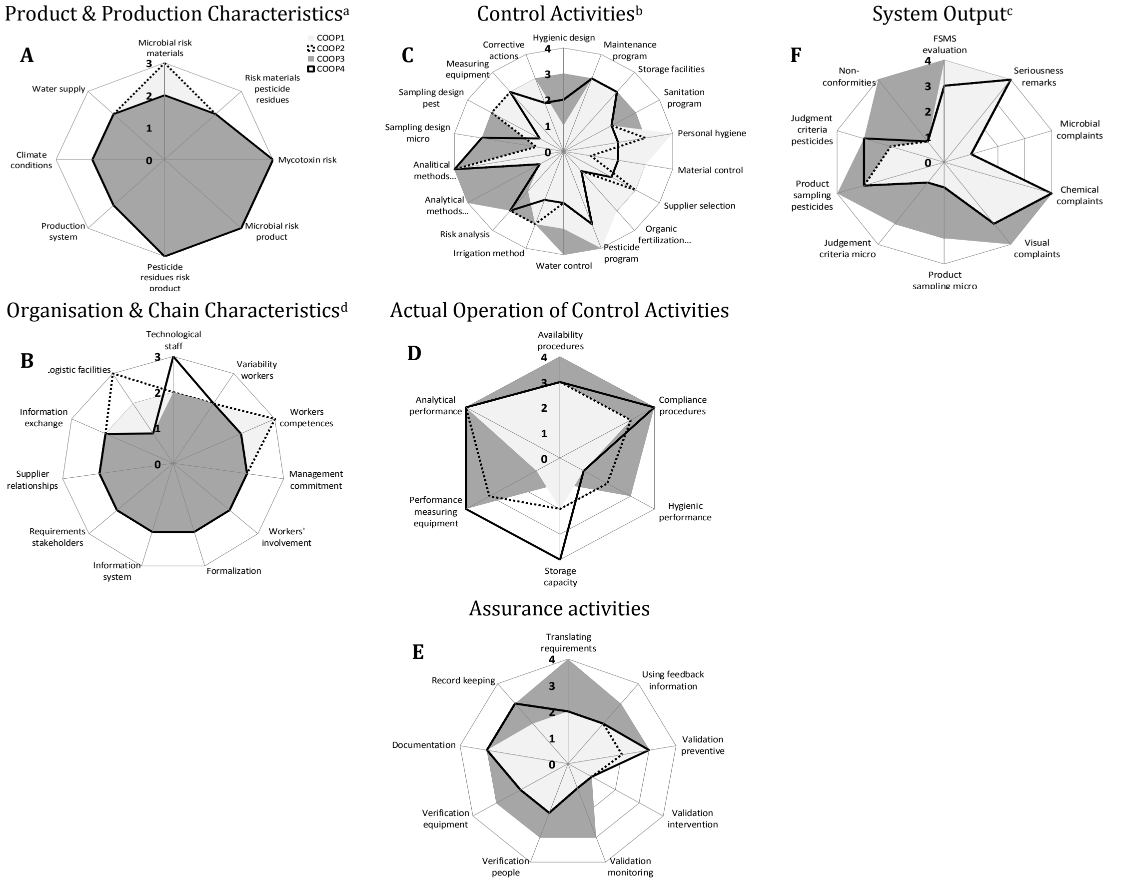

Figure 5.3: Median scores of the indicators in the diagnostic instrument for the farmers in each cooperative

[a] The scale for product and production, organisation and chain characteristics represents low (1), medium (2) and high (3) risk situations, corresponding with low, potential and high chance of microbiological or chemical contamination.

[b] The scale for control and assurance activities corresponds to: low level (1) → absent, not applicable, unknown; basic level (2) → lack of scientific evidence, use of company experience/history, variable, unknown, unpredictable, based on common materials/equipment; average level (3) → best practice knowledge/equipment, sometimes variable, not always predictable, based on generic information/guidelines for the product sector; advanced level (4) → scientifically underpinned (accurate, complete), stable, predictable, and tailored for the specific food production situation.

[c] The scale for FSMS output corresponds to: no information (1) → absent, not applied, unknown; poor output (2) → ad-hoc sampling, minimal criteria used for evaluation, various food safety problems due to different problems in the activities; moderate output (3) → regular sampling, several criteria used for evaluation, restricted food safety problems mainly due to one (restricted) type of problem in the activities; good output (4) → systematic evaluation, using specific criteria, no safety problems.

[d] The scale for organisation and chain characteristics represents low (1), medium (2) and high (3) risk situations, corresponding with supportive, constrained and lacking administrative chain conditions or low, restricted and high dependence on other chain actors.

Figure 5.3D shows the results for the indicators of the **actual operation of control activities**. COOP3 scored 4 (advanced level), corresponding to easily available and understandable procedures that were regularly updated. However, the other three cooperatives scored at average level (3). Workers in COOP3 and COOP4 were aware about the content of procedures and were strictly following them (score 4, advanced level), while workers in COOP1 and COOP2 were mostly working according to habits and controlled by supervisors (score 3, average level). All analytical analyses were done by external accredited labs (score 4, advanced level). Some indicators scored lower. Actual performance of equipment and tools was not known by the farmers from COOP1 and COOP4 (score 1, low level). Actual storage capacity was not checked by farmers in COOP1 and COOP2, and well-known and tested for COOP4. Farmers in COOP3 did not have any in-house storage facilities (score 1).

Assurance activities scored mostly 2 (basic level), which means that is was done by own people and only upon problems (Figure 5.3E). An exception was the farmers in COOP3, which were validating and verifying their activities by external expert (score 3, average level), and pro-actively translating stakeholder requirements (score 4, advanced level). All farmers had documentation and record keeping at average level (score 3), structured, up-to-date and centrally accessible.

Figure 5.3F reveals the results for the indicators of the **system output**. All farmers were audited by two and more third parties (score 3 and 4), did not have any major remarks (score 4) and no complaints about pesticide residues (score 4). COOP3, however, showed better results for several indicators, as farmers had few visual complaints (score 4), the cooperative has established a microbiological sampling plan (score 3) with strict criteria (score 3), and was recording the non-conformities of received products (score 4). All were sampling for pesticide residues on a cooperative level (score 3). COOP1, 2 and 4 showed similar basic results for the indicators of microbiological sampling and non-conformities, as these were not systematically detected.

5.4.2. Characteristics of cooperative members

Table 5.2 shows the characteristics of the farmers interviewed in each cooperative. Farmers in the four cooperatives were all family-owned with one to four permanent workers, and temporary workers during the high season ranging from four to seventy. All farmers were selling all of their products through the cooperatives. However, farmers in COOP1 were selling all their products through the auction clock, while the other three were selling both via the clock and contracts. Still, COOP2 farmers had a larger percentage of sales via the auction clock compared to COOP3 and COOP4 (Table 5.2). All farmers were certified against GlobalGAP, and several also had certification against other private standards.

Table 5.2. Characteristics of the farmers in the cooperatives

Farm code	**Size** Hectares	Tons	**Workforce** Perm. staff	Temp. workers	**Sales**[a] Clock %	Contract %	**Standards**
COOP1							
A01	10.0	130	2	30	100	-	GlobalGAP; Flandria
A02	15.0	180	3	50	100	-	GlobalGAP; Flandria
A03	8.0	200	2	30	100	-	GlobalGAP; Flandria
A04	7.0	300	2	40	100	-	GlobalGAP; Flandria
A05	3.0	140	1	20	100	-	GlobalGAP; Flandria
A06	23.0	800	4	60	100	-	GlobalGAP; Flandria
A07	15.0	900	4	70	100	-	GlobalGAP; Flandria, ICQC
					100		
COOP2							
B08	6.5	280	2	40	50	50	GlobalGAP
B09	6.0	250	3	50	-	100	GlobalGAP
B10	1.5	70	2	50	20	80	GlobalGAP; AH
B11	6.0	240	1	10	100	-	GlobalGAP
B12	1.3	150	4	9	90	10	GlobalGAP
B13	5.0	180	2	15	90	10	GlobalGAP
B14	3.0	300	3	20	80	20	GlobalGAP
					61	**39**	
COOP3							
C15	2.0	220	2	50	40	60	GlobalGAP
C16	40.0	400	4	70	-	100	GlobalGAP
C17	15.0	200	2	60	20	80	GlobalGAP
C18	20.0	570	2	40	30	70	GlobalGAP; QS
C19	24.0	630	3	50	-	100	GlobalGAP; QS; M&S; Tesco
C20	2.0	200	1	9	50	50	GlobalGAP
C21	1.0	200	2	6	30	70	GlobalGAP
					24	**76**	
COOP4							
D22	2.2	170	2	10	40	60	GlobalGAP
D23	15.0	350	1	20	75	25	GlobalGAP
D24	3.0	450	4	60	50	50	GlobalGAP; Tesco
D25	20.0	350	3	50	-	100	GlobalGAP
D26	15.0	350	3	30	40	60	GlobalGAP
D27	2.0	150	1	10	100	-	GlobalGAP
D28	2.1	160	3	9	-	100	GlobalGAP
					44	**56**	

[a] *Percentage of sales via auction clock and via contracts for each farmer*

Table 5.3 presents the support services that cooperatives provided to their members. While COOP1 and COOP2 were using various external logistic companies, COOP3 and COOP4 invested in their own with refrigerated conditions. COOP 3 was even providing and sanitizing the crates. The cooperatives were providing information and training on quality and safety management to a different degree, with most efforts put by COOP3 which was organising trainings every year, and upon changes of standards, new methods and equipment. In the last year COOP3 and COOP4 began performing microbiological control. They also provided support to assurance activities of farmers, such as translation of new requirements into the food safety management system and validation of pest control methods.

Table 5.3: Services cooperatives provide to their members (results from the interviews)

Activities	COOP1	COOP2	COOP3	COOP4
Logistics	Various logistic companies; mostly uncontrolled conditions	Various logistic companies; mostly uncontrolled conditions	Own logistic company; controlled conditions; provision and sanitation of crates	Own logistic company; controlled conditions
Specification	Packaging material, payment conditions, basic product quality and process requirements	Packaging material, payment conditions, basic product quality and process requirements	Packaging, payment conditions, norms on product and process quality; via contract- also price and quantity	Packaging, payment conditions, norms on product and process quality; via contract- also price and quantity
Information / training	Information evenings when new methods or equipment are available	Training is organised when becoming a member and every year afterwards	Training is organised when becoming member, every year, and upon changes of standards, new methods and equipment	Training /education when becoming a member, and sporadic afterwards. Information, data and advice from the cooperative upon request.
Chemical control	Control when products are received at the cooperative warehouse, corrective actions implemented by the cooperative	Control when products are received at the cooperative warehouse, corrective actions implemented by the cooperative	Control when products are received at the cooperative warehouse, corrective actions implemented by the farmer	Control when products are received at the cooperative warehouse, corrective actions implemented by the farmer
Physical control	Control when products are received at the cooperative warehouse	Control when products are received at the cooperative warehouse	Control when products are received at the cooperative warehouse	Control when products are received at the cooperative warehouse
Microbiolo-gical control	Not applied yet	Not applied yet	Systematic control when	Systematic control when

			products are received at the cooperative warehouse	products are received at the cooperative warehouse
Complaint registration	Complaints received and analysed by the cooperative	Complaints received and analysed by the farmers	Complaints received and analysed by the cooperative	Complaints received and analysed by the cooperative
Support for assurance activities	None	Technical advisors upon request	Instructions about translation of new requirements from legislation or standards and validation of new methods e.g. for pest control (pesticides)	Instructions about validation of new methods e.g. for pest control (pesticides)

5.5. Discussion

5.5.1. The role of cooperatives for food safety management

The objective of this study was to explore the influence of cooperatives on the status of FSMS at production of fresh produce on member-farms. Overall, farmers from all the cooperatives had core control activities such as personal hygiene requirements, pesticide management, water control, irrigation method and storage control at average or even advanced level. This can be related to their GlobalGAP certification, as average levels correspond to following recommendations and standards and using best available equipment and tools. Still, some activities like hygienic design of equipment and tools, sanitation program, material control and microbiological analysis were scoring at basic level for three of the four cooperatives, which may be explained to the lower attention paid to these in current legislation and standards *(355)*. In contrast, pesticide residues legislation is well established in the EU, and all four cooperatives have been coordinating the pesticide monitoring of the products of their members. Farmers of COOP3 demonstrated average levels for microbiological sampling (Figure 3C). This was because the cooperative firm had an established sampling program for the products arriving in the warehouse, and was communicating the results back to the farmers (Table 3). COOP4 was also taking samples, but not (yet) in a systematic manner. Furthermore, the results from both microbiological and pesticide residues sampling were not communicated to the farmers from COOP4. The status of assurance activities was closely related to support from cooperatives to farmers, especially in providing training about verification of people and equipment, validation of methods and in introducing changes and improvements in the FSMS. Farmers from COOP3, which was providing regular training and advice, demonstrated advanced levels of assurance activities.

Despite the differences between the farmers members of different cooperatives, compared to other research, *(95, 258)*, in this study farmers demonstrated higher levels of control and especially assurance activities.

5.5.2. Supply chain governance via cooperatives

Farmers in the cooperatives with higher percentage of contract sales (COOP3 and COOP4) demonstrated more advanced levels of FSMS activities and less risky organisation and chain characteristics. These differences can be partially attributed to differences in the governance of transactions in the fresh produce sector in the Netherlands and Belgium. The fresh produce market in both countries includes a large number of small famers organised in marketing cooperatives *(47, 173)*. The latter sell respectively about 95% and 85% of all fruits and vegetables *(48)*. The sales via cooperatives, however, are organised differently in Belgium and the Netherlands. While in Belgium products are still largely marketed in a spot-market via a cooperative auction clock *(326)*, in the Netherlands contractual relationships with retailers or wholesalers have a much bigger percentage *(48)*. Moreover, Dutch cooperatives have introduced more complex business functions, they acquired foreign subsidiaries and increased their product diversification to supply the needs of various customers; whereas, Belgian cooperatives kept the traditional spot-market sales and did not diversify much *(48, 49)*.

In general, the two cooperatives (COOP1 and COOP2) with predominant spot-market sales, one located in Belgium and one in the Netherlands, showed less advanced FSMS than the cooperatives with more hierarchy-based transactions. This can be attributed to certain disadvantages that were discussed before. The relative anonymity of the spot market may lead to lower information exchange between buyer and seller, losing quality due to the extra step in-between and the lack of incentive for famers to improve quality and safety *(51)*. Collective reputation that does not reveal the identity of the individual producers can lead to lower quality levels *(484)*.

The more hierarchical COOP3, with less products sold through the auction clock and more through contracts, demonstrated more advanced levels of control and assurance activities. Moreover, hierarchical cooperatives invested in logistic services (Table 3), which is associated with lower riskiness of context characteristics. Similarly in another study, investor-owned companies producing lettuce invested in initial materials and logistic services to satisfy the demands of big supermarket chains *(255)*. Compared to the auction clock, where products from different farmers are combined and sold in one lot, increased sales through contracts allow for specifying quality and safety requirements. The latter provide more incentives for farmers to improve their FSMS. Furthermore, additional training and advise by the cooperative correlated to more advanced levels of activities, especially regarding the knowledge-intensive assurance activities. These efforts were triggered by demands from retailers and other buyers as the cooperative was selling a large percentage of the berries via contracts.

5.5.3. Collaboration and coordination in the supply chain

Cooperatives contribute to collaboration and coordination in the supply chain in two ways: vertically and horizontally. Vertical includes collaboration with customers and suppliers, and horizontal – with competitors and other non-competitor organisations (31). Cooperative firms in this study invested in vertical collaboration as they provided services to the farmers, such as, monitoring for hazards, analysis of complaints, validation of preventive methods, training and education (Table 3). There was some variation in the services that each cooperative provided. Training was organised systematically only by COOP3, while others provided assistance only sporadically. Interestingly, this was the cooperative that showed most advanced FSMS and good output (Figure 3). A previous study demonstrated that cooperatives that provide information on quality improvements have more committed members *(448)*. Commitment is essential to implement a quality assurance strategy and to invest in more advanced FSMS activities *(74)*.

In general, market mechanisms are supposed to contribute positively to food safety and quality management, as members expect to get higher prices *(74)*. However, when cooperatives get complex business operations, they may face difficulties with horizontal collaboration among the cooperative members due to dissatisfaction, lack of trust, involvement and commitment of their members *(339)*. Interestingly, members of COOP4 showed average and even basic levels for some control and assurance activities, meaning that they were not putting efforts into adapting their activities and checking the effectiveness for the particular farm. These results might be explained with losing commitment by the members to the strategies of the cooperative firm. COOP4 was the biggest of the four in our study, with many different members and complex business functions. This cooperative had large heterogeneity between members triggered by different market aims *(51)*. Previous studies discuss the difficulties experienced by cooperatives with losing commitment of members due to heterogeneity and power struggles *(196)*.

5.6. Conclusions and suggestions for future research

The main objective of this study was to explore the role of cooperatives in food quality and safety management in the fresh produce chain, focussing on the food safety management systems implemented on the farms. Our literature study identified a two-step role of cooperatives in managing quality and safety in the supply chain. On the one hand, they are responsible for the supply chain management, including tactical decisions about collaboration and coordination of quality and safety between farmers, the cooperative firm and the customers. On the other hand, cooperative firms sell the products of their members and make strategic decisions about the governance of transactions in the supply chain, which ultimately may have an impact on the supply chain management and the implemented FSMS on the farms.

The case studies revealed that hierarchy-like governance of transactions has a positive influence on quality and safety management systems in the fresh produce farms. This was associated with more efforts put in supply chain (quality) management and services by the cooperative firms to support collaboration and coordination in the chain, such as hazards monitoring, training and advise to the members to implement quality assurance standards, providing logistics, sorting and packaging of the products. On the contrary, cooperatives with predominantly market-based governance of transactions demonstrated less advanced FSMS, mostly following standards and missing some core activities. Interestingly, however, the largest cooperative – with many members and complex business functions, showed mostly average levels of FSMS that were designed and operated according to best available knowledge, but without scientific basis and without checking their effectiveness. These might be related to losing commitment and social capital of the members.

This study was a first exploration of the factors affecting set-up and operation of FSMS in fresh produce supply chains as linked to supply chain quality management and the role of cooperatives. The case studies approach allowed us to dive into the differences between different cooperative structures and their effect on FSMS implemented at farm level, but did not permit us to include different product groups. Moreover, the research was conducted only in cooperatives located in the Netherlands and Belgium, which limits the generalizability of conclusions towards other parts of the world. Further research should address a larger sample of cooperatives and farmers of different production sizes and product groups, as these can influence behaviour and commitment of cooperative members. Moreover, comparison with farmers that are not cooperative members would contribute to better understanding the role of cooperatives to safety management. Longitudinal studies about changes in the supply chain governance structures and the relationship to quality management could be used to further inform food quality and safety management decisions.

5.7. Acknowledgements

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Chapter 6:
Factors affecting the status of food safety management systems in the global fresh produce chain

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Abstract

Increase in global trade raised questions regarding the status of food safety management systems in fresh produce companies, especially from developing and emerging countries. The aim of this study was to investigate the status of food safety management systems (FSMS) implemented at primary production companies of fresh produce, to examine the potential differences between companies operating in European Union (EU) and non-EU (developing and emerging) countries, and to explore the underlying factors. Primary production companies (n=118), located in the EU and in international cooperation partner countries exporting to the EU, were assessed by using a diagnostic tool. The results from the study indicated that several factors have a dominating effect on the status of FSMS in the global fresh produce chain. International export supply chains promote capacity building within companies in the chain, to answer the stringent requirements of private brand standards. This was shown to be an important factor in emerging and developing countries, where local institutional environments often fail to support companies in setting and implementing their FSMS. Moreover, the legislative framework in these countries still requires improvements in the establishment and enforcement. All this has negative consequences for the FSMS in companies supplying the local markets. In companies located in the EU, sector and other produce organisations facilitate the sampling for pesticide residues and collaboration in the sector. Overall, farmers showed less knowledge and overall awareness regarding microbiological hazards, which is related to the less attention paid to these in the current legislation and standards. Furthermore, standards are an important tool to trigger the maturation of the systems as companies that were lacking any pressure to comply to standards operated at a very basic level - with only few activities implemented. The insights from this study indicate the need of stratified measures and policies to support companies in the fresh produce chain in designing and operating their FSMS according to the institutional environment in which they operate.

6.1. Introduction

The world production of fresh produce raised by 38% in the last decade *(138)*. The demand for seasonal and exotic fruits and vegetables has also increased and trade with fresh produce is more and more international *(100)*. Simultaneously, food safety problems linked to fresh produce have been repeatedly reported, for instance, recent outbreaks with pathogenic microorganisms such as EHEC in sprouted seeds in Germany and France, *Listeria monocytogenes* in melons in USA, and norovirus in berries in Northern Europe *(41, 123, 156, 271)*. Moreover, breach of pesticide residue limits is a common problem *(377, 485)*. Some of these food safety scares involved multiple sources and countries of consumption, making it difficult to trace back the (single) point source of contamination in the country of origin *(124, 297)*. Fresh produce is often imported from warmer climates located in developing and emerging economies, and these were frequently associated with the problems *(377)*.

To address food safety, every company in the global food chain needs to implement a food safety management system (FSMS) *(66, 67)*. Each FSMS is company specific because it is a result of the implementation of various quality assurance and legal requirements into a company's unique production, organisation and environment *(228)*. FSMS implemented in companies at primary production are based on good agricultural and good hygiene practices, by following national and international, public and private standards and guidelines *(67, 176)*. These are put into place to assure product quality and safety across countries and regions. Certain countries and regions however (e.g. the European Union) have put more stringent requirements about food safety, which are difficult to reach by some companies in less developed countries *(269, 270, 400, 459)*.

Studies on the implementation status of FSMS across industries of animal-derived products in different countries and sectors highlighted that small and medium companies can also demonstrate advanced systems *(101, 289)*. A body of research investigated the adoption of quality assurance standards in developing and emerging economies as driven by export supply chains, and their role as barriers and facilitators to economic growth *(e.g. 199, 200, 206, 232)*. However, safety is still considered as less important than price, quality and delivery conditions during the selection of suppliers *(473)*. To address these issues, extra controls are established in the EU for import products of non-animal origin with a history of safety problems, and these include a number of products from emerging and developing countries *(117, 119)*. Moreover, scientific evidence suggested that FSMS implemented in fresh produce companies in developing and emerging economies are not sufficiently addressing the food safety risks *(95, 400, 462)*. However, deeper understanding is needed about the actual status of FSMS in different world countries involved in fresh produce trade. Moreover, insight is lacking about the factors determining differences in the FSMS status, for instance between companies in the EU and in (importing) developing and emerging countries.

The objective of this study was to investigate the status of FSMS implemented at primary production companies of fresh produce, to examine the potential differences between companies operating in EU and non-EU (developing and emerging) countries exporting to the EU, and to explore the explaining factors.

6.2. Materials and methods

6.2.1. Diagnostic tool for assessing the status of FSMS in the fresh produce chain

The data for the study was collected with a recently developed diagnostic tool that allows assessment of the FSMS in the fresh produce chain, independently from type of product and production, location, standards and guidelines used for the development of the system *(256, 259)*. An FSMS is this part of the quality management system of a company that is specifically addressing food safety *(295)*. The diagnostic tool allows assessment of the core control and assurance activities in the FSMS *(256)*, and the context factors (product, production, organisational and chain characteristics) affecting design and operation of activities in the FSMS *(259)*. Finally, the tool allows to measure the system output and the insight a company has on its performance (*e.g.* results of external inspections or audits, results of sampling) *(256)*. The diagnostic allows for assessment throughout the FSMS applied in the supply chain. In this work the diagnostic tool for farm level is applied, including activities as part of the good agricultural practices or any other implemented standards and guidelines. Indicators and grids with stereotypical situations are defined for each activity (Table 6.1). The overall assumption behind the assessment is that high context riskiness requires an advanced level of activities to achieve good output.

Table 6.1: Mutual characteristics of the different situations and levels in the diagnostic tool

Context factor	Low risk (1)	Moderate risk (2)	High risk (3)
Product and production characteristics	Low chance of microbial or chemical contamination, growth or survival of pathogens and undesired microorganisms	Potential chance of microbial or chemical contamination, growth or survival of pathogens and undesired microorganisms	High chance of microbial or chemical contamination, growth or survival of pathogens and undesired microorganisms
Organisational characteristics	Supportive administrative conditions for appropriate decision-making.	Constrained (restricted) administrative conditions for appropriate decision-making	Lack of administrative conditions for appropriate decision-making
Chain characteristics	Low vulnerability or dependability on other chain actors	Restricted vulnerability or dependability on other chain actors	High vulnerability or dependability on other chain actors
Food safety management*	**Basic level (2)**	**Moderate level (3)**	**Advanced level (4)**
Control activities	Standard equipment, unknown capability, use of own experience/general knowledge, incomplete methods, restricted information, lack of critical analysis, and non-procedure-driven activities, regular unexpected problems, unstable	Based on expert (supplier) knowledge, use of (sector, governmental) guidelines, best practices, standardised, sometimes problems, causes known	Use of specific information, scientific knowledge, critical analysis, procedural methods, adapted and tested in the specific production circumstances, stable, robust
Assurance activities	Problem driven, only checking, scarcely reported, not independent positions	Active translation of requirements, additional analysis, regular reporting, and expert support	Pro-active translation of requirements, actual observations and testing, independent positions, scientifically underpinned, and systematic
System output*	**Poor output (2)**	**Moderate output (3)**	**Good output (4)**
	Ad-hoc sampling, minimal criteria used for evaluation, and having various food safety problems	Regular sampling, several criteria used for evaluation, having restricted food safety problems mainly due to one (restricted) type of problem	Systematic evaluation, using specific tailored criteria, and having no safety problems

**For all control and assurance activities and the system output, a level 1 is included to address situation when the activity is not applied (low level), or no information is available about the system output.*

6.2.2. Data collection

Hundred and eighteen (118) companies from twelve (12) countries participated in the study on voluntary ad-hoc basis. The data was collected within case studies, which were selected by following the criteria of:

vulnerability to food safety hazards (microbiological, pesticide residues), economic relevance, vulnerability to climate change and consumption patterns and trends *(231)*. Companies involved were from countries in the European Union (EU): Belgium (leafy greens and strawberries), the Netherlands (leafy greens, strawberries and tomatoes), Spain (leafy greens); and the European Economic Area: Norway (leafy greens and strawberries). The companies in this group of countries were operating under the general food law of the European Union *(108)*. A second group of companies were from international cooperation partner countries (ICPC): Brazil (leafy greens), China (apples), Egypt (leafy greens and strawberries), India (mangoes), Serbia (raspberries), Kenya (green beans), South Africa (leafy greens and fruits), and Uganda (hot peppers). The companies in these countries operated under their own legal framework. Data was collected with the diagnostic tool by interviewing the quality assurance manager or farm owner for about one hour and a half by an on-farm visit by the researchers. In several countries (the Netherlands, Spain, South Africa) workshops were organised to fill in the diagnostic tool with help by the researchers. Part of the assessments were paired with visits and microbiological sampling, which will be presented in other manuscripts. Definitive conclusions about the actual food safety levels, however, should be made with caution, because we could compare only with a limited number of companies. In India, China and Egypt, data was collected via interviews with experts in the particular production sector. These were people from national agencies, involved in the establishment of FSMS at farm level. The study cannot be conclusive for the countries involved, as the sample was not representative for all sectors and supply chains. Contacts with companies were established via the researchers in the countries involved, and based on voluntary participation.

6.2.3. Data analysis

A database was designed in Microsoft Excel 2010 with numbers given (1, 2, 3 and 4) to represent companies' situation for each of the 69 indicators. Descriptive statistics was performed to determine frequencies and median scores for the companies operating under and outside of the EU general food law. These were also compared statistically by using Mann-Whitney U nonparametric test, with significance of results established at $p < 0.05$. Hierarchical cluster analysis of z-scores was performed by using the furthest neighbour method. Further on, principal component analysis (PCA) with direct Oblimin method and 6 retained factors, was used to investigate the principal factors that explain the variation between the companies and to explore which indicators are differentiating the three clusters. Modes were calculated to plot the results in spider web diagrams. All statistical tests were performed by using software package SPSS Statistics 21 for Windows.

6.3. Results

6.3.1. Overall status of FSMS in companies under and outside the EU food law

Table 6.2A displays frequency distributions and median scores for indicators of FSMS activities for the companies operating under and outside the EU food law. Significant differences were reported in the design of several core preventive measures such as, storage facilities, incoming materials control, water control, supplier control, pesticide program, maintenance and calibration program, and irrigation method. The majority of EU companies were following standards and guidelines (median score 3 for 9 out of 12 indicators), and using best available tools and equipment, whereas the non-EU companies showed larger variation and common basis for the activities was the use of own knowledge and experience (median score 2 for 7 out of 12 indicators). Monitoring activities were mostly lacking in the non-EU companies (all indicators with median score 1), but they were also not implemented in many EU companies (Table 6.2A). This was especially the case with microbiological sampling (frequency 32/69). Still, EU companies had better insights into actual operation of control measures as indicators for availability and compliance to procedures and performance of measuring equipment scored at average (3) and advanced level (4). Most companies, both in and outside the EU, had limited information about actual hygienic performance of equipment (1). Assurance activities in the majority of the EU companies were set up according to standards and guidelines (median score 3 for 6 out of 9 indicators), while for the non-EU companies they were missing (1) or at basic level (2). The exception was documentation which scored 3 for companies in both EU and non-EU countries.

Table 6.2B presents the frequency distributions of the indicators scores of **FSMS output** for the companies operating under and outside the EU general food law. All indicators scored significantly different between companies in EU and non-EU countries, except for the indicators of microbiological sampling and judgement criteria. Most companies did not have information for these, as product sampling for microbiological analysis was not performed. The majority of EU companies were audited by two and more third parties, while half of non-EU companies were not audited at all, and half - by only one-third party. Most

EU companies had a complaints management system and few customers' complaints, whereas a smaller percentage of the non-EU companies demonstrated the same results. Similarly, pesticide sampling on a sector or company level was common in the EU, but not in the companies outside of the EU.

Table 6.2C presents the frequency distributions and median of the results for **context** indicators for the companies operating under and outside the general food law of the EU. Product characteristics exhibited medium (2) to high-risk (3) scores, due to the nature of the commodities included in this study, such as leafy vegetables and berries. Moreover, final products are mostly eaten raw and possibilities for removal of both microbiological and chemical contamination are limited. The features of the production system were also assessed as high risk (3), as most companies were operating open field where contamination can occur from people and environment (e.g. wild life). Climate conditions and water supply were assessed mostly at moderate risk (score 2) for the companies in the EU, because they typically operate in moderate climate zones and use underground water sources. The risk was high (3) for the companies operating outside of Europe, as many were located in tropical and sub-tropical countries and were commonly using surface water. For all companies organisational characteristics were mostly at moderate (2) and high risk (3), which represent technical staff with limited knowledge on safety, use of seasonal workers with low competences and involvement, and general quality/safety policy as e.g. introduced by the retailer. The majority of EU companies operated in moderate riskiness (2) of context due to more formalization and supporting information system. Bigger differences were observed between EU and non-EU companies for the chain characteristics. Most EU companies showed lower risk of chain context (5 indicators at score 2, and 3 at score 1) compared to the non-EU companies (5 indicators at score 4, and 3 indicators at score 2). This was because of the regular information exchange, local supply, sophisticated logistic facilities, supportive food safety authority, external support (such as sector organisations) and legal framework. However, they had to answer stricter stakeholder requirements, compared to their non-EU counterparts. Common for all companies was the moderate risk (2) of stakeholder requirements.

Table 6.2A: Frequency of the individual scores and median for the FSMS activities for EU and non-EU companies (The scores represent 1 – low level, 2 – basic level, 3 - average level, and 4 – advanced level), most frequent score indicated in bold.

FSMS activities	EU (n=69)				Non-EU (n=49)				EU	Non-EU
	1[a]	2	3	4	1	2	3	4	median	
Preventive measures design										
Sophistication of hygienic design of equipment & facilities	19	15	29	6	**41**	7	1		3	1
Specificity of maintenance program*	4	9	**43**	13	8	24	7	10	3	2
Adequacy of storage facilities*	9	4	**36**	**20**	**29**	12	4	4	3	1
Specificity of sanitation program	12	**18**	**28**	11	18	13	14	4	3	2
Extent of personal hygiene requirements*		17	**37**	15	9	**26**	12	2	3	2
Sophistication of incoming materials control*	6	**34**	21	8	24	12	11	2	2	2
Adequacy of packaging	**47**	4	10	8	**34**	5	7	3	1	1
Sophistication of supplier control*	6	20	**39**	4	15	15	15	4	3	1
Specificity of fertilizer program	**35**	4	15	15	15	19	13	2	1	2
Specificity of pesticide program*	3	4	**25**	**37**	5	13	**24**	7	3	2
Sophistication of water control*	5	8	**33**	23	24	10	13	2	3	3
Adequacy of irrigation method*		**24**	**39**	6	15	21	12	1	3	2
Intervention method design										
Adequacy of partial physical intervention	**40**	9	15	5	**25**	16	6	2	1	1
Monitoring system design										
Appropriateness of hazard analysis*	14	11	**38**	6	**29**	8	10	2	3	1
Adequacy analytical methods for microbiological hazards	**41**	1	2	25	**39**		4	6	1	1
Adequacy of analytical methods for pesticide residues*	15		2	**52**	30		5	14	4	1
Specificity of microbiological sampling plan*	**32**	9	14	14	**35**	3	10	1	2	1
Specificity of pesticides' sampling plan*	**21**	6	**30**	12	**37**	3	9		3	1
Adequacy of measuring equipment*	12	3	**28**	**26**	**41**	1	7		3	1
Extent of corrective actions*	10	19	24	16	**32**	1	13	3	3	1
Actual operation of control activities										
Availability of procedures*	5	9	**30**	**25**	**20**	9	14	6	3	2
Compliance to procedures*	4	8	**41**	16	13	18	15	3	3	2
Actual hygienic performance of equipment & facilities	**33**	3	19	14	**32**	4	8	5	2	1
Actual cooling and storage capacity*	19	9	18	23	**36**	1	5	7	3	1
Actual capability of partial intervention	**51**	2	10	6	**42**	1	6		1	1
Actual capability of packaging	**51**	4	7	7	**37**	1	5	6	1	1

Actual measuring equipment performance*	12	3	**28**	**26**	**37**	1	7	4	3	1
Actual analytical equipment performance*	**25**	**1**	1	**42**	**39**	2	2	6	4	1
Assurance activities										
Sophistication translating external requirements*	2	18	32	17	17	14	12	6	3	2
Extent of systematic use of feedback information*	7	20	28	14	21	17	6	5	3	2
Sophistication validating preventive measures*	15	18	32	4	24	12	11	2	3	2
Sophistication validating intervention strategies	39	10	17	3	**31**	7	9	2	1	1
Sophistication validating monitoring system	26	14	27	2	**28**	11	9	1	2	1
Extent verifying people related performance*	5	34	16	14	**31**	8	9	1	2	1
Extent verifying equipment & methods performance*	4	30	25	10	**25**	10	11	3	3	1
Appropriateness documentation*	2	11	**43**	13	**19**	5	**21**	4	3	2
Appropriateness record-keeping system*	1	12	**48**	8	16	11	19	3	3	2

[a] Situations 1, 2, 3, and 4 for control and assurance activities correspond to: low level (1) → absent, not applicable, unknown; basic level (2) → lack of scientific evidence, use of company experience/history, variable, unknown, unpredictable, based on common materials/equipment; average level (3) → best practice knowledge/equipment, sometimes variable, not always predictable, based on generic information/guidelines for the product sector; advanced level (4) → scientifically underpinned (accurate, complete), stable, predictable, and tailored for the specific food production situation.

** Significant differences ($p<0.05$) between scores of EU and non-EU companies*

Table 6.2B: Frequency of the individual scores and median for the FSMS output for EU and non-EU companies (The scores represent 1 – no information, 2 – poor output, 3 - moderate output, and 4 – good output), most frequent score indicated in bold.

FSMS activities	EU (n=69)				Non-EU (n=49)				EU	Non-EU
	1[a]	2	3	4	1	2	3	4	median	
Comprehensiveness external evaluation*	3	9	**28**	**29**	25		21	3	3	1
Seriousness of remarks*	3	1	6	**59**	**27**	4	8	9	4	1
Type of microbiological complaints*	**21**	3	8	**37**	**23**	8	8	10	4	2
Type of chemical food safety complaints*	8	1	**21**	**39**	**21**	7	13	8	4	2
Type of visual quality complaints*	6	13	**41**	9	16	14	13	6	3	2
Advancedness of microbiological sampling*	**39**	5	9	16	**36**	8	5		1	1
Comprehensiveness of judgement criteria for microbial FS	**38**	5	15	11	**34**	8	6	1	1	1
Advancedness of pesticides sampling*	14	5	**39**	14	**34**	4	7	4	3	1
Comprehensiveness of judgement criteria for chemical FS*	14	10	19	26	**31**	7	7	4	3	1
Type of non-conformities*	20	3	28	18	**29**	3	13	4	3	1

[a] Situations 1, 2, 3, and 4 for system output correspond to: no information (1) → absent, not applied, unknown; poor output (2) → ad-hoc sampling, minimal criteria used for evaluation, various food safety problems due to different problems in the activities; moderate output (3) → regular sampling, several criteria used for evaluation, restricted food safety problems mainly due to one (restricted) type of problem in the activities; good output (4) → systematic evaluation, using specific criteria, no safety problems.

** Significant differences (p<0.05) between scores of EU and non-EU companies*

Table 6.2C: Frequency of the individual scores and median for the contextual factors for EU and non-EU companies (The scores represent 1 – low risk, 2 – moderate risk, and 3 - high risk), most frequent score indicated in bold.

Context factors	EU (n=69)			Non-EU (n=49)			EU	Non-EU
	1[a]	2	3	1	2	3	median	
Product characteristics								
Microbiological risk of initial materials*	11	19	**39**	10	**26**	13	3	2
Risk of initial materials to pesticide residues	18	**60**	1	6	**33**	10	2	2
Risk of initial materials due to mycotoxins*	1	**33**	**35**	**20**	**22**	7	3	2
Microbiological risk of final product*	1	7	**61**	1	15	**33**	3	3
Risk of final product to pesticide residues	4	12	**53**	5	2	**42**	3	3
Production characteristics								
Susceptibility of production system*	17	17	**35**		1	**48**	3	3
Risk climate conditions of production environment*	9	**51**	9		11	**38**	2	3
Susceptibility of water supply*	10	**45**	14	8	12	**29**	2	3
Organisational characteristics								
Presence of technological staff	15	30	24	5	17	**27**	2	3
Variability of workforce composition*	22	38	9	14	19	16	2	2
Sufficiency competences of operators	5	32	32	2	19	**28**	2	3
Extent of management commitment*	14	**44**	11	8	16	**25**	2	3
Degree of employee involvement	12	34	23	5	17	**27**	2	3
Level of formalization*	16	**45**	8	7	13	**29**	2	3
Sufficiency of supporting information system*	10	**49**	10	10	10	29	2	3
Chain characteristics								
Severity of stakeholder requirements*	10	**45**	14	**21**	**24**	4	2	2
Extent of power in supplier relationships*	10	**44**	15	5	19	**25**	2	3
Degree of information exchange in supply chain*	21	38	10	10	11	**28**	2	3
Sophistication of logistic facilities*	**33**	**27**	9	4	20	**25**	2	3
Supportiveness of food safety authority*	**31**	**26**	12	12	10	**27**	2	3
Degree of globalization of supply*	**44**	20	5	13	21	15	1	2
Specificity of external support*	**60**	7	2	13	7	**29**	1	3
Specificity of food safety legal framework*	**69**			**24**	11	14	1	2

[a] Low (1), medium (2) and high (3) risk situations for product and process characteristics correspond to low, potential and high chance of microbiological or chemical contamination. Ffor organizational and chain characteristics they correspond to supportive, constrained and lacking administrative chain conditions or low, restricted and high dependence on other chain actors.

** Significant differences (p<0.05) between scores of EU and non-EU companies*

6.3.2. Clusters of companies differing in FSMS status

A hierarchical cluster analysis was performed to further explore how companies group according to their FSMS status and adaptation of FSMS to the riskiness of the context, which resulted in three clusters (Figure 6.1). Table 6.2 is showing the distribution of the companies in the clusters according to type of product, size, and certifications. Cluster 1 consists of forty-seven companies located in both EU and non-EU countries. These companies have implemented and were certified against several voluntary private standards, such as GlobalGAP, BRC, ISO, and private brand standards. In cluster 2 forty-two companies were grouped from both EU and non-EU countries. However, these were certified only against national standards and GlobalGAP, and no other private standards were included. In the last cluster 3 twenty-nine companies were grouped, that were small and from non-EU countries. These companies were not certified against any standard.

Figure 6.2. presents the median score results for the context, FSMS activities and output indicators. Product and process characteristics scored similar for cluster 1 and 2 companies. However, the lower score (1) for the indicator 'microbial risk of initial materials' was due to treatments of seeds and seedlings (UV, chemical disinfection). Climate conditions and water source scored 3 (high risk) for the companies in cluster 3, which was related to tropical and sub-tropical conditions, and the use of uncontrolled surface water sources (see also Table 6.2C).

A similar pattern was observed for the indicators of organisational and chain characteristics, as cluster 1 demonstrated least risky (scores 1 and 2), and cluster 3 - most risky profile (mostly scores 3). The latter showed lack of organisational (i.e. lack of technical staff, low competences of workers, lack of management commitment and workers' involvement), and supply chain support (i.e. lack of power in supply chain and information exchange, lack of logistic facilities and support from authorities and other organisations). Still, low risk scores (1) were given to the indicators of 'variability of workers', 'severity of stakeholder requirements' and 'specificity of food safety legal framework'. These scores can be explained by the fact that cluster 3 contained small family farms, oriented mainly towards local markets and ethnical shops in the EU countries.

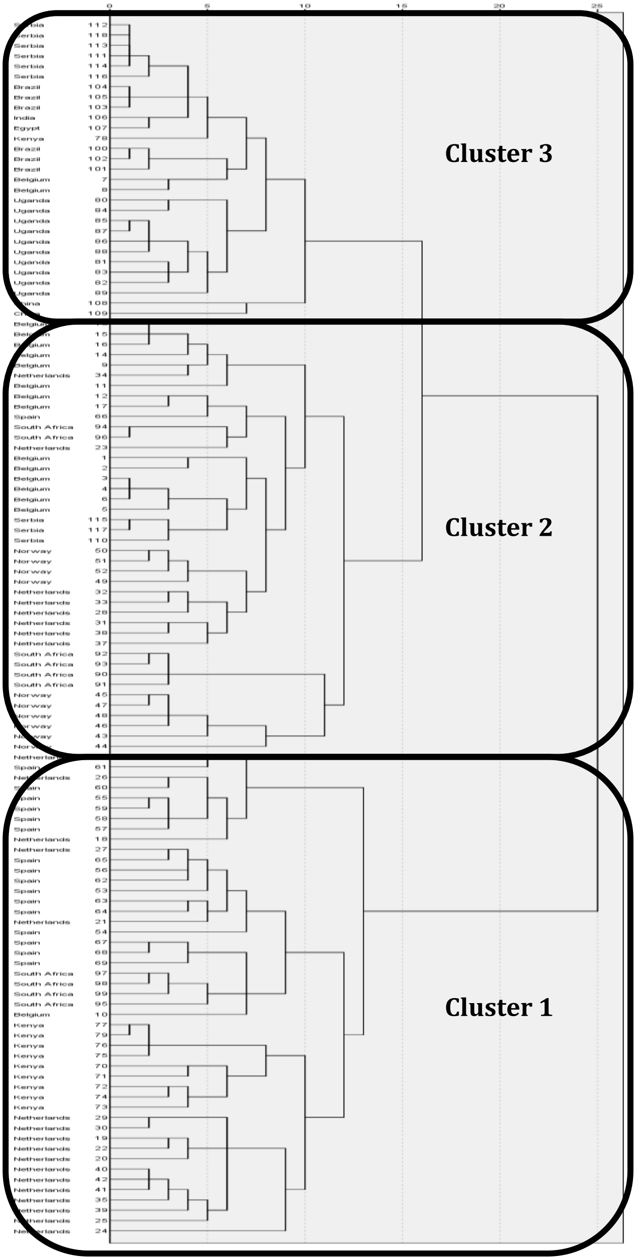
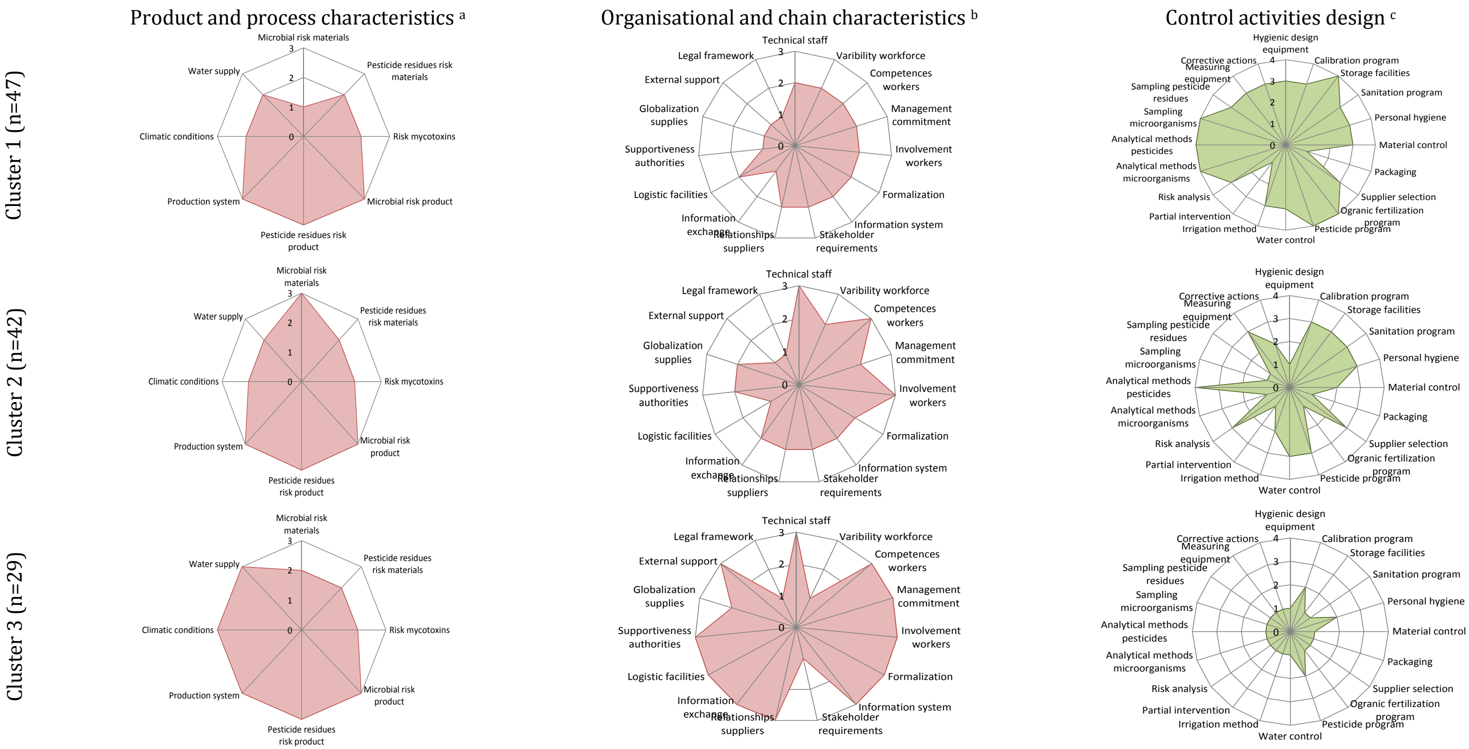


Figure 6.1: Dendrogram analysis of individual scores of 118 companies and identification of three clusters



[a] *Low (1), medium (2) and high (3) risk situations for product and process characteristics correspond to low, potential and high chance of microbiological or chemical contamination.*

[b] *Low (1), medium (2) and high (3) risk situations for organizational and chain characteristics they correspond to supportive, constrained and lacking administrative chain conditions or low, restricted and high dependence on other chain actors.*

[c] *Situations 1, 2, 3, and 4 for control and assurance activities correspond to: low level (1) → absent, not applicable, unknown; basic level (2) → lack of scientific evidence, use of company experience/history, variable, unknown, unpredictable, based on common materials/equipment; average level (3) → best practice knowledge/equipment, sometimes variable, not always predictable, based on generic information/guidelines for the product sector; advanced level (4) → scientifically underpinned (accurate, complete), stable, predictable, and tailored for the specific food production situation.*

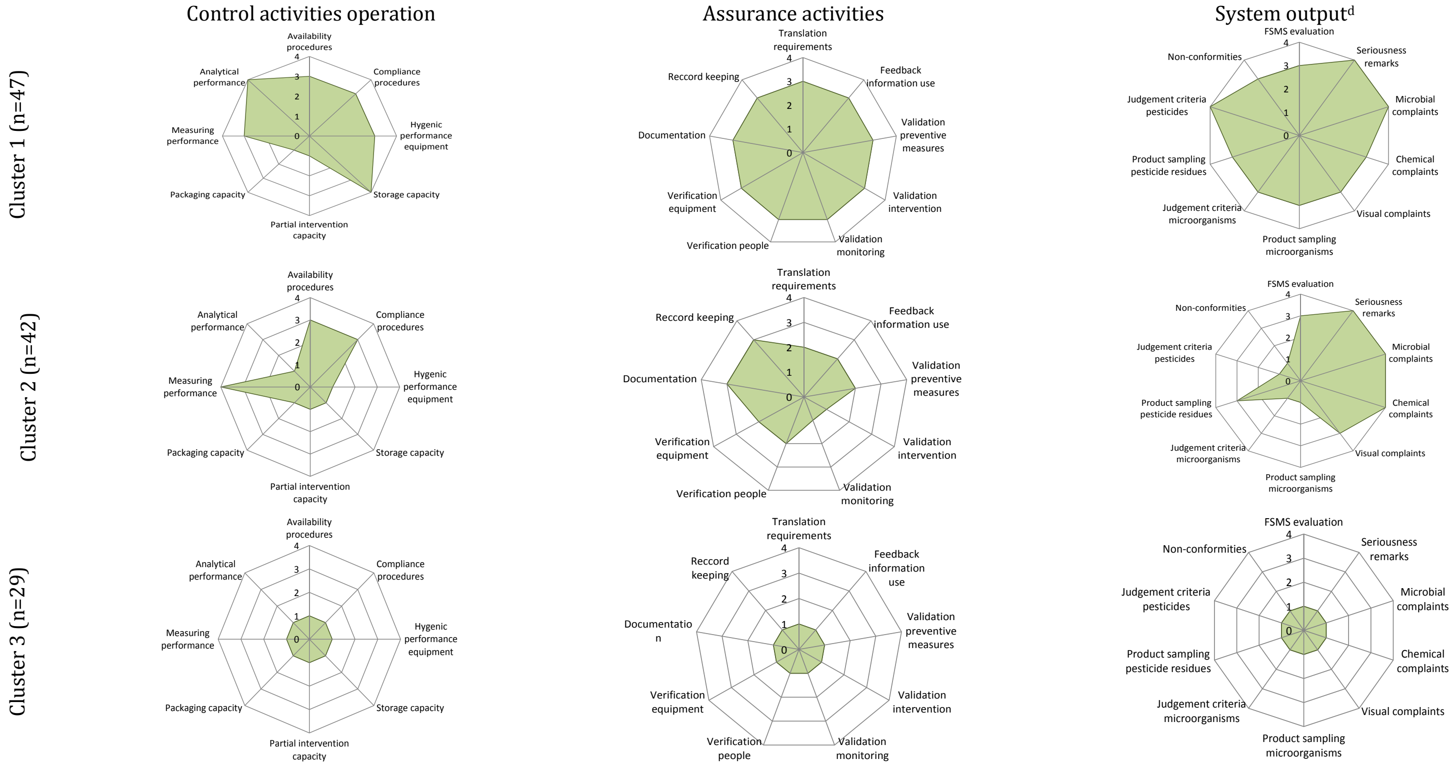


Figure 6.2: Median score results for the indicators in the diagnostic instrument for the three identified clusters of farms active in fresh produce production

[d] *Situations 1, 2, 3, and 4 for system output correspond to: no information (1) → absent, not applied, unknown; poor output (2) → ad-hoc sampling, minimal criteria used for evaluation, various food safety problems due to different problems in the activities; moderate output (3) → regular sampling, several criteria used for evaluation, restricted food safety problems mainly due to one (restricted) type of problem in the activities; good output (4) → systematic evaluation, using specific criteria, no safety problems.*

FSMS activities of the companies in cluster 1 were mostly at level 3, design according to the standards and using standard equipment and methods. Even more advanced level 4 was given for storage facilities, fertilisation program, pesticide management, and sampling for pesticide residues and microorganisms. Level 4 is attributed when activities are adapted to fit-for-purpose and tested for specific farm/company situation. Companies in cluster 2 scored mostly at 3 (average level), but several activities such as hygienic design of equipment, material control and irrigation method demonstrated even lower level (2). This score was given to activities designed according to historical knowledge and own experience. Companies in cluster 3 had basic control activities. Only few activities (these are, maintenance program, personal hygiene requirements, and pesticide program) were actually implemented in these companies.

Companies in cluster 1 had also average level (3) for the indicators about actual operation of control activities, and even advanced level (4) for actual storage capacity and performance of analytical equipment. Companies in cluster 2 did not have information about many of the activities. Still, procedures were available, updated ad-hoc and mostly complied to. No information about actual operation was available in the companies from cluster 3.

Assurance activities in companies of cluster 1 were at average level (3), meaning that companies were actively following the changes, regularly updating the system, validating via external experts, regularly verifying the activities internally, and systematically documenting. Most of the activities were at basic level (2) in the companies in cluster 2, and validation was not done (1). Still, systematic documentation and record-keeping were at place (3). Validation activities were lacking completely for the companies in cluster 3.

Regarding the information for the **system output**, companies in cluster 1 were regularly audited by several third parties for their multiple standards (3), had few remarks and complaints from customers (4). These companies were taking systematic samples for pesticide residues and even a sampling plan for microorganisms was present (3). Companies in cluster 2 showed similar results for FSMS evaluation, complain registration and pesticide sampling. However, they were lacking sampling plans microorganisms (1), and non-conformities registration (1). Again, companies in cluster 3 did not have any information about their output (1).

6.3.3. Exploring the main factors behind differences between the clusters

A Principle Component Analysis (PCA) was performed to investigate the main factors explaining the variation and differentiation between clusters of companies. Four indicators were excluded because the Kaiser-Meyer-Olkin measure of sampling adequacy was below 0.5; namely 'microbial risk of initial materials', 'risk of initial materials to pesticide residues', 'microbial risk of final product', 'risk of final product to pesticide residues' and 'variability of workers'. Figure 6.3 presents the loading plots for the first three principle components. The first component (PC1) explains 36.9%, the second component (PC2) - 7.3%, and the third component (PC3) - 5.1% of variation (49.3% of the total variation). The next three components explain below 5% of the variance, 4.1% (PC4), 3.6% (PC5) and 3.2 (PC6), and they were not further investigated.

When riskiness of organisational and chain characteristics load negatively on PC1 (lower risk), then design of several core control activities (these were, sanitation program, maintenance program, supplier control, material control), actual operation of control activities (availability of procedures and hygienic performance), and all assurance activities load positively, with more advanced levels (Figure 6.3). This principle component may be linked to availability of specific, scientific based information within the company and the supply chain to support control and assurance activities. When requirements from stakeholders load as low risk and support from authorities load as high risk on PC2, then adequacy of analytical equipment for pesticide residues loads low (lower level), and packaging and partial intervention load positively (higher levels). This principle component can be linked to the support of public and private organisations in monitoring (of pesticide residues), providing information about post-harvest intervention strategies and the factors affecting their effectiveness. Storage loads positively on PC3, together with irrigation method, personal hygiene and hazard analysis. This could be linked to companies that invest in storage and related main control measures (e.g. export oriented).

PCA score plots were constructed with a total variance of 49.3% (PC1 and PC2; Figure 6.4A and 4B) to demonstrate the differentiation between clusters. Cluster 1 was separated from cluster 3 by PC1, while cluster 2 was somewhere in between and most companies were split by PC2. However, eleven companies loaded positively on PC2 and ten of them were from Norway. From Figure 6.4A it can be derived that cluster 1 companies were mostly separated from the rest by PC1. Cluster 2 companies were fragmented by both PC1 and PC2. Figure 6.4B shows that cluster 3 was split from cluster 1 by PC3, while companies in cluster 2 were again scattered.

6.4. Discussion

6.4.1. Status of FSMS in view of the context riskiness

The data was collected with the diagnostic tool, which allows assessment of the core control and assurance activities in an FSMS, the system output *(256)*, and the context factors affecting design and operation of activities in the FSMS *(259)*. The general assumption behind the diagnostic tool used for data collection is that companies working in high-risk context need advanced level of activities to achieve a good system output *(294)*. The combination of high risk-context characteristics and simple (basic level) FSMS imply a higher risk of food safety problems *(95, 462)*.

All companies in this study were dealing with risky product linked to type of cultivated produce, open field production and potential microbiological or chemical contamination of fresh produce, and high risk organisational characteristics, such as high turnover of workers with low involvement and competences. These are typical issues that fresh produce farms face *(9)*. However, most EU companies were working in a lower or moderate risk of production and supply chain context, compared to the non-EU companies (Table 6.2C). This was due to the use of controlled water sources, protected cultivation, sophisticated infrastructure, and collaborative supply chain. Protected cultivation and controlled water sources are used to increase yields, control abiotic factors and promote pest management in integrated fresh-cut and other added-valued supply chains *(337)*.

Many non-EU companies had simple FSMS based on own knowledge and experience, which in combination with their high-risk context characteristics induce a higher risk on safety problems (Table 6.2A). Previous studies discuss shortcomings in FSMS leading to food safety problems *(269, 462)*. In comparison, most companies within the EU had control activities based on standards, using expert knowledge and standard equipment (Table 6.2A). Studies done in developing and emerging countries were discussing the lack of knowledge and competences in the companies, particularly smallholders *(165, 269, 400, 450)*. Assurance activities were following similar trend with the exception of validation of monitoring systems and verification of people, which were mostly ad-hoc in the EU companies and lacking in many non-EU companies. A study in the meat and dairy sectors in Europe showed similar difficulties in setting verification and other assurance activities *(227, 289, 397)*. It was stressed before that verification is crucial for assuring effectiveness of activities, but requires knowledge and resources *(295, 336)*.

Following the basic assumption behind the diagnostic tool, the EU companies showed better system output, and generally more information about it was available to them (Table 6.2B). They were audited by two and more third parties, which was not done or only by one in the non-EU companies. This could be explained by the fact that audits in developing countries are commonly done by the importers (retailers) only in companies aimed at exporting *(201, 234)*. Multinational retail chains have a dominating role in imposing quality and safety standards and in many situations the role of the local institutions is still weak *(38)*.

In general, EU companies had also more information about the output of their FSMS due to company sampling and sector monitoring for pesticide residues. In developing countries that was mainly done in the export farms, as local governments and organisations lack infrastructure, capacity and resources to conduct monitoring *(2, 233)*. Pesticide residues have been regulated in the EU *(115)*, and by Codex Alimentarius Commission *(68)* for some years now. Companies have put lots of efforts in the management of pesticides, and this was evident also from our study as 93 (out of 118) companies demonstrated average (3) and advanced levels (4) (Table 6.2A). In comparison, microbiological hazards only recently received some attention in (international) recommendations, as a reaction to outbreaks *e.g.* sprouted seeds - EU 2011 *(421)*, spinach - USA 2006 *(77)*, and Jalapeño peppers - USA 2008 *(33)*. Moreover, guidelines and standards for core control activities to prevent microbiological contamination such as control of irrigation water quality exist only in several regions and there is no internationally accepted recommendation for the quality of water *(355)*. Still most companies do not have enough knowledge and awareness about microbiological hazards, and few of the companies in this study performed sampling (score 1).

However, not all non-EU companies were facing the hurdles discussed above. A group (clusters 1 and 2; Table 6.2) of non-EU companies also demonstrated average to advanced FSMS (Figure 6.2). Actually, non-EU companies were present in all the three clusters of companies with differing FSMS status. After the cluster analysis typical profiles of companies irrespective of their location and legislation followed (EU or not) were distinguished, and several main factors that define these profiles were defined.

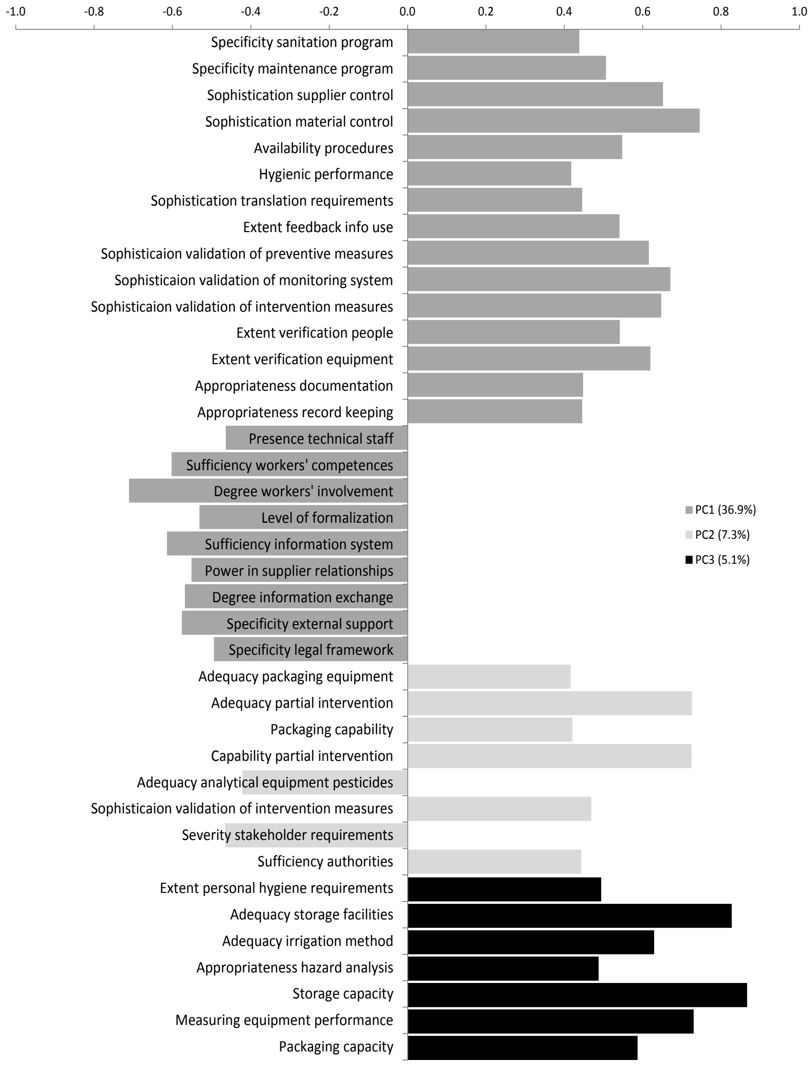


Figure 6.3: Loading plots of the first three principle components explaining 49.3% of variance

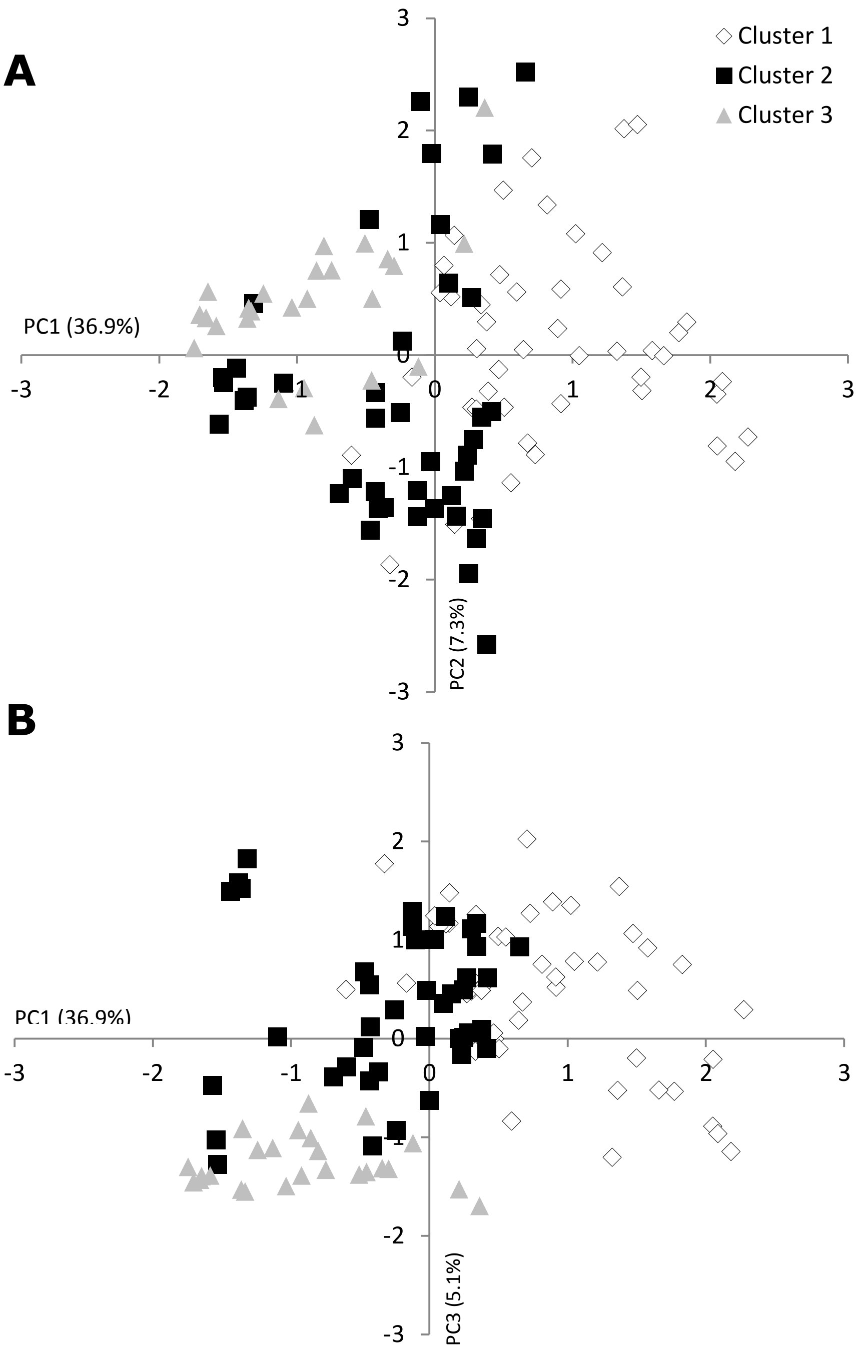


Figure 6.4: PCA score plots for comparison between the clusters

6.4.2. The role of supply chains and private standards

From the study it became clear that collaborative/supportive supply chains (PC1; figure 6.3 and 6.4) contribute to more advanced FSMS and good system output (cluster 1; figure 6.2), as companies demonstrated advanced knowledge and expertise about safety and quality management. The results were independent from company size (micro, small, medium or big), and location (EU or non-EU). However, the companies in this cluster were part of leading fresh produce supply chains (in Spain, the Netherlands, Kenya, and South Africa). Moreover, these companies had several certifications including many strict private standards(Table 6.2). Studies reported that some exporters have invested in infrastructure, quality management and even own product-testing laboratories in order to meet strict requirements of the (EU) markets *(199, 234, 346)*. In contrast, the companies in cluster 3 did not have any standards implemented and were operating in less demanding chains supplying the local market or ethnic grocery shops in the EU. They had only few control activities implemented scoring at basic level, which means that they were following own knowledge and experience. No assurance activities and no information about the system output were available. These results were linked to the lack of information and expertise within companies and supply chains. Similarly, Trienekens & Zuurbier *(450)* report difficulties in the implementation of GAP and GHP in least developed countries, and strive for implementation of international standards in emerging export countries. Moreover, our findings are in line with studies demonstrating the lower levels of safety and quality of horticultural products sold at wet markets and local supermarkets in developing countries *(e.g. 180, 366)*.

All companies in cluster 2 were following national standards or GlobalGAP, which is in line with empirical evidence showing that prescriptive national standards lead to average levels of FSMS activities, but companies still experience difficulties to tailor to their specific circumstances *(7, 397)*. Interestingly this was the case also with the companies that were only GlobalGAP certified, indicating the baseline status of this standard. Baseline standards put minimum requirements, focusing on core activities from a public health perspective *(141)*.

Table 6.2: Distribution of the companies in the clusters

Country	Product				Size[a]				Standard				
	Leafy greens	Berries	Fruits	Other	Micro	Small	Medium	Large	National	Global GAP	BRC	ISO	Other
Cluster 1 (n=47)													
EU													
– Belgium (1)		1					1		1	1			
– Netherlands (17)	3	6	1	7	4	4	9			15	2		4
– Spain (16)	13	3				1	4	12	3	16	5	7	7
Non-EU													
– Kenya (9)				9		4		5	5	9		1	5
– South Africa (4)	3		1			1	3			4		5	3
Cluster 2 (n=42)													
EU													
– Belgium (14)	6	8			8	5	1		14	14			
– Netherlands (8)	4	3		1	4	4				8			
– Norway (10)	6	4			1	5	4		10	1			
– Spain (1)		1				1			1	1			
Non-EU													
– Serbia (3)		3			2		1			3			
– South Africa (6)		1	5			1	2	3		6			
Cluster 3 (n=29)													
Non-EU													
– Brazil (6)	6					6							
– China (2)			2				2						
– Egypt (1)		1				1							
– India (1)			1			1							
– Kenya (1)													
– Serbia (6)		6			1	5							
– Uganda (10)				10		10							
TOTAL	**41**	**37**	**10**	**27**	**20**	**49**	**27**	**20**	**34**	**78**	**7**	**10**	**16**

[a] *Size of companies is defined according to Commission recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC).*

6.4.3. The role of the institutional environment

Sector organisations and non-governmental organisations (NGOs) that support companies were another important factor affecting the status of FSMS, especially in the case of small and medium companies. These were largely represented in clusters 2 and 3. In both clusters activities, such as, hygienic design of equipment, initial material control, and monitoring, were not implemented. Even basic activities were lacking in cluster 3, and there was no or only ad-hoc information about actual operation of control activities in both clusters. Companies in cluster 2 and 3 had limited insights about the output of their systems (Table 6.2B) due to e.g. shortcomings in monitoring of pesticide residues. In some EU countries these activities are done or coordinated by sector organisations, but improvements are possible in the structure and scientific base of the, e.g., sampling activities *(255)*. Coordinated sampling for pesticide residues was not done in many of the companies located in emerging countries in clusters 2 and 3 (Figure 6.2). They were well established in the companies from cluster 1, which were part of leading export chains and certified against international standards. Henson, Masakure, and Cranfield *(202)* defined two key factors for companies in developing countries to acquire GlobalGAP certification: 1) being in an established export country and 2) receiving technical and financial assistance. If companies are not part of export supply chains, and support by foreign importers is lacking, then the room for support is left to the (local) sector organisations or NGOs. However, in many cases these are missing, dysfunctional or covering only staple crops production *(38, 331)*.

Furthermore, the promulgation of a legal framework and its enforcement are the very foundation for a good functioning FSMS, and especially important in the absence of supporting (export) supply chain. This was demonstrated by the risky context due to low requirements of stakeholders and restricted operation of local food safety authority (PC2), which was linked to basic FSMS (cluster 1). Companies in all the three clusters testified that a legal framework that follows the international recommendations of Codex Alimentarius is in place in their country (Figure 6.2). This is indeed so, as many countries have implemented the requirements of Codex Alimentarius into their legal framework, but still having difficulties with risk assessment, and with establishing sound policies and enforcement strategies that consider the local social, technical and economic circumstances *(2, 82, 121)*. Moreover, evidence from emerging and developing countries suggests that weaknesses in the institutional environment hinder the enforcement *(269, 270, 450)*.

6.5. Conclusions

This study demonstrated that several factors have a dominating effect on the status of primary production FSMS in the global fresh produce chain. International export supply chains promote capacity building within companies in the chain, to answer the stringent requirements of private brand standards. This is especially an important factor in emerging and developing countries where local institutional environments often fail to support companies in setting and implementing their FSMS. Moreover, the legislative framework in these countries still requires improvements in the set-up and enforcement. All this has negative consequences for the FSMS in companies supplying the local markets.

In companies located in the EU, sector and other produce organisations facilitate the sampling for pesticide residues and collaboration in the sector. However, farmers showed less knowledge and overall awareness regarding microbiological hazards, which is related to the less attention paid to these in the current legislation and standards. Furthermore, standards are an important tool to trigger the maturation of the systems as companies that were lacking any operated at a very basic level - with only few activities implemented.

The insights from this study indicate the need of stratified measures and policies to support companies in the fresh produce chain in designing and operating their FSMS according to the institutional environment in which they operate. This study was a first attempt to provide evidence about major factors affecting the status of FSMS in the fresh produce chain based on semi-quantitative data analysis. More in-depth case studies into supporting contexts could provide understanding about best strategies and practices to improve the status of FSMS.

6.6. Acknowledgements

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Chapter 7: Towards strategies to adapt to pressures on safety of fresh produce due to climate change

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Abstract

This article outlines the findings from a Delphi study aimed to generate insights from a systems perspective about responding to climate change in terms of food safety of fresh produce. The study identified pressures to food safety of fresh produce at primary production, related to contamination of water sources and production environment with microorganisms, pesticide residues, mycotoxins and heavy metals due to heavy rainfalls and floods, droughts, increased temperature and change in seasonality, as results of climate change. First response to these pressures is realised by the core control activities implemented at farm, and depends on their current implementation and actual operation. The experts highlighted the need to strengthen activities, such as water control (including water treatment and quality monitoring), irrigation method, pesticide management (and pre-harvest intervals), personal hygiene requirements and (cold) storage control. Validating the effectiveness of control activities for the changed circumstances, guidance and training to the farmers was emphasized. Moreover, response strategies were proposed for farms to cope with the pressures immediately after occurring and to adapt long-term with support at the community level.

The participating experts represented countries from the global north with industrialised food systems, and from the global south — with structured and traditional food systems. They assessed the likelihood of most pressures as higher for the countries from the global south, which was explained by existing response strategies in the global north. It was proposed that the adaptive and coping capacities of companies, regions and sectors are determined by the currently available adaptation and coping strategies. The pressures to food safety can differ per company, supply chain, region and sector due to variability of current climate vulnerabilities, control activities, and adaptive capacity. This paper argues that future adaptation actions should take into account the context of countries, sectors and companies, thus, focus on improving adaptive capacity from a systems perspective.

7.1. Introduction

Fruits and vegetables are produced around the globe, in various climate conditions, following different production practices and food safety legislation. Trade with these commodities grew markedly in the last years *(116)*. However, an increase was observed in the number of reported microbiological hazards *(297, 414)*, pesticide residues *(e.g. 207, 485)* and mycotoxins *(e.g. 142, 377)*, which may indicate inadequacies in the control activities currently implemented in companies. Some of these food safety incidences have been associated with climate events and extremes. For instance, increased occurrence of certain enteric diseases has been linked to seasonality and heat waves *(90, 266, 267)*. Rapid increases in environmental contamination have been documented after heavy rainfalls, storms and floods *(301, 371, 410, 426, 457)*. Moreover, application of pesticides and risk of residues are presumed to increase due to climate change and extreme events *(58, 264)*. Mould growth and mycotoxin formation are also linked to warmer temperatures and more humid conditions *(465)*. The risk to food safety and vulnerabilities in the current control activities at primary production are indeed expected to be further exacerbated by climate change *(281, 324, 443)*. According to the latest climate change scenarios, the frequencies of climate extremes are predicted to become more common in the future *(222, 223)*. Climate adaptation studies discuss the response strategies needed to cope with climate pressures on agriculture, and stress the lack of adaptive capacity due to already existing vulnerabilities in the context of a country and region, particularly in the global south compared to the global north *(*e.g. *61)*. The potential effects of climate change on food safety have been extensively reviewed *(58, 134, 281, 323, 324, 360, 403)*. However, only general and scattered evidence exist about how primary producers may respond to the changes in climate in terms of food safety *(e.g. 304, 443)*. In many cases, response strategies are undermined into few arbitrary measures, the context of their application is not considered, and a systematic approach is lacking.

Therefore, the overall objective of the study was to generate insights from a systems perspective about which climate-induced events can put pressure on safety of fresh produce, and what response strategies can be applied at primary production. The following research questions have been defined: Q1) What changes in climate can be expected to put pressure to food safety of fresh produce in the near future? Q2) Which are the most important and feasible strategies that can be applied to respond to the pressures? Q3) What response strategies can be applied at company and community level? Q4) Which response strategies determine the adaptive capacity of companies and regions, and do they differ globally?

7.2. Research methodology

7.2.1. Driving force - pressure - state - impact - response (DPSIR) analytical framework

The DPSIR framework was employed for conceptualisation and definition of the relationships between increasing pressures due to climate change on food safety of fresh produce, and responses needed to adapt. The DPSIR framework, along with its earlier incarnations (i.e. PSR, DSR), is widely accepted and a commonly used framework for interdisciplinary system and model conceptualization, indicator development and integrated assessments *(e.g. 54, 345, 475)*. The DPSIR framework systemises the relationships between humans and the environment in: driving forces that exert pressures on the environment, resulting in a certain state of the environment, that has an impact on humans and society, which may stimulate responses on any of the previous four elements *(122, 345)*. In the case of food safety and climate change, the framework was modified to address the needs of this study. Climate change is recognised as a driving force leading to climate-induced events, which exert pressure on the current state of food safety management in farms, which ultimately may impact human health and society (Fig. 7.1). Moreover, the framework includes the response from society (farms/companies, government or private organisations) through different measures, policies and strategies. A valuable point in this analytical framework is that it recognises the dynamic nature of the processes under investigation. This is especially important in the case of climate change, because it is a process that will gradually change the risks and required responses.

In this study, focus is made on the analysis of the driving force of climate change, through its vectors (e.g. temperature, rainfall), which may lead to events that put pressures on safety of fresh produce. Moreover, a central point of the study was to explore the response strategies at farm and community level. By following the public health perspective, we define the response strategies as actions taken in advance of climate change or reactions after perceived or real public health risks *(106)*. The impact of human health and society is taken into account by defining the hazards of concern for fresh produce (those are, pathogenic microorganisms, pesticide residues, mycotoxins, and heavy metals) *(464)*. The major control activities at farm represent the current state (Fig. 7.1), as based on previous work *(256)*.

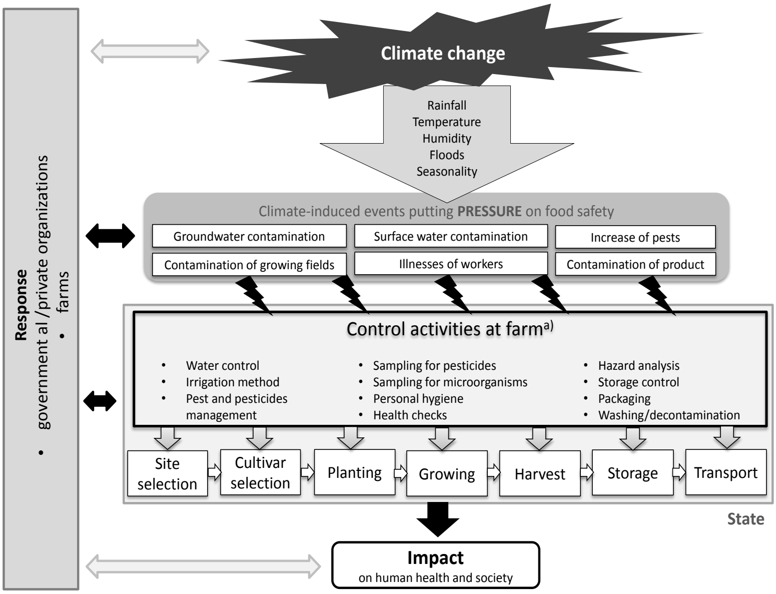

Figure 7.1: DPSIR analytical framework used to analyse climate change pressures on for food safety management in fresh produce

a) The major practices shown in the figure are based on previous work (256)

7.2.2. The Delphi method

To analyse the possible pressures on food safety of fresh produce due to climate change, the Delphi method was employed. The Delphi method is a technique for structuring the discussion of experts distributed among different domains in order to find solutions to complex problems *(279)*. The ultimate goal of most Delphi-studies is to reach a consensus between experts. The level of consensus should be pre-determined, and ranges between 51-80% have been suggested as acceptable *(191)*. However, a special group of studies, the so-called policy Delphi studies, are not aimed at generating consensus, but rather at collecting opinions, even opposing ones, in order to support informed decisions. The objectives of this study were closer to these of the policy Delphi, rather than to these of the traditional Delphi techniques, because it did not intend to identify an ultimate consensus. Instead, it was intended to generate opinions of experts from different geographical locations and domains. Nevertheless, consensus was sought for judging the importance and feasibility of the responses, in order to generate another round of discussion if these exhibited large variation.

7.2.3. Study design and data analysis

The study started by extracting the major projected climate changes from the regional IPCC reports *(222)*. Furthermore, these were used as an input for identifying a list of pressures to food safety of fresh produce. These two served as basis for conducting the Delphi study, which took place in the period May-November, 2013. It was designed in three rounds and the questionnaires were disseminated and implemented via a web-based tool for building surveys (http://qualtrics.com/). In the first round, experts were requested to rank the likelihood of occurrence in their region of climate-induced events derived from literature that may put pressure on food safety of fresh produce. The pressures were rated on a 5-point Likert scale ranging from 1 (not likely) to 5 (very likely). The experts were also stimulated to suggest other, missing pressures and to comment their choice. No consensus was strived for due to the geographical dispersion of the experts and the specifics of each region in terms of climate and landscape. After McCullough, Prabhu, and Kostas *(310)*, the experts were grouped in the following groups: 1) experts from countries with industrialised food systems (global north), and 2) experts from countries with predominantly structured and traditional food systems (global south). The experts from the global north (n=15) were representatives from Belgium, Netherlands, Norway, South Korea, Spain, United Kingdom, and United States of America. The experts from the global south (n=10) came from Brazil, Egypt, India, Kenya, Malaysia, South Africa, Tanzania and Uganda.

In the first round of the Delphi study, the experts provided also ideas (open-ended questions) for potential response strategies to each pressure on farm/company and community level. At a community level response strategies by organisations with support function were considered, such as extension or farmer/produce organizations, NGOs, and or governmental organisations. These ideas were compiled, coded and analysed by using the MAXQDA 10 qualitative data analysis program *(307)*. The coding was following the conventional content analysis approach to derive the response strategies by inductive category development *(214)*. Directed content analysis was used for classifying the response strategies into farm/company and community response, and into coping and adaptation strategies *(214)*. Coping is a short-term adaptation, which uses existing resources during or immediately after a climate-induced event, whereas adaptations refer to strengthening the coping capacities, setting preventive measures and building resilience *(Table 7.1; 8, 71)*.

Table 7.1: Characteristics of 'coping' and 'adaptation'

Coping	Adaptations
Short-term and immediate	Practices and results are sustained
Oriented towards instant results	Oriented towards longer-term food safety
Not continuous	A continuous process
Motivated by crisis; reactive	Involves planning
Often leads to destruction of produce	Uses resources efficiently and sustainably
Prompted by a lack of alternatives	Focused on finding alternatives
	Combines old and new strategies and knowledge

Modified from (71)

The list of response strategies per type of pressure generated in the first round were used in the second round of the Delphi study, during which experts were requested to rank them for their importance and feasibility. The criteria used for the ranking is described in Table 7.2. The answers from the second round of the study were analysed by calculating the mode (M) and the quartile coefficient of dispersion (QCD) *(56)*. If the latter was above 0.3 a third round of the study would be required to seek agreement between the experts.

7.2.4. Characteristics of the experts

For the study, experts were invited in the area of climate change, food safety (microbiology, pesticides, mycotoxins), agronomy, agriculture, food technology, quality assurance and food safety management. The experts were identified through the consortium of VEG-i-TRADE project and via literature search. Furthermore, the 'snow-ball sampling technique' was employed (114), as the experts were asked to suggest other experts (not participating in VEG-i-TRADE project) that have expertise relevant to the topic. The final panel of experts included representatives from universities (including university extensions), research institutes, fresh produce organisations and government. Fifty-six (56) experts were identified and contacted for the study. Thirty-one (31) of them answered positively, and received the questionnaire for the first round of the study. Twenty-five (25) filled in the first round of the Delphi study and thirteen (13) experts responded to the second round (Table 7.3).

Table 7.2: Criteria for assessing the response strategies

Criteria	Most unimportant (1)	Unimportant (2)	Moderately important (3)	Important (4)	Very important (5)
Importance	Should be dropped as an item to consider - no priority - no relevance - no measurable effect	Not determining the adaptation - low priority - insignificantly relevant - has little impact	May be determining the adaptation - third order priority - may be relevant to the issue - may have impact	Does not solve fully the problem - second order priority - is relevant to the issue - significant impact but not until other adaptations are covered	Must be implemented - first order priority - most relevant to the issue - has direct effect on the issue
	Definitely infeasible (1)	**Probably infeasible (2)**	**Uncertain (3)**	**Probably feasible (4)**	**Definitely feasible (5)**
Feasibility	Cannot be implemented - needs basic research (no relevant technology exists, basic scientific knowledge is lacking) - unprecedented allocation of resources would be needed - unacceptable by the general public or politically	Some indication that cannot be implemented - major research and development efforts are needed (existing technology is inadequate) - large scale increase in the existing resources would be needed - not acceptable by large portion by the general public	Contradictory if this can be implemented - indeterminable research and development effort is needed (existing technology may be inadequate) - increase in available resources would be needed - some indication that this may not be acceptable by the general public	Some indication this can be implemented - some research and development work needed (existing technology needs to be expanded or adopted) - available resources would have to be supplemented - some indication this might be acceptable by the general public	Can be implemented - no research or development work required (necessary technology is presently available) - definitely within available resources - will be acceptable to general public

Modified from (279)

Table 7.3: Characteristics of participating experts

Expert Code	Country	Type of organisation	Primary expertise										Secondary expertise								
			Climate change	Microbiology	Mycotoxins	Pesticides	Agronomy	Agriculture	Food technology	Quality assurance	Food Safety Management	Other	Climate change	Microbiology	Mycotoxins	Pesticides	Agronomy	Agriculture	Food technology	Quality assurance	Food Safety Management
E1	Netherlands	Research institute			x			x		x	x			x		x			x		
E2	Brazil	University					x	x							x	x				x	
E3	Netherlands	Research institute			x						x	x	x	x			x	x			
E4*	Netherlands	Governmental agency		x				x					x								x
E5*	Norway	Produce organisation					x	x											x	x	x
E6*	UK	University						x		x	x		x	x	x	x	x			x	
E7*	UK	University					x	x			x			x						x	
E8*	South Africa	University		x																x	
E9*	Belgium	Produce organisation				x				x	x										
E10*	Belgium	University				x															
E11	Netherlands	Research institute		x													x	x			
E12	Tanzania	NGO		x					x	x	x										
E13	Spain	Research institute		x				x											x		
E14	USA	University extension		x						x	x			x							
E15*	Kenya	Government					x	x											x	x	x
E16	South Africa	Research institute		x								x		x				x			
E17*	Egypt	Governmental lab		x						x					x	x					
E18*	Egypt	University		x						x	x								x		
E19	Belgium	University				x							x								
E20	Malaysia	University								x	x							x	x		
E21	India	University		x															x		x
E22*	Spain	Research institute					x							x							
E23*	Netherlands	University	x											x							
E24	Uganda	Government							x	x	x			x	x	x					
E25*	Korea	University				x					x										
			1	**10**	**2**	**4**	**5**	**8**	**2**	**9**	**11**	**2**	**4**	**9**	**4**	**5**	**3**	**4**	**7**	**6**	**4**

**Experts who responded to the II round of the Delphi study*

7.3. Results

7.3.1. Climate change projections

The projected climate changes from the IPPC country regional reports were extracted, considering only those that have a relationship to food safety of fresh produce (Table 7.4), thus, not taking into consideration climate events having effect on e.g. staple food yields, tourism, or coral reef extinction. Under food safety were considered increased prevalence of microbiological hazards (i.e. enteric bacterial and viral pathogens), pesticide residues, and mycotoxin formation (as a results of increased mould growth). The table shows that heavy rainfalls and floods are likely to increase in many regions. They are even more likely in locations that are close to big water basins (e.g. sea, rivers). Heavy rainfalls are expected (medium confidence) to increase even in regions with projected decrease of total rainfall. Floods and land-slides can be associated with the melting of big snow masses, thus more likely in northern regions with temperate climate in Asia, Europe and North America. In the south, like in Africa and Southern Europe, droughts, leading to water scarcity and worsening of (irrigation) water quality are very likely to happen. Number of tropical storms and other extreme events is likely to increase in North America, Asia and Australia.

Table 7.4: Projected regional climate changes relevant to food safety of fresh produce *(222, 223)*

Regions	Projected climate changes	Likelihood
Africa *(55)*	• More droughts leading to scarcity of water and worse quality of the water sources • Increased risk of heavy rainfall and floods • Increased risk of illnesses	• very high confidence • high confidence • high confidence
Asia *(89)*	• Increased risk of flooding by sea and rivers • Increased risk of land- and mud-slides • Increased risk of diarrheal diseases in east, south, and southeast Asia • Increase frequency of tropical storms and other extreme events	• high confidence • medium confidence • high confidence • high confidence
Australia and New Zealand *(198)*	• More droughts leading to scarcity of water and worse quality of the water sources • More severe storms and coastal flooding will likely impact coastal areas • Extreme storm events are likely to increase failure of floodplain protection and urban drainage and sewerage • More heat waves/change of seasonality	• high confidence • high confidence • high confidence • high confidence

Europe *(11)*	• Increased variety of pests, new pests • Heat wave and seasonal change-related health impacts to the population • Southern Europe: higher temperatures and drought may reduce water quality and availability • Northern Europe: more frequent winter floods, increased risk of land- and mud-slides	• medium confidence • very high confidence • medium confidence • very high confidence
Latin America *(298)*	• Worsening of droughts leading to scarcity of water and worse quality of the water sources • Sea level rise is projected to increase risk of flooding in coastal areas • Changes in precipitation patterns and the melting of glaciers are projected to significantly affect water quality and availability	• high confidence • high confidence • high confidence
North America *(145)*	• Increase frequency of storms and other extreme events • Increase winter flooding and run-offs • Less summer water flows leading to reduction of water quality and availability • Increased variety of pests, new pests • Heat wave-related health impacts to the population • Stress on coastal communities and habitats, worsening the existing stresses of development and pollution	• very high confidence • very high confidence • very high confidence • very high confidence • high confidence • very high confidence

7.3.2. Pressures to safety of fresh produce due to climate change

Based on the expected changes in the climate, a literature review of the events that have shown to affect microbiological and chemical (pesticide residues, mycotoxins, contaminants such as heavy metals) safety of fresh produce (i.e. pressures) was conducted. As a result, twelve (12) climate-induced events were defined that may put pressure on food safety of fresh produce via the environment, for instance, surface, ground or sewage water, soil, workers, and pests (Table 7.5). All of these can become a source of contamination due to changes in climate such as heavy rainfalls, floods, droughts, changes in seasonality (e.g. heat waves), increase of number and variety of pests and plant diseases.

Table 7.5 presents the results for the likelihood of each climate-induced event to occur in the country of origin, assessed by the experts in the first round of the Delphi study. The modes were calculated for the experts from countries in the global north with industrialised food systems and from countries in the global south with structured and traditional food systems. The experts from the global south assessed all pressures as likely to happen, with the pressures linked to misuse of pesticides and manure - as very likely. However, the pressure about the use of larger amounts of potentially contaminated animal manure showed large variation in the answers. The scores of the experts from the north were lower, and none of the pressures was assessed as very likely. The pressures linked to microbial contamination of water, fields and fresh produce, as well as the pressures about the use of ineffective pesticides, and increased mycotoxin production scored the highest (somewhat likely, 4). Contamination of surface water and growing sites with toxic substances such as heavy metals due to land and mud-slides scored the lowest (not likely, 1). However, these two showed large variation.

Table 7.5: Pressures that may affect microbiological and chemical safety of fresh produce derived from literature and supported by experts (represented as mode and quartile coefficient of dispersion, calculated from the experts' answers about likelihood of an event to occur)

Type	Via	Pressure *climate induced event affecting food safety*	Literature	Experts	
				North (n=15)	South (n=10)
Contamination of water sources	**Surface water**	*Pressure 1:* Microbiological contamination of surface irrigation water sources due to heavy rainfalls or floods	Curriero, Patz, Rose, & Lele, 2001; Johnson et al., 2003; Charron et al., 2004; Presley et al., 2005 ; Shehane, Harwood, Whitlock, & Rose, 2005	4[a] (0.1)	4 (0.1)
		Pressure 2: Contamination of surface water sources with toxic substances due to land- and mudslides	Cunningham, 2005; Marvin et al., 2013	1 (0.6)	4 (0.1)
	Ground-water	*Pressure 3:* Microbiological contamination of groundwater sources used for irrigation or production of fresh produce, due to surface run off of heavy rainfalls or floods	Howell, Coyne, & Cornelius, 1995; Curriero et al., 2001; Jamieson, Gordon, Sharples, Stratton, & Madani, 2002; Auld, MacIver, & Klaassen, 2004	4 (0.0)	4 (0.2)
	Sewage water	*Pressure 4:* Use of untreated sewage water for irrigation due to droughts and shortage of water	Liu, Hofstra, & Franz, 2013	4 (0.1)	4 (0.2)
Microbial contamination of production environment	**Flood waters**	*Pressure 5:* Microbiological contamination of growing fields due to heavy rainfalls or floods	Rosenzweig, Iglesias, Yang, Epstein, & Chivian, 2001; Hora, Warriner, Shelp, & Griffiths, 2005; Casteel, Sobsey, &Mueller, 2006; Ge, Lee, &Lee, 2012	4 (0.6)	4 (0.2)

	Manure	*Pressure 6:* Use of larger amounts of potentially contaminated animal manure due to faster depletion of nutrients in soil at high temperatures	Johnson et al., 2003; Liu, Hofstra, & Franz, 2013	1 (0.5)	5 (0.5)
	Workers	*Pressure 7:* Increase of illnesses of workers due to higher temperatures or changed seasonality (e.g. heat waves)	Bentham, 2002; Hall, D'Souza, & Kirk, 2002; D'Souza, Becker, Hall, & Moodie, 2004; Kovats et al., 2004; Kovats, Edwards, Charron, & al, 2005; Fleury, Charron, Holt, Allen, & Maaroug, 2006; Naumova et al., 2007; Jagai, Castronovo, Monchak, & Naumova, 2009; Lake et al., 2009;	2 (0.2)	4 (0.2)
	Soil	*Pressure 8:* Increased survival of microorganisms on produce due to increased humidity, temperature, change of seasonality	Sinton, Braithwaite, Hall, & Mackenzie, 2007; Sidhu, Hanna, & Toze, 2008	4 (0.3)	4 (0.2)
Chemical contamination of production environment	**Soil**	*Pressure 9:* Contamination of growing fields with toxic substances due to land- and mudslides	Abel et al., 2010; Marvin et al., 2013	2 (0.5)	4 (0.2)
	Pests	*Pressure 10:* Use of unapproved pesticides due to increased number and variety of pests and plant diseases	Chen &McCarl, 2001; Rosenzweig et al., 2001; Bloomfield, Williams, Gooddy, Cape, & Guha, 2006; FAO, 2008	4 (0.1)	5 (0.1)
	Pests	*Pressure 11:* Use of larger amount of pesticides due to reduced effectiveness after wash-off of heavy rainfalls or floods		3 (0.1)	5 (0.4)
	Fungi	*Pressure 12:* Increased mycotoxin production due to droughts or increase of temperature or humidity	Kakde, Kakde, & Saoji, 2001; Blesa, Soriano, Moltó, Mañez, 2006; Cotty & Jaime-Garcia, 2007; Miraglia, De Santis, &Brera, 2008; Boxall et al, 2009; Peterson & Lima, 2010; Iqbal, Bhatti, Asi, Bhatti, & Sheikh, 2011; Magan, Medina, & Aldred, 2011; Peterson & Lima, 2011	4 (0.3)	4 (0.2)

[a] *Likelihood of event to happen: not likely - 1; somewhat unlikely - 2; neutral - 3; somewhat likely - 4; very likely – 5*

7.3.3. Response strategies

Table 7.6 shows the response strategies that were generated from the answers of the experts for each of the pressures to food safety of fresh produce. Experts responded only to the pressures that they considered themselves competent to answer. The response strategies were classified on company (individual farm) and community level (private and public support organisations), and as coping and adaptation strategies. The response strategies for each pressure have been sorted in 3 groups according to their importance and feasibility (Table 7.6A, 7.6B and 7.6C). In the first group (dark grey) were considered those that are very important (5) or important (4), and probably (4) or definitely feasible (5). In the second group (light grey) were classified those that are very important (5) or important (4), but feasibility is uncertain (3). In the third group (white) were considered the response strategies that are moderately important (3), and feasibility is uncertain (3). The quartile coefficient of dispersion (QCD) represents the level of agreement between the experts, with lower numbers meaning higher agreement. All QCD results were equal or below 0.3, that is why no third round of the Delphi study was performed.

Response strategies to contaminated water sources (surface, ground or sewage water) - pressures 1, 2, 3, 4

Table 7.6A shows the response strategies to contamination of water sources. Water sources can become contaminated with microorganisms after heavy rainfalls or floods. Moreover, floodwaters or land- and mudslides can bring chemical contaminants. The most important response strategies (importance = 5) were evolving around water control, including selection of water source, water treatment, microbiological sampling and criteria. The experts proposed sampling to determine the contamination levels to cope after event occurs, and monitoring water sources on a regular basis for long-term adaptation. Of high importance (5) was assessed also training and guiding farmers about water control (i.e. selection of water source, water treatment, water quality, sampling plan and criteria on water quality), and the comments were that specifics of country and region should be considered. In the case of land- and mud-slides and contamination of underground water, they advised (importance = 5) mapping of risk areas and water sources. Treating of water and disinfection of produce after harvest were indicated as important (4) and feasible (4) when surface water is used. Treatment was highlighted for sewage water (very important, 5), but considered more difficult to implement in case of chemical contamination (feasibility = 3). Response strategies that involved changes in the physical environment, protection of the water source and involvement of new systems and ways of working were also assessed as important (4), but with uncertain feasibility (3). This was the case even for underground water sources.

Response strategies to increased microbiological contamination of production environment - pressures 5, 6, 7 and 8

In Table 7.6B are presented the response strategies to microbiological contamination of production environment. Contamination of growing fields due to floods can occur and lead to uptake of the contamination into the plant even when it is not directly exposed to the waters. Again, recommendations to the farmers and building awareness about microbiological risks were judged as most important (5). Sampling was advised to assess the level of contamination after an event. (Re)validation of the waiting period before harvest and re-planting was seen as most important (5). Stress was put on (importance=4) weather warning and predictive systems. To avoid risky behaviour of farmers regarding application of manure the experts suggested (4, important) either temporary addition of chemical nutrients or a long-term implementation of agronomic methods such as crop rotation.

Increased survival of microorganisms in the environment due to heat waves and other climate changes, is expected to affect the illnesses of people and contamination of produce. The most important (5) and feasible (5-4) responses regarding illnesses of workers were strengthening current control activities in the farms regarding personal hygiene and health, and improving the cold chain. Strategies on community level for health screening of food handlers and agricultural workers, preventive vaccination and early warning for epidemics were also judged as very important (5), but with uncertain feasibility per country and region (3). Moreover, very important (5) and feasible (4) scores were given to fostering research by governments and international organisations to investigate survival and adaptation of microorganisms in different environmental conditions.

Table 7.6A: Derived response strategies proposed by the experts to contaminated water sources (surface, ground or sewage water) from round I of the Delphi study (expressed by n experts out of N=25), and results for importance and feasibility from round II (N=13) (mode (M) and quartile coefficient of dispersion (QCD))

Type	Level	Response strategy	Summary of responses from round I	Round II			
				Importance		Feasibility	
				M	QCD[a]	M	QCD
Pressure 1: Surface irrigation water sources contamination with microorganisms after heavy rainfalls or floods (n=21[b])							
A[c]	F[d]	– *Monitor quality of water source*[e] (n=8[g])	Regular sampling/monitoring of the farm water source for indicator organisms (coliforms, enterobacteriaceae) and pathogens (E.coli O157:H7)	5[f]	0.1	5	0.1
A	S	– Training and guidance on water control (n=7)	Educating the farmers about water control (i.e. selection of water source, water treatment, water quality, sampling plan and criteria), contamination risks due to livestock systems or manure-treated fields for the nearby water sources, especially after heavy rainfalls or floods; Include recommendations in (national) guidelines	5	0.1	5	0.3
C	F/S	– Sample water source after a flood or heavy rainfall (n=8)	Investigative sampling to locate the source of contamination (e.g. sewage works, animal husbandry), determine range of contamination, i.e. which water sources and contamination levels	5	0.3	5	0.3
A	F/S	– *Treat irrigation water* (n=18)	Building community shared treatment plants/filtering stations or increasing their capacity/number; Installing in-line UV-treatment or constructing dams for sedimentation of water at farm	4	0.0	4	0.1
C	F	– *Treat produce after harvest* (n=4)	Washing with potable water; Using for cooked or canned products	4	0.1	4	0.1
A	F	– Alternative irrigation water source (n=10)	Diverting to the use of rain water, constructing rain water harvesting systems; Setting up alternative water source for the farmers, e.g. valley dams, sinking boreholes	5	0.3	3	0.0
A	F	– *Pre-harvest interval* (n=2)	Avoid irrigating leafy and salad crops during periods close to harvest	5	0.3	3	0.1
A	F	– *Localized irrigation methods (drip)* (n=5)	Selection of the irrigation method depending on the type of crop to avoid contact with edible parts of the plant, e.g. driptape	5	0.3	3	0.2
A	S	– Contamination warning system (n=4)	Alerting the farmers about contamination in the water source; Extending current systems for potable water to include alerts to the users of irrigation water	4	0.1	3	0.1
A	F/S	– Protective or segregation structures to prevent	Protect water sources by e.g. using plastic covering; Establishing buffer vegetation strip to reduce run-offs into the water sources	4	0.1	3	0.3

		contamination of water sources (n=8)					
A	S	– Monitor water sources in county/region (n=10)	Identifying the most risky areas and regularly sample/monitor these in the region or country (risk-based); Extending monitoring of potable water to irrigation water sources	3	0.1	4	0.1
		Pressure 2: Surface water sources contamination with toxic substances due to land- and mudslides (n=19)					
A	S	– Analyse water sources at risk and warn farmers (n=11)	Analyse and identify water sources at risk and alert farmers	5	0.1	4	0.1
A	S	– *Monitor quality* of *water source* (n=6)	Monitoring/regular sampling of farm water source for toxic substances	5	0.1	4	0.3
C	F/S	– Sampling of water source after event (n=2)	Investigative sampling of water sources for toxic substances after land or mud-slide	4	0.1	4	0.1
C	F	– *Treat irrigation water* (n=9)	Provide on-site treatment or filtering	4	0.0	3	0.1
A	F/S	– Alternative irrigation water source (n=5)	Diverting the farm to other sources of irrigation water (e.g. rain water)	4	0.1	3	0.0
A	S	– Protective or segregation structures to prevent contamination (n=11)	Investing in reinforcement structures and soil stabilisation techniques to prevent land-slides	4	0.1	3	0.2
A	S	– Monitor water sources in county/region (n=6)	Regular sampling/monitoring of the quality of water sources used for irrigation in the country and publishing the results to communicate to the farmers	3	0.1	3	0.1
		Pressure 3: Contamination of groundwater sources with microorganisms due to surface run off of heavy rainfalls or floods (n=20)					
A	S	– Analyse water sources at risk and warn farmers (n=9)	Risk mapping of the water sources on a local level and create awareness among users of water sources that are prone to contamination	5	0.1	4	0.1
A	F	– *Monitor quality of water source* (n=5)	Implementing continuous sampling plans	5	0.1	4	0.1
C	F/S	– Sample water source after a flood or heavy rainfall (n=4)	Investigative sampling after floods or heavy rainfalls	5	0.3	4	0.1
A	F/S	– Alternative irrigation water source (n=6)	Develop alternative ways of harvesting water and storing it safely, e.g. deeper wells, rain water.	5	0.1	3	0.2
A	F	– *Localized irrigation methods* (n=5)	Converting to drip irrigation and using strategies that avoid contact with the edible portion of the crop for at least two weeks prior to harvest	4	0.1	3	0.0
C	F	– *Treat irrigation water* (n=14)	On-site treatment of water at farm, e.g. fermentation, trickling filters, UV	4	0.1	3	0.1

A	F	– Protective or segregation structures to prevent contamination of water sources (n=8)	Building diversion infrastructure, e.g. backflow devices; Protect well heads before heavy rainfalls	4	0.3	3	0.2
A	S	– Monitor water sources in country/region (n=11)	Regular sampling of groundwater quality and warn farmers in case of problems	3	0.3	3	0.1
Pressure 4: Use of sewage water for irrigation due to droughts and shortage of water (n=20)							
A	S	– Information and education of farmers (n=7)	Farmer guidance and training about the risks of using sewage water for irrigation in different crops and incorporating in national guidelines or legislation	5	0.0	5	0.1
C	F/S	– *Treat sewage water before use for irrigation* (n=13)	Implementing sewage water treatments (waste-stabilization ponds, aerobic systems/activated sludge, anaerobic digesters); Consider cost/benefit of treating sewage	5	0.0	4	0.1
A	F/S	– *Monitor quality of sewage water* (n=11)	Monitoring/sampling to determine contamination levels on a regional level; Provide testing results to the public/farmers who are using the sewage water so they understand the risks; End product sampling when sewage water is used	5	0.1	4	0.2
A	F/S	– Alternative water sources (n=9)	Building rain harvesting systems, ponds, water transport systems	5	0.1	3	0.1
C	F	– Divert to low risk crop (n=6)	Consider the type of crop and the risk of sewage water use; Use sewage water for irrigation of orchards (e.g. lemon, orange), or crops that will be cooked/processed in a way to reduce risks before consumption	4	0.0	3	0.0
A	F	– *Localized irrigation (drip)* (n=4)	If the sewage water is used by a fresh produce, then the farm should be using drip irrigation water system to reduce contamination on aerial parts of the plant and to save water	4	0.1	3	0.0

[a] *QCD (quartile coefficient of dispersion) is calculated according the formula QCD=(Q3-Q1)/(Q3+Q1) (56)*
[b] *Number of experts that assessed the likelihood of this pressures in the first round of the Delphi study*
[c] *A- adaptation; C - coping*
[d] *F - farm level; S - support organisations on community level (e.g. produce organisations, cooperatives, government)*
[e] *In italic – (part of) core control activities at farm as described by (256)*
[f] *Number of experts citing this response option in the first round of the Delphi study*
[g] *Criteria for the scores of importance and feasibility is described in Table 7.2*

Table 7.6B: Derived response strategies proposed by the experts to increased contamination of the cultivation environment (growing fields, produce or workers) from round I of the Delphi study (expressed by n experts out of N=25), and results for importance and feasibility from round II (N=13) (mode (M)

Type	Level	Response strategy	Summary of responses from round I	Round II			
				Importance		Feasibility	
				M	QCD[a]	M	QCD
Pressure 5: Microbiological contamination of cultivation sites due to heavy rainfalls or floods (n=19[b])							
A[c]	S[d]	Recommendations to farmers about risks of contamination from floods or run-off waters (n=4[e])	Recommendations how to prepare and react in cases of floods or heavy rainfall; Develop trusted communication channels so growers know where to go when they have questions about safety; Implement trainings and short courses to build and increase awareness and knowledge	5[f]	0.1	4	0.1
C	F	*Pre-harvest*[g] *and* re-planting intervals (n=12)	Waiting with planting/harvest, so the site to be 'cleaned' by UV	5	0.1	4	0.1
C	F/S	Sample fields and produce after a flood or heavy rainfall (n=8)	Sample to check contamination levels in flood waters, and in case of positive results - monitoring of produce on the presence of pathogenic microorganisms; Soil testing and research to define risks from soils that have been flooded	4	0.1	5	0.1
A	S	Local/regional warning systems for floods and heavy rainfalls (n=5)	Follow the weather forecasts; Early warning for flood and heavy rain risk, communicated to the farmers	4	0.0	4	0.1
C	F	Structures to prevent/avoid contamination (n=8)	Building protective structures around the field, e.g. use sand sacks to protect the farm; Foresee dikes, dams or other systems to drain water from fields in lower areas or areas susceptible to flooding; Moving to plasticulture	4	0.1	4	0.1
C	F	Destruct/dispose flooded crops (n=6)	Disposal of produce, especially in the case of leafy vegetables	4	0.1	4	0.1
C	F	Decontaminate produce (n=7)	Introducing decontamination, or extra washing step; In countries where lack of food is an issue, some crops could be designated as "must be cooked prior to consumption" to reduce the risk.	4	0.0	3	0.1
A	F/S	Divert to other applications or land use (n=6)	Avoid growing horticultural crops in fields prone to flooding, e.g. consider growing grain crops, cotton, or crops used for biofuel	3	0.2	3	0.2
Pressure 6: Use of larger amounts of potentially contaminated animal manure due to faster depletion of nutrients in soil at high temperatures (n=20)							
C	F	Validate the pre-harvest interval (n=7)	Manure to be applied at least 3-6 months before planting to ensure all pathogenic microorganisms are extinct; Waiting period between application of manure and harvesting of produce and validation of this period through microbial sampling	5	0.1	4	0.0

A	S	Training and guidance on manure management (n=14)	Recommendations and training of farmers how to treat/compost and how to apply manure considering also climate conditions; Manure spreading plan for whole farm linked to risk assessments; Update guidance to take into account likely changes in climate	5	0.1	4	0.1
C	F	Provide additional nutrients through chemical fertilizers (n=5)	Adding chemical fertilizers in case of depletion of nutrients	4	0.1	4	0.1
A	F	– Implement agronomical techniques (n=1)	Mulching and crop rotation techniques to prevent loss of nutrients in soil	4	0.1	4	0.1
A	F	– Implement precision farming (n=1)	Precision farming, to know exactly where what amount of nutrients is required, and preventing the use of more manure	4	0.1	3	0.1
Pressure 7: Increase of illnesses of workers due to higher temperatures or changed seasonality (n=20)							
A	F	– *Strict health checks* (n=11)	Monitoring the health of workers and ban from work if sick (especially seasonal workers); Mandatory health checks before workers are employed; Ensure regular health checks (including worker self- assessment) are part of the labour management plan	5	0.1	5	0.3
A	F	– Validate personal hygiene requirements (n=12)	Provide, adapt and validate hygiene equipment and accommodation for (seasonal) workers to respect good hygiene (i.e. washing hands prior to handling fresh produce) in changed circumstances	5	0.1	5	0.2
A	F/S	– Train farm owners and agricultural workers on personal hygiene requirements (n=18)	Educating famers and workers (especially seasonal workers), and creating awareness (e.g. awareness campaigns, label systems) about illnesses, symptoms and consequences, and how to react	5	0.1	4	0.3
A	S	– Strict national/regional health screening of food handlers (n=3)	National/regional health screening of workers before they start working in the food industry and agriculture; Periodic spot checks linked to local government screening	5	0.3	3	0.1
A	S	– Preventive vaccination/immunization (n=2)	On site immunization/vaccination to prevent illnesses	5	0.3	3	0.1
A	S	– Early warning systems (n=6)	Hospitals monitoring for epidemics and issuing warnings for epidemics on a national/regional level	5	0.3	3	0.2
Pressure 8: Increased survival of microorganisms on produce due to increased humidity, temperature, change of seasonality (n=20)							
A	S	– Outreach and education about strengthening control activities in changed climate conditions (n=10)	Providing outreach and education to both consumers and farmers are aware of risks and how to avoid them; Providing recommendations on how to strengthen control activities and cold storage, and how to link it to warmer seasons; Creating awareness about survival of microorganisms in different environments and conditions	5	0.1	5	0.1
A	S	– Fostering research on survival of	Fostering fundamental research and awareness, also among	5	0.1	4	0.3

		microorganisms (n=6)	specialists that human pathogens may persist in the natural and agronomic ecosystems; Pathogens may easily adapt by exchanging gene material with other genomes and build eco-competences; Identifying eventual abnormal increases in pathogenicity				
A	F	– *Improve storage control and cool chain from field to store and beyond* (n=11)	Building cold storages with adequate capacity, it is important to have also capacity for rapid cooling; Temperature control from harvest to shop in cooperation with the whole supply chain; Stress on the cold storage and transport, especially in the warmer months; Distribute at night if it is too warm and cold transport is not available	4	0.1	4	0.1
C	F	– *Implementing intervention for removal of (superficial) contamination of crops* (n=11)	Implementing intervention for removal of superficial contamination; Using of decontamination techniques, extra wash steps, cooking	4	0.0	3	0.1

a QCD (quartile coefficient of dispersion) is calculated according the formula QCD=(Q3-Q1)/(Q3+Q1) (56)
b Number of experts that assessed the likelihood of this pressures in the first round of the Delphi study
c A- adaptation; C - coping
d F - farm level; S - support organisations on community level (e.g. produce organisations, cooperatives, government)
e Number of experts citing this response option in the first round of the Delphi study
f Criteria for the scores of importance and feasibility is described in Table 7.2
g In italic – (part of) core control activities at farm as described by (161)

Table 7.6C: Derived response strategies proposed by the experts to increased contamination with pesticides and mycotoxins (pressures 9, 10, 11, 12) from round I of the Delphi study (expressed by n experts out of N=25), and results for importance and feasibility from round II (N=13) (mode (M) and quartile coefficient of dispersion (QCD))

Type	Level	Response strategy	Summary of responses from round I	Round II			
				Importance		Feasibility	
				M	QCD[a]	M	QCD
Pressure 9: Contamination of cultivation sites with toxic substances due to land- and mudslides (n=18[b])							
C[c]	F/C[d]	– Sample after event (n=6[e])	Investigative sampling to determine type of contamination and its levels; Provide resources to support farmers testing land/soil that may be contaminated; Provide list of substances likely to be present and lists of labs that can test for contaminants of concern	5[f]	0.1	4	0.1
A	S	– Predictive modelling of land and mudslides (n=2)	Predicting risks of land- and mud-slides by modelling, by using data on land properties, slopes, etc.	4	0.1	4	0.3
A	S	– Map risk areas and forbid growing produce in risk areas (n=9)	Mapping the risks and prevent crop production in high risk areas; Local administration has to implement relocation to less risky areas; Change land use to non-food crops or other applications	5	0.1	3	0.1
C	F	– Construct protective structures to avoid spread of contamination (n=11)	Understand risks surrounding farm land and make attempts to protect land prior to an event; Invest in infrastructure to prevent toxic substance release, and landslides, especially in agricultural, food production areas.	4	0.0	3	0.1
C	F	– Destruct contaminated crops (n=6)	If produce is contaminated with toxic pollutants to unacceptable levels produce has to be disposed; Supply logistics for farmers to enable safe disposal of such contaminated produce	4	0.0	3	0.1
C	F	– Divert farm production to other applications (n=4)	Do not deliver as a food, divert to other applications, e.g. biofuel	3	0.3	3	0.2
Pressure 10: Use of larger amount or unapproved pesticides due to increased number and variety of pests and plant diseases (n=19)							
A	F	– Revise and validate pest(icide) management program (n=15)	Revising and validating the spraying methods and procedures, and the waiting period before harvest for the concrete farm situation	5	0.1	5	0.1
A	S	– Training and guidance on pest(icide) management (n=16)	Educating/training farmers about best practices for pesticides management, including pesticide options and spray schedules; Updating training of operators to include climate change risks (i.e. new pests and applicable pesticides); Required courses for all users of pesticides, giving them licence, which they will lose if not following the rules; Educating farmers about other control methods (e.g. biological treatments, integrated pest management)	5	0.1	5	0.3

A	S	– Monitoring of pests and introducing a local/regional pest warning system (n=5)	Performing scouting and trapping to identify pests of concern that are present in the area; Integrating the monitoring of pests in official monitoring schemes; Introducing pest warning system to alert the farmers for new or most problematic threats; Local weather warning systems about the weather conditions indicating also the right time for application of pesticides	4	0.1	4	0.1
A	S	– Fostering research on new pests and control methods (n=5)	Fostering research or search for appearance of new pests and development of new and innovative control methods	5	0.1	3	0.1
A	F	– Implement agronomic methods or integrated pest management (n=8)	Applying agronomic methods for prevention (e.g. rotation schemes); Implementing integrated pest management including increased monitoring of (new) pests and apply pesticides targeted at the problem pests.	5	0.1	3	0.1
A	F	– Adopt cultivation of resistant or less susceptible species or cultivars (n=3)	Switching to more pest resistant produce, if available	4	0.1	3	0.0
A	S	– Risk assessment (n=2)	Performing seasonal risk assessments, linked to likely challenges (including climate) and types of pesticides	4	0.1	3	0.0
		Pressure 11: Reduced effectiveness of pesticides due to wash-off after heavy rainfalls or floods (n=17)					
A	F	– Weather forecast/monitoring systems (n=10)	Farmers to consider weather forecasts when selecting time of application and avoid use of pesticides when heavy rainfall is expected within 4 hours, preferably the weather should be fine for the next 24 hours, after one day no big impact of heavy rainfall	5	0.1	5	0.3
A	F	– Validate pest(icide) management program (n=8)	Validating the effectiveness of type of pesticide, concentration, dose, time and method of application. After validation assess the need to add adjuvants for better absorption or use systemic pesticides to reduce wash-off	5	0.1	5	0.3
A	F	– Implement agronomic methods or integrated pest management (n=5)	Use non foliar pesticides, use treatment alternatives (bio, chemical), switch to alternative produce not requiring treatment; Adapting of crop rotation with a non-food crop	5	0.1	4	0.1
A	S	– Training and guidance on pesticide application (n=9)	Inform, communicate and educate on pesticide use in rainy conditions and what to do in cases of wash-off	5	0.1	3	0.3
A	F	– Infrastructure to protect critical production (n=3)	Protect critical production areas with high tunnels or other infrastructure to protect fields from flooding	4	0.1	3	0.2
A	S	– Local systems for weather monitoring, forecasting and warning (n=6)	Linking the local weather forecasts to warning systems for pests; Integrating agricultural information for the farmers in the weather system and issuing warning	4	0.3	3	0.1

A	S	– Risk assessment (n=1)	Local risk assessment to identify risks of pesticides application	3	0.1	3	0.1
		Pressure 12: Increased mycotoxin production due to droughts or increase of temperature or humidity (n=19)					
A	S	– Building awareness about risk of mycotoxins (n=12)	Creating awareness and providing information to farmers and companies about most common fungi and mycotoxin producing fungi, and methods to prevent it, e.g. storage conditions, visual checks, sorting	5	0.1	5	0.3
A	F/S	– Validate storage capacity (n=15)	Validating existing or establishing new storage facilities to assure conditions (temperature, humidity) that avoid fungal growth and mycotoxin production; Set up adequate cooperative storage facilities for small farmers	5	0.1	3	0.1
A	S	– Predictive methods for mycotoxins in fruits (n=2)	Developing and using predictive models for fungi and mycotoxins	4	0.0	3	0.0
A	F	– Implement agronomical techniques (n=4)	Implementing deep tillage of soil to prevent fungal diseases;	4	0.0	3	0.0
A	S	– Warning systems for fungi and mycotoxins in fruits (n=7)	Implementing weather forecasting and warning system for fungal and mycotoxin risks	4	0.1	3	0.1
A	F	– *Monitoring fungi in field* (n=8)	Introducing regular visual checks on the field and in storage to be able to eliminate mouldy products	4	0.1	3	0.3

a QCD (quartile coefficient of dispersion) is calculated according the formula QCD=(Q3-Q1)/(Q3+Q1) (37)
b Number of experts that assessed the likelihood of this pressures in the first round of the Delphi study
c A- adaptation; C - coping
d F - farm level; S - support organisations on community level (e.g. produce organisations, cooperatives, government)
e Number of experts citing this response option in the first round of the Delphi study
f Criteria for the scores of importance and feasibility is described in Table 7.2

Response strategies to increased chemical contamination of production environment - pressures 9, 10, 11, 12

In Table 7.6C are presented the response strategies to chemical contamination of production environment. Climate change is expected to lead to reduced effectiveness and thus use of larger amounts, different or even unapproved pesticides, due to increased number and species of pests or wash-off after extreme events. The experts assessed as most important (5) response strategies and definitely feasible to implement (5) the (re)validation of the pest management program and consulting the weather forecasts to avoid e.g. spraying before rain. Furthermore, they stressed the importance of communities in providing guidelines for pesticide management (5), monitoring for (new) pests and alerting the farmers (4). The experts assessed also as most important (5) the implementation of agronomic methods and integrated pest management.

Climate change is expected to lead to increased mycotoxin production. The experts assessed as the most important (5) and definitely feasible (5) response strategy creating awareness about the risk factors leading to the formation of mycotoxins in fruits. They stressed the importance (5) of validating storage capacity, but acknowledged the uncertainty regarding feasibility (3) in different companies/farms. Important (4) to implement by the farmers but may or may not be feasible (3) were the good agricultural practices. On community level developing predictive methods and warning systems were seen as important (4), still their feasibility was assessed as uncertain (3).

7.4. Discussion

The objective of this study was to generate insights in a systematic way about climate-induced events affecting safety of fresh produce at farm and response strategies that can be applied. Response strategies were identified on company and community level, addressing both coping to the pressures after they occur, and adaptations to build long-term adaptive capacity.

7.4.1. Regional character of the pressures to food safety of fresh produce

Most pressures were assessed higher by the experts from the global south than by the experts from the global north. The latter explained that several response strategies are already in place in their countries. These results link also to the lower societal capability of many countries with structured and traditional food systems (in e.g. Africa, Asia, Latin America) to adapt to climate-induced pressures on infrastructure, agriculture and healthcare *(55, 89, 298, 325)*. Still, many pressures have been assessed as somewhat likely also in the countries from the global north, with industrialised food systems. For instance, three of the pressures associated with microbiological contamination of surface and groundwater sources, as well as growing sites after heavy rainfalls and floods (pressures 1, 2 and 5), scored equally important for the countries in the global south and the global north. Such contamination events were already reported, for instance, after floods in the USA *(93, 189)* and Europe *(426, 457)*. Two of the pressures associated with heavy metal contamination due to land- and mud-slides of surface water sources and growing sites were assessed as unlikely for the northern countries, but the variability of opinions varied considerably (0.5 and 0.6). This can be explained by landscape differences, because participants originated from a lowland country such as the Netherlands, but also experts from countries with more variable landscape such as Spain and USA, where land and mud-slides are more common *(24, 452)*. The pressure about the use of larger amounts of potentially contaminated animal manure also received a low likelihood score (not likely, 1) for countries in the global north, which was in contrast to the high likelihood for the countries in the global south (very likely, 5). For years already, many countries (e.g. Belgium, the Netherlands, USA) have strict legislation about manure application, including pre-harvest intervals, time of year, amounts, etc. *(316, 335)*. Another pressure that was assessed as unlikely (somewhat unlikely, 2) in the global north was the increase of illnesses of agricultural workers due to higher temperatures or changed seasonality (e.g. heat waves). Pre-employment health screening of agricultural and food workers and their health monitoring in companies is more established in Europe and in the USA, while it is not so common in developing countries *(422)*. Reduced effectiveness of pesticides due to wash-off after heavy rainfalls or floods was assessed as neutral (3) for the global north, compared to the high likelihood score for the global south (very likely, 5). The reduced effectiveness is mainly associated with time between application of pesticides and extreme event. Weather forecast systems, which provide agricultural decision-making information (e.g. water management, fertilizers and pesticide application), can be used and are available in many countries via different internet and mobile applications *(94)*. However, this information is not always effectively established and used by the farmers in the north *(70)*. Such systems are often lacking, in embryonic stage or fail to address the needs of the farmers in developing countries *(94, 486)*.

7.4.2. Towards adaptation

First response to the pressures to food safety due to climate change will be given by the control activities implemented in companies and the response depends on their current implementation and operation. The experts highlighted the need to strengthen the core control activities, such as water control (including water treatment and quality monitoring), irrigation methods, pesticide management (and pre-harvest intervals), personal hygiene requirements and (cold) storage control. Furthermore, support is needed from community level to validate control activities for the changed circumstances, as well as to train and guide farmers. New response strategies, beyond current core control activities, should also be implemented for farms to cope and adapt. Among suggested by the experts were sampling of water after (flooding) event, waiting periods after flooding event, building protective and segregation structures to avoid spread of contamination, alternative water sources, decontamination and even destruction of crops. Long term adaptation should be supported by strategies at community level, such as weather forecasting, monitoring and warning systems, predictive modelling, mapping of risk areas, and research.

7.4.3. Most important strategies

Among the most important response strategies suggested by the experts for flooded growing fields were sampling of flooded areas, respecting pre-harvest and re-planting intervals, and protective structures (Table 7.6B). In the USA, the Food and Drug Administration (FDA) already issued a guidance to the industry to evaluate the safety of crops affected by flooding, including recommendations about sampling, re-planting period, and buffer zone between flooded and non-flooded areas (FDA, 2011). The experts stressed the need of guidance which takes into consideration the local specifics and risk areas. Interestingly the experts in our study assessed the waiting period as very important for microbial contamination, but with uncertain feasibility. This may be explained by the need of recommendations to the industry and public sector in many countries about effective, scientifically underpinned waiting intervals. A guidance for the industry was stressed as most important also for the use of sewage water. Indeed, an international guideline was issued by the World Health Organisation about the use of wastewater, excreta and grey water *(479)*. Furthermore, the experts commented that provision of easily accessible and understandable information and training to the farmers in the different regions is needed. Several of them stressed that crucial for eliminating microbiological contamination is treatment of water, especially surface and sewage water, or produce itself. Treatment of sewage sludge and pre-harvest intervals are included already in a recommendation for the farmers in the United Kingdom (5).

The most important strategies for chemical contamination of water sources were in terms of adaptation at community level – mapping the risk areas and their regular monitoring, modelling to predict contamination after extreme events. Possible approaches for modelling and establishing early warning systems have been discussed extensively in a recent paper of Marvin et al. *(304)*. The experts assessed also the need of building awareness as very important, providing information and education to producers about recent scientific developments.

The most important strategies to address increased illnesses among workers identified in our study were the establishment and strengthening of the health checks and providing necessary sanitation equipment and facilities (both part of control activities) and educating the farm workers. These are already included in various standards and guidelines for the farms/companies. However, problems are still reported, indicating the need for improving their implementation. Moreover, changes in climate conditions may require validation for the new circumstances. Additional adaptations at community level were proposed, including health screening, vaccinations and early warning system. These received score 3 (uncertain) for their feasibility, which might be linked to regional or national differences *(*e.g. *422)*.

The most important response strategy to the pressures related to pesticides was the validation of the pesticide management at farm (Table 7.6C). Although current guidelines and standards include pest and pesticide management *(*e.g. *67)*, they do not recommend how farms need to adjust their programs (e.g. by adding adhesives) and validate their effectiveness, especially in the case of extreme weather conditions. As very important were considered also the use of agronomic methods and integrated pest management. Efforts to promote these were already established within the European Union *(118)*. Important adaptations at community level were also proposed, including the introduction of pest warning systems, monitoring and identification of new and existing pests of concern.

Concerning mycotoxins, the experts emphasized the need to build awareness among farmers and companies about risks of mycotoxins and ways to prevent their formation. Mycotoxins in cereals, apples and grapes are a well-known problem, which has been regulated and recommendations have been published for the industry in the EU *(110)*. However, recently concerns have emerged also for the safety of other fruits and their derived products *(465)*.

7.4.4. Coping, adaptation and building adaptive capacity

It became clear that the likelihood of a pressure was considered as a function of the likelihood of a climate event to occur in the region (Table 7.5), and the adaptive capacity of a company, sector and country. The adaptive capacity has been defined previously as the extent to which a system is capable to modify its circumstances (respond and recover) to move to a less vulnerable condition *(92)*. To increase the adaptive capacity, adaptations, rather than coping strategies need to be developed.

In many developing countries investments are made to cope with climate change disasters, but less focus is put on building adaptive capacity *(325)*. This was also demonstrated in our study regarding safety of fresh produce, as the likelihood of some pressures to occur was higher for countries in the global south. Interestingly, the response strategies that were proposed by the experts in our study were mostly adaptations, aimed at longer-term food safety and sustaining results and practices (column 1, Table 7.6). The adaptations scored also higher in importance. The only exceptions were the coping strategies to sample possibly contaminated growing sites with heavy metals after land- or mudslides (importance=5). However, most of the strategies for this pressure were copings, and those that were not, namely modelling to predict mud and landslides and mapping the risk areas, scored lower for their feasibility (3). It was demonstrated before that such adaptation strategies require a scientific approach and depend on the capacity of local institutions *(302)*. Several of the response strategies were assessed as being very important but having low feasibility, which indicates the need for further research, investment and implementation efforts. An example of such is the introduction of localized irrigation, which is still expensive for many small scale farmers, especially in developing countries *(372)*.

Recently attention has been put on the development of proactive predictive systems for known food safety hazards, for instance, the early warning systems for mycotoxins in cereals and tree nuts *(239, 466)*. Holistic approaches have been also introduced as they were considered more appropriate to alert for emerging food safety hazards *(304)*. The holistic systems are focused on food safety hazards, but involve also hazards originating in other sectors outside the particular production chain *(262, 303)*. Early warning systems are not yet developed for safety of fresh produce in relation to climate (change). Still, an approach for an early warning system of potential impacts of natural disasters on food safety has been proposed by Marvin et al. *(304)*. None of these systems and approaches, however, considers the current adaptive capacity of the farmers/companies, sectors and countries. Moreover, different types of hazards require other types of responses. Some hazards are linked to singular occurrence of a climate event, while others are building-up over days or months after an event, with each event or even without an event in that particular sector or area *(223)*. Enhancing the adaptive capacity is crucial for the latter type of hazards. For instance, contamination due to run-off from animal production can take days to build-up and reach a fresh produce farm or water source. Therefore, in our study the ideas of the early warning systems were extended, by considering the response strategies at farm and community level, and thus their coping and adaptive capacity.

7.4.5. Methodological considerations

The DPSIR approach used for structuring the study proved to be useful in identifying key pressures that may affect safety of fresh produce, and the possible response strategies on farm and community level. Moreover, it considered the response to both the pressures from climate change and the current control activities at farm, which took into account the adaptive capacity of the systems. The DPSIR approach has shown some limitations in sustainability research *(*e.g. *72)*. However, the DPSIR approach has also proved to be a robust problem structuring method, especially when used in participatory and systemic multi-methodology, combining other tools *(*e.g. *36)*.

In our study the Delphi method was used for structuring and organizing the group discussion, and it brought together direct knowledge and experience from geographically and domain dispersed experts. The Delphi method was however criticised for lacking credibility due to lack of decision trail and bringing only a watered down version of the best opinion *(367)*. This was addressed in this study by clearly explaining the decisions in selecting the experts, designing the different rounds (consensus levels, decision criteria, means of dissemination and implementation). To avoid loss of data in the consensus part (round II), a summary with examples was compiled from the detailed answers of the experts.

7.4.6. Usefulness of the study

Companies, sectors and regions can have different vulnerability to the changes in climate as well as to the pressures to food safety. The response strategies that were compiled in our study for each pressure to food safety of fresh produce can be used as a checklist to screen and assess the current coping and adaptive capacity of a farm and community in certain sector and or region/country. Moreover, suitable responses can be identified from the list, and considered for their importance and feasibility in the concrete situation. Similar type of screening tools have been created for climate change adaptation projects including changes or introduction of new agricultural methods and infrastructure *(476)*. However, these were not designed to consider the adaptation to climate change in terms of food safety.

7.5. Conclusions

Adaptations to climate change are needed not only to mitigate against the physical damages resulting in lower yields of commodities, but also to safeguard food safety. One of the commodities vulnerable to changes in climate is fresh produce, because it can be directly or indirectly exposed to different climate-induced events triggering pressures on food safety. This paper sought to systemise the pressures affecting microbiological and chemical safety of fresh produce and to generate a list of important and feasible response strategies at company and community level. The pressures are due to extreme events (i.e. floods, heavy rainfalls, storms), increase of temperature and change in seasonality, and can affect microbiological and chemical contamination (pesticide residues and heavy metals) of water resources and cultivation sites, increased presence of pesticide residues and mycotoxins (Q1). A first response is realised by the core control activities in a food safety management system implemented at farm, and depends on their current level of implementation and operation (Q2). The next step is to focus on validating the effectiveness in changed circumstances, guidance and training to farmers (Q2, Q3). Moreover, additional strategies can be applied at farm to cope with pressure immediately after occurring or adaptations supported at a community level to building long-term adaptive capacity (Q3, Q4). It was highlighted that the adaptive and coping capacity of companies, regions and sectors is determined by the currently available adaptation and coping strategies (Q4). It can be concluded that the pressures to food safety can differ per company, supply chain, region and sector due to variability of current vulnerabilities in climate, control activities, and adaptive capacity. Further research and adaptation actions to address the food safety pressures due to climate change should take into account the context of the countries, sectors and companies, thus, focusing on improving the adaptive capacity from a systems perspective.

7.6. Acknowledgements

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Chapter 8:
General discussion

8.1. Background of the research

Food safety management is aimed at controlling the risks and protecting human health *(136)*. This involves the establishment of a legal framework and its enforcement in the countries and sectors, with the goal to induce compliance by companies in the food supply chain as they set-up and implement FSMS. Next to the public requirements, many private standards emerged posing additional demands to food companies *(91)*. FSMS are the result from the translation of all these various standards and guidelines into specific company's circumstances *(295)*. Furthermore, food safety management is exercised in different contexts – countries, sectors, supply chains. This is relevant for all food sectors, but especially challenging for fresh produce, which is increasingly produced, traded and distributed across the world. Therefore, the objective of this thesis was to get insight into the context and its influence on FSMS implemented and operated in the fresh produce chain. An interdisciplinary approach was applied for the purpose, integrating technological and managerial theories and models *(290)*. Moreover, further connections were established with the social sciences disciplines of public policy and supply chain management to explore the influence of context on food safety management systems in companies.

This discussion starts with a description of the main findings, followed by contribution to existing concepts and theories, methodological considerations, and implications to food safety management on policy and company level. Finally, future perspectives and main conclusions of the research are described.

8.2. Main findings

To study the food safety management systems within a company specific context, a diagnostic tool was developed (Chapters 2 and 3). It includes assessment of the FSMS activities, FSMS output and company-specific context factors that affect decision-making in the FSMS (so called, FSMS context). The tool enables assessment that is independent from type of product and company, standards and guidelines implemented. It provides a snap-shop picture of the current status of the FSMS and allows mapping of FSMS in various sectors, countries and supply chains. The tool was validated by expert opinion and tested in companies across the supply chain.

Further on, the diagnostic tool was used in three case studies of leafy greens production regions in Belgium, Norway and Spain (chapter 4). Additional empirical data was collected via semi-structured interviews about the specifics of the regions with their so called "broad context". The latter was defined as including: food safety governance, agro-climatic, market and public policy environments. Identified differences in the FSMS in the three regions suggested that the "broad context" affects the set-up and operation of FSMS and their company specific FSMS contexts.

Food safety management in supply chains was explored in chapter 5, with a focus on the role of cooperatives as a form of supply chain integration. Data was collected with the diagnostic tool at farmers, which were members of four cooperatives, each with increasing degree of vertical integration. It was derived that increase in the vertical integration positively contributes to the FSMS activities. However, increased complexity in the business function of cooperatives may negatively influence FSMS.

A quantitative study was conducted in chapter 6 to investigate the status of FSMS in companies operating in and outside the European Union (EU), and the factors that may explain potential differences. Hierarchical cluster analysis revealed three clusters of companies with different status of their FSMS, mostly independent from their operation in the EU or not. One main factor explaining the differences between the clusters emerged from a principle component analysis. This was the availability of information, expertise and collaboration within the supply chain of the company, which was linked to the increased integration of supply chains triggered by the stringent requirements of private standards. Another factor was linked to the support by sector organisations and NGOs for small and medium companies, in cases when supply chains are less integrated and only national standards or GlobalGAP are followed. The companies with lowest scores of their FSMS were linked to lack of support in supply chain or country, and no standards or guidelines implemented. These companies were only small ones located in developing and emerging countries.

A Delphi study was performed to explore the pressures due to climate change that can affect safety of fresh produce (chapter 7). Experts were invited to represent countries in the global North - with industrialized food systems, and in the global South - with structured and traditional food systems. The defined pressures were linked to contamination of water resources and production environment with microorganisms, pesticide residues, mycotoxins and heavy metals. A list of response strategies was generated for each pressure, including coping strategies immediately after a pressure occurs, and adaptation strategies to increase adaptive capacity. The insights from the study revealed that a first response to climate change will be realised by the FSMS activities implemented in companies. The experts stressed the need to strengthen and adapt some of the activities, and validate their effectiveness for the changed circumstances. It was concluded that differences in the pressures to food safety in companies, supply chains, regions and sectors can be attributed to differences in climate vulnerability, FSMS, and its adaptive capacity.

8.3. Contribution to existing theories and concepts

8.3.1. Diagnosing food safety management systems

A diagnostic tool was developed previously to assess the status of FSMS in processing industries, which was validated for animal-derived products *(230, 286, 294, 295)*. The assumptions behind this tool served as a basis for the development of the tool for fresh produce (chapters 2 and 3). Many indicators that were applicable to all FSMS were retained from the previous tool, especially for processing companies. New indicators and assessment grids were created to specifically address the issues in fresh produce, and to cover the supply chain from primary production, through processing and trade. Major modifications with new indicators and grids were necessary to adapt the tool for primary production, and some minor changes in the grids - for the trade tool. The concept for FSMS assessment was extended to include food safety management in the supply chain, as the output of one actor is the input for the next. Indicators were added to assess activities and factors important for the management of food safety in the supply chain, such as, ‘degree of information exchange in supply chain’, ‘sophistication of logistic infrastructure’, ‘degree of globalization of supply’ and ‘sophistication of supplier control’. Another innovation in the tool for fresh produce was the inclusion of chemical safety aspects. Indicators and judgement grids were introduced to address pesticide residues and mycotoxins.

8.3.2. Food quality management functions model

Luning & Marcelis *(291)* proposed a model explaining the functions contributing to food quality from a managerial and technological perspective, by considering the complex behaviour of foods and humans. The model takes into account also the environment in which companies operate, but without strictly defining its components and the relationships with quality management functions. Later on, the context that affects decision-making in FSMS was defined, consisting of product, production, organisational and chain characteristics *(294)*. However, this is the narrow company context of FSMS in a company, and the environment considered in the food quality management functions model is more in view of the broad social, political, economic and technological circumstances *(291)*.

The explorative study (chapter 4) indicated that both FSMS and its narrow FSMS context are influenced by the "broad context". The latter showed to affect also the final system output. Thus, we can derive that the "broad context" has also an influence on the final food quality, as expected by customers/consumers. Four sub-systems of the "broad context" have been assumed to impact FSMS and its FSMS context. Food safety governance is aimed to directly influence FSMS and to induce compliance by companies to public and private standards and guidelines (chapter 4). Market and supply chain integration emerged as a main factor influencing maturity of FSMS (chapter 4, 5 and 6). Agricultural public policies and agro-climatic conditions also play a role and were touched upon in chapter 4. Finally, we postulate that the final system output is a function of the FSMS system with its narrow FSMS context, and the broad context of a sector and country in which company operates. The impact of the "broad context" on FSMS can be direct and indirect. Although the studies described in this thesis were not specifically designed to distinguish and investigate separately direct and indirect relationships, some observations were possible and they are summarized in table 8.1.

More in detail, food safety governance is aimed at directly influencing the set-up and operation of FSMS. This is realised through the establishment of standards and guidelines, auditing and sampling to provide information about performance of the FSMS. Moreover, indirect influence can be achieved by providing information and education of companies. This empowers companies with knowledge and skills to establish their FSMS. Thus, it lowers the riskiness of context by reducing ambiguity and uncertainty.

Table 8.1: Mechanisms of influence of the broad context on FSMS and their output

Sub-system and aspects	FSMS activity or output	Mechanism	Chap-ter
Food safety governance			
• Standards	FSMS	**Direct** requirements on FSMS	4
• Audits	FSMS output	**Direct** information of output	4
• Sampling	Monitoring	**Direct** provision of information	4
• Sanctions/ stimulus	FSMS	**Indirect** through organisational characteristics	4
• Information &	FSMS	**Indirect** through organisational characteristics	4, 5, 6

education			
Agro-climatic environment			
• Climate zone	FSMS	**Indirect** through market	4, 7
• Production season	FSMS	**Indirect** through market	4
Market			
• Market structure	FSMS	**Indirect** through organisational and chain characteristics	4, 5, 6
• Supply chain integration	FSMS	**Indirect** through organisational and chain characteristics	4, 5, 6
Public policy			
• Subsidies	FSMS & output	**Indirect** through product, production, organisational and chain characteristics, and **direct** on FSMS activities (e.g. irrigation, storage)	4, 5
• Tariff measures	FSMS	**Indirect** through market	4

Agro-climatic environment has an influence on FSMS indirectly, through the interaction with the sub-system of market environment. Favourable climate and longer production seasons contribute to production increase and market growth, which promotes the overall resources of the company (chapter 4). Integrated market and supply chain allow for pooling up of resources, which decreases the riskiness of organisational and chain characteristics (chapter 4, 5, 6). Agricultural policy tools such as subsidies can target improvements in the FSMS. For instance, cooperatives in the Netherlands and Belgium facilitated the acquisition of subsidies, which were used for investments in storage and packaging equipment at farms (chapter 5). Tariff measures were employed in Norway to curb competition and thus protect domestic small farmers (chapter 4). This had indirect effect on FSMS through improving the power position in the chain.

8.3.3. Risk governance and systemic risks

The concept of systemic risk was created in the last decade to describe the risks affecting the systems on which society depends, such as food, health, transport, environment, etc. *(344)*. The concept recognises the fact that risks to human health and environment are embedded in a broad context of social, financial and economic systems *(382)*. There are strong interconnections between these different systems and systemic risks can occur at the junction between them *(224, 344, 381)*.

Systemic risks can be the result from the interaction between natural events (affected or not by humans), economic, social and technological systems, and policy actions both at national or international level *(382)*. Climate change is such a natural event. It can create pressures to food safety management on a company and regional level (chapter 7). The pressures are created because the variability of climate can exceed current levels, and thus exceed the contamination levels FSMS can deal with *(197)*. These may not be (yet) included in existing standards and guidelines to the industry. In addition, FSMS in certain companies struggle to address even the present situation.

Risk governance is established to recognise and deal with systemic risks *(382)*. Governance in the broader sense describes the structures and processes of collective decision making, including public and private actors *(343)*. Structures for food safety governance are put into place to provide human health protection. Scientific research deals with food safety governance by following the traditional risk analysis approach, based on risk assessment, risk management and risk communication. In practice risk management is put into the hands of food companies, and their behaviour is steered by different public and private stakeholders. Most studies, however, focus on investigating either the status of FSMS *(e.g. 289, 352)* or the mechanisms of establishing public and private enforcement *(e.g. 241, 285, 391)*. The link between these two is mostly missing. Moreover, the traditional risk analysis approach has been criticized on its inability to handle new challenges and systemic risks, because it ignores the "broad context" of social and economic systems *(382)*.

The contribution of this thesis and particularly chapter 4, was the definition of the "broad context" of FSMS, with its four sub-systems (food safety governance, agro-climatic, market and public policy environments), which influence the food safety management in companies. To better understand the main factors determining the status of FSMS we wanted to unravel the relationships between the systems. From our studies it became clear that supply chain integration plays an important role in shaping FSMS on national (Spanish companies in chapter 4 and Dutch cooperatives in chapter 5) and international (cluster 1 in chapter 6) level. However, it is primarily triggered by private interests (e.g. of retailers) imposed via private brand standards. In less integrated supply chains, following national or widely used private standards, such as GlobalGAP, the status of FSMS is dependent on the support from sector organisations or NGOs (chapter 6). Such public-private organisations are common in the EU (i.e. produce and sector organisations), and they are involved in the enforcement (chapter 4). The latter was differently organised in the countries involved in our study, which was linked to the national traditions of public policy. The possible influence of culture to explain the differences in public-policy making styles has been discussed previously *(224, 245)*. However, empirical data in the field of food safety was lacking. Our results demonstrated inability of public-private enforcement in a fragmented market, consisting of many small farmers (chapter 4). Impact of food safety governance on FSMS in different supply chains deserves further investigation.

8.3.4. Supply chain quality management

Integration of supply chains is in the scope of supply chain management, which is aimed at organising operations, reducing costs, increasing customer satisfaction, revenues and competitiveness *(427)*. To achieve this broad range of organisational goals, companies shifted their attention to supply chain quality *(412)*. For all companies in the supply chain that means to take care of their internal quality management, but to also consider the external factors.

The dominating role in food supply chain quality management has been played by the retailers through the introduction of strict quality assurance standards to the suppliers *(450)*. Scientific evidence about the role of these standards has been controversial. On the one hand, they have been criticized for posing non-tariff barriers to developing countries and to negatively affecting small-scale farmers; on the other hand, they have been cited as a catalyst to growth *(38, 379)*. Nevertheless, failures have been reported that testify to the fact that standards are no guarantee for food safety and quality *(420)*. Many companies still consider safety as less important than price and delivery conditions *(473)*. Previous research has been trying to unravel the role of standards in supply chain quality management *(e.g. 378, 478)*. However, heterogeneity of standards and the mixture of private and public regulation made conclusions about their actual effect on quality and safety difficult *(200)*.

This thesis shed some light on the mixture of public and private enforcement and differences between standards as they affect FSMS. Leading export oriented supply chains were dominated by private brand standards (Spanish case in chapter 4, and cluster 1 companies in chapter 6). Companies in these chains demonstrated also the most supportive supply chain activities and advanced FSMS, scientifically based, adapted and tested for their own production. On the contrary, companies following public and widely used private standards (e.g. GlobalGAP) exhibited average FSMS, strictly following the recommendations, but not adapted and tested for specifics of organisation and production (Norwegian case in chapter 4 , and cluster 2 companies in chapter 6).

Another aspect of supply chain quality management is the horizontal integration of primary producers in cooperatives. The latter, however, have a dual nature, as they promote both vertical and horizontal integration *(313)*. They contribute to setting-up and operating FSMS at farm, and to coordinating safety and quality objectives, among others, in the supply chain. Cooperatives focus largely on integrating vertically, but that may negatively impact horizontal integration and FSMS at the farms (chapter 5).

8.3.5. Systems thinking in food quality management research

This research was based on the systems thinking approach, which is aimed to understand the behaviour of systems as constituted of different components, and in interaction with their context and other systems *(470)*. In the core of systems thinking are the concepts of hierarchy and emergence. Systems can be expressed as a hierarchy of levels of organisation, each more complex than the one below, and each level having emergent properties arising from the way parts are organised *(225, 415)*. Systems can be embedded parts in larger systems, called suprasystems *(415)*. Emergence represents the synergetic effect of the system as a whole, which is lost when the system is dismantled into its parts *(225)*. Problem-solving based on the systems thinking approach seeks to understand the fundamental differences between one level of complexity with the other, and to explain the relationships between these different levels. To achieve that, systems based approaches commonly search for patterns, to increase understanding of the problem and enable response.

Systems thinking has been introduced in food quality management research by Luning & Marcelis *(290)*. They defined the FSMS with their components and narrow FSMS context *(286, 294, 295)*. The contribution of this thesis is the further study of the next levels of complexity – the “broad context” in which FSMS operate (chapter 4).

Another major concept of the systems theory is the one of communication and control, related to the imposition of constraints from an upper to a lower level of hierarchy. The lower level should exhibit specific emergent properties as a result of the imposed constraints *(79)*. FSMS result from public and private enforcement, thus, we can consider FSMS as the lower level of the suprasystem of food safety governance (figure 8.1). Enforcement aims to induce FSMS implementation in companies, by control and communication, with the final goal to achieve food safety. Thus, food safety can be seen as the emergent property of the FSMS and food safety governance as a whole. Moreover, as demonstrated in chapter 4, enforcement strategies are influenced by the culture of public policy. Thus, we adapted the model from chapter 4, by hypothesising that the broad context will influence the overall food safety governance, consisting of enforcement and resulting FSMS (figure 8.1). The influence of the other systems on food safety governance need further exploration.

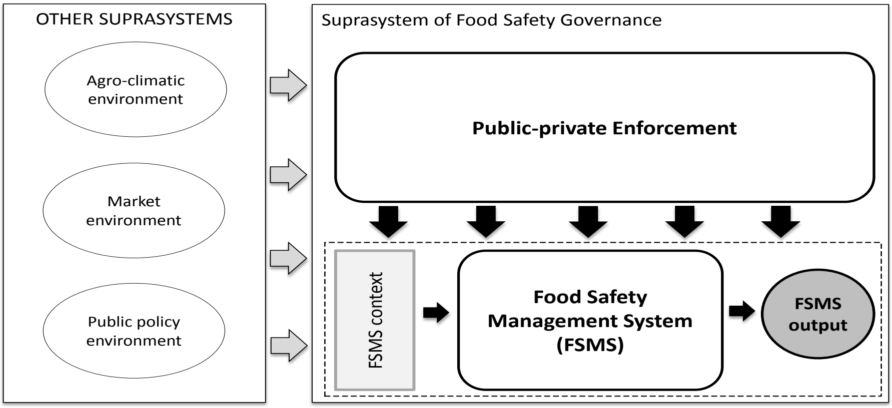

Figure 8.1: Interaction between the systems

Control as defined in the systems theory requires four conditions: goal, action, model and observability *(22)*. These were also addressed in defining the enforcement practices of food safety. The goal is the implementation of FSMS. The actions to affect the state of the FSMS are realised through various incentives, including sanctions, stimulus, information and education. Model condition is provided through setting standards and guidelines. Audits and sampling plans are aimed at achieving observability of this status.

Of even higher level of complexity are the other three systems discussed in chapter 4: agro-climatic, market and public-policy environments. Suprasystems show greater variation in their organisation and behaviour than their separate sub-systems *(415)*. Exploration of the systems in chapter 4 led to the formulation of several hypotheses regarding their effect on FSMS:

- Large companies in integrated supply chains, following strict private brand standards will show advanced FSMS (science based, modified and tested in own production);
- Small and medium sized companies in integrated supply chains, following national or commonly used private standards (e.g. GlobalGAP) will

demonstrate average FSMS (based on standards but not adapted and tested for own circumstances);

- Small and medium sized companies in fragmented supply chains, following national or commonly used private standards will demonstrate basic FSMS (based on own knowledge and experience).

Moreover, another hypothesis could be added as based on the quantitative study (chapter 6):

- Small companies with no pressures from stakeholders to implement standards or follow guidelines, will have only few activities at low levels, and poor information about their system output.

These hypothesis are a step towards conceptualisation of the broad context. However, it needs further definition and investigation of relationships with the other systems and their effect on food safety.

Systems show relatively constant behaviour (within certain limits) when they are put under pressures from their context. Still, this can vary between systems. Certain systems show better response to such pressures than others. This is explained by the adaptive capacity of systems - their ability to recover after a pressure and return to a stable state *(92)*. An example of such situation is the pressure due to climate change put on FSMS in fresh produce. In chapter 7 we discussed the responses needed to improve adaptive capacity of FSMS in different countries and sectors. To adapt to the agro-climatic/natural environment, FSMS have to establish links with it, for instance, by acquiring weather forecast information or monitoring information about quality of water sources. Thus, the long-term adaptive capacity of FSMS can be assured by continuous use of information to adapt the control and assurance activities. However, this is not always within the capabilities of a single farm or company, and adaptive capacity is dependent on the other systems of market and public policy (so called community level in chapter 7).

8.4. Methodological considerations

8.4.1. Validation of the diagnostic tool

Thorough validation was part of the development of the diagnostic tool, explicitly addressing reliability and validity. The latter included content, criterion and construct validity. Reliability was tested as data was collected from different people in the same company to compare the results and check if the tool consistently comes up with the same measurements. Content validity refers to the extent to which the items in an instrument assess the same content or how well the content material is sampled in an instrument *(96)*. This was addressed by a systematic literature review and consulting experts from academia and industry. Criterion validity compares with other measures or outcomes (the criteria) already held to be valid *(96)*, which was done by comparing our results to microbiological data from the same companies *(*e.g. *95)*. Construct validity refers to how well the results we obtain fit with theoretical expectations when using the instrument *(96)*. This part of the validation was checked throughout the case studies, by reflecting on the assumption behind the diagnostic tool that high risky context requires advanced FSMS to achieve good output. Most products in our study were high risk and the hypothesis was indeed confirmed for them. Definitive conclusions about the actual food safety levels, however, should be made with caution due to lack of sampling data, and we could compare only with the limited number of companies participating in the project.

8.4.2. Case studies design

Case studies have been designed in this thesis to investigate the influence of the broad context on FSMS. A case studies approach is widely used in academic research, because it allows unravelling "holistic and meaningful characteristics of real-life events" *(490)*. It has been especially popular in operations (and quality) management as a very powerful method for theory building *(472)*. Still, it has been criticized to be prone to bias, lack robust designs and create difficulties to generalize conclusions *(148)*. We have specifically addressed these weak points during the design and execution of the case studies. Triangulation of data from different sources was employed to avoid bias. For instance, studies in chapter 4 included data collection with the FSMS diagnostic tool at companies, interviews with enforcement organisations, and document analysis. Similarly, in chapter 5 we collected data with the tool, and performed interviews with farmers and executives in the cooperatives. Some bias might still be present as companies and farms involved in the research were all willing to participate and thus probably more pro-active than some others in the sector. In choosing the number of case studies we were searching for the right balance. One case allows for in-depth observations, while multiple cases increase the generalizability and reduce bias *(128)*. Literature suggests that multiple case studies are likely to produce more robust and testable theory, with 4-10 cases working well *(32)*. Multiple case studies in chapters 4 and 5 were selected to fit within this range.

8.4.3. Systems thinking

Outcomes from systems thinking depend heavily on how a system is defined because systems thinking examines relationships between various parts *(415)*. This issue was addressed by extensive validation of the diagnostic tool. Moreover, in the case studies we have employed both a deductive and inductive approach. The deductive approach begins with an expected pattern that is tested against observations, while the inductive approach begins with observations and looks for patterns in order to formulate a theory *(177)*. An example is chapter 4 where we looked into the status of FSMS as we expected differences due to country of operation and climate conditions. The data revealed more issues to contribute to the differences, and more data was collected to further explain that and create theory.

8.4.4. European transdisciplinary research

The research presented in this thesis was part of an European Union project called VEG-i-TRADE, which involved researchers from different scientific domains, representatives from industrial and public organisations, and companies, from Europe and beyond. The approach can be considered transdisciplinary as the members of the project collaborated for a period of four years to facilitate the development of new methods and concepts *(389)*. It can be related to the European transdisciplinary movement, which was described as "trans-sector, goal-oriented research including wide range of stakeholders" *(261)*. Critics of this approach point out that it is goal and problem driven, focusing on the methodology, but having weak and fragmented conceptual frameworks *(225)*. Contrary to this viewpoint, this research paid close attention to developing and validating inter-disciplinary concepts.

The studies described in this book benefitted to large extent from the transdisciplinary collaboration by gaining access to a wide range of case studies and to leading experts in the field, which led to robust validation of the tools and concepts. Nevertheless, some difficulties were also encountered. Researchers in other countries were employed for some of the data collection and a training was organised to instruct them how to apply the diagnostic tool. Although they were trained to use the tool in the same way, some bias might be present. Moreover, the case studies in chapter 6 were selected by the researchers in each of the countries, based on the relevance to local economy and food safety. In some of the countries data collection was not possible due to cultural and logistical hurdles. All this led to an unbalanced design of the study. Still, the overall dataset used in chapter 6 provided a good indication about the main factors affecting the status of FSMS on a global scale.

8.5. Policy implications

Food safety management nowadays is realised in a cooperation between several different sectors. According to Motarjemi & Lelieveld *(330)* these sectors are: governments, industry, science and consumers, each of them having its role and responsibilities. In their general overview of food safety management in society, risk management decisions are listed in the governmental and industry part. Governments are responsible to promulgate legislation and enforce it according to the risk management priorities set in the risk analysis process, whereas industry needs to implement an FSMS *(330)*.

In reality, however, the process of food safety governance (as defined in this thesis) is not that straightforward and may involve several public, private and hybrid organisations. This is commonly the case in the EU, which follows the principles of subsidiarity and multi-level governance (chapter 4). The general food law *(108)* was established in the EU "driven by the need to guarantee high and uniform level of food safety" *(436)*. Several directly applicable regulations have also been promulgated *(112-114)*. Still, lots of room is left for the member states in the interpretation and enforcement *(213)*. Some countries define their own standards and guidelines (Belgian case, chapter 4), while others leave it to market self-regulation (Spanish case, chapter 4). In reality public and private standards are not discrete, and they operate intertwined *(141)*. These are then imposed to the companies and translated in their FSMS. The enforcement can be facilitated by different organisations: public, private or hybrid (figure 8.2).

On the international level, voluntary general codes of practices are put forward by the Codex Alimentarius Commission with the goal to protect health of consumers and assure fair trade practices around the globe *(66)*. These codes serve as a reference point in international disputes regarding food safety and consumer protection *(436)*. Similarly as in the EU, next to such international guidelines governments can enforce their own, or leave it to market self-regulation via private standards.

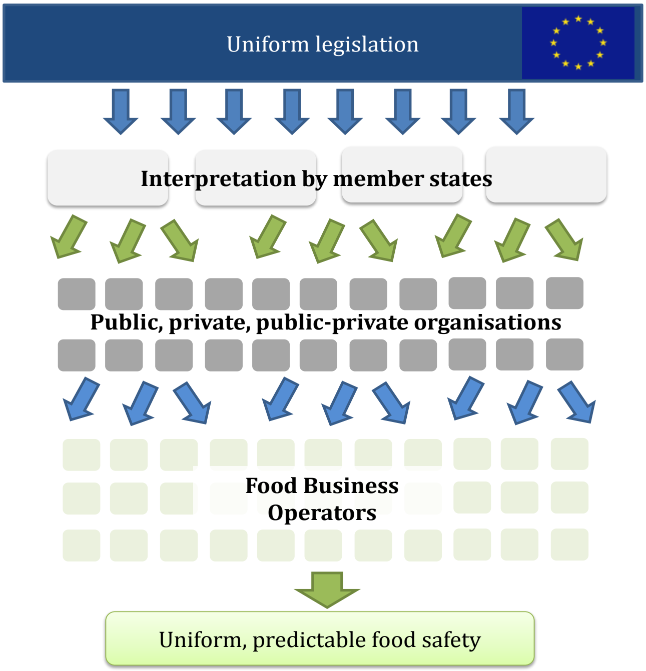

Figure 8.2: Food safety governance in the European Union

Therefore, we have modified the general overview of food safety management in society, proposed by Montarjemi & Lelieveld *(330)*, by including also the public, private and hybrid organisations involved in the enforcement (figure 8.3). Governments and governmental agencies set risk management priorities and promulgate legislation. They follow enforcement philosophy, which commonly follows the public policy traditions (chapter 4). Alternative enforcement strategies and practices need to be assessed for their cost and benefit *(178, 300)*. In many countries and sectors, the actual enforcement practices are in the hands of governmental, private or hybrid organisations (chapter 4).

Governmental agencies are also responsible for communicating the risk. They need to select strategies to achieve effective communication, based on how risks are assessed scientifically and how they are perceived by the public in different contexts *(97, 251)*.

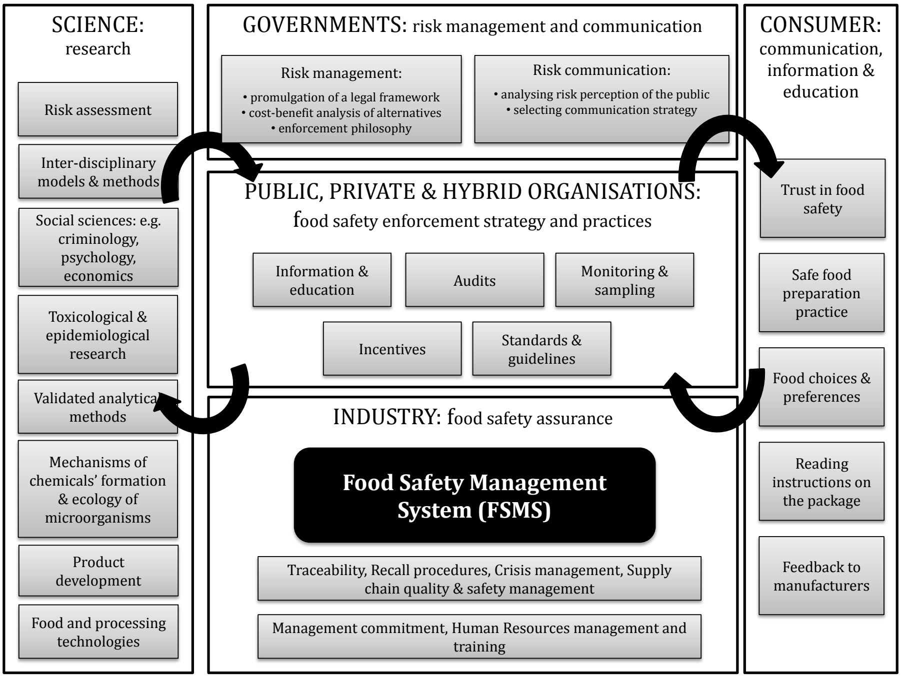

Figure 8.3: General overview of the organization of food safety management in society *(*Based upon *330)*

The role of science in food safety management has been traditionally seen in the domain of natural sciences to explain occurrence of hazards, propose new production methods and products, search for patterns, causes, and effects of health and disease conditions on the population *(330)*. However, this viewpoint is overlooking the contribution of social sciences and the abilities they have to inform governments on risk management and risk communication. For instance, challenges to food safety management related to food fraud and food safety culture *(186, 409)*, would benefit from input from criminology and psychology. Economic disciplines would contribute to finding e.g. the most effective and efficient enforcement strategies and practices, integration of supply chain and food safety management. Inter-disciplinary models and methods are needed to link social and natural science disciplines and enable goal-oriented research to address the complex issues in food safety management. Consumers should also be taken into account, not only as final users of the food, but also as formally and informally setting requirements on policy and industry.

8.6. Recommendations to companies and enforcement organisations

Increased prevalence of private standards in the last years has raised questions regarding their legitimacy *(199)*. However, conclusions were difficult as private standards differ in their content and institutional arrangements. They address food safety but also other non-food safety attributes, and represent different interests *(200)*. Chapter 6 of this thesis provides some evidence that the detailed technical requirements of private brand standards serving the interest of the global retail chains, lead to capacity building in the export supply chains, and trigger more advanced levels of FSMS, as companies focus on adapting and testing the effectiveness of activities in their particular circumstances. Furthermore, both companies themselves and auditors focus on checking the output of the FSMS as a whole, by systematically collecting and analysing customer complaints, sampling for pesticide residues and microorganisms. However, companies following less demanding private and public standards demonstrated less mature FSMS, some activities not (adequately) addressed, and lack of structured sampling and in-house controls.

In practice standards are actually checklists of very detailed technical requirements against which companies are audited *(10)*. These requirements were criticized for lacking scientific basis and importance ranking *(158)*, which creates possibility for exceeding the core requisites for food safety or for not addressing them sufficiently. For instance, huge differences were identified in the recommendations for irrigation water control, none of which was actually based on scientific evidence *(355)*. Such core activities clearly need scientific input, which are to be translated into guidelines or even public standards. What is more, the private standards are not updated systematically. Instead, only the number of requirements in the checklist is increased, which may fail to address new challenges and systemic risks (section 3.3). A systems-based approach of upgrading the standards would improve their adaptive capacity regarding new threats (chapter 7).

Last but not least, private standards are heavily dependent on third-party audits. Audits and inspections demonstrated not to be sufficient to prove effectiveness of FSMS, as they are people-dependent and prone to subjectivity and influences *(10, 368)*. They should be paired with other controls, such as sampling and in-house check-ups *(368)*. Neither content of standards or requirements to audits or auditors are commonly regulated by the governments or independent (international) organisations.

All data collected for this thesis was used to compare with current international recommendations of the World Health Organisation *(480)* and Codex Alimentarius Commission *(66, 67)*. Recommendations were derived for companies on the main issues: personal hygiene, sanitation, safe water, manure management, protection of fields, equipment control, pesticides and people management, and documentation. The recommendations for companies were mostly linked to implementation of current guidelines and tailoring to specific production and organisation (Table 8.2). Several new recommendations were identified from our data, related to assurance activities such as validation and verification, logistic facilities and relationships in the supply chain. These provide room for intervention by support organisations, as many small and medium-sized farmers and companies do not have the capacity and resources to address on their own. Another role for such organisations was identified in communicating and advising companies about content of procedures, corrective actions and documentation for feedback use.

Table 8.2: Quality assurance guidelines to FSMS, linked with the 5 keys for growing safer fruits and vegetables of WHO *(480)* (key 1 to 5), Codex requirements for fresh produce chain *(66, 67)*(key 6 to 9) and newly identified keys from the system assessment (key 10, 11 and 12)

Key	Recommendation
1 Personal hygiene	Establish procedures and instruction on personal hygiene requirements
2 Sanitation	Establish procedures and instruction on sanitation of (harvesting) equipment and (storage) facilities
3 Safe water	Implement or strengthen water control
4 Manure management	Implement manure management program (including requirements and procedures for composting, storage, etc.)
5 Protection of fields	Assess hazards at farm and establish preventive measures
6 Equipment control	Establish procedures and instruction on equipment control
7 Pesticide management	Establish procedures and instruction on pesticides management
8 People management	Invest in training and motivation of (seasonal) workers
9 Documentation	Establish procedures, corrective actions, documentation system
10 Assurance activities	Establish verification and validation activities
11 Logistic facilities	Invest in logistic facilities
12 Relationships in the supply chain	Strengthen information exchange about food safety issues with suppliers and customers

These quality assurance guidelines were developed to address the current status of FSMS in fresh produce. However, they do not account for the diversity between companies. Results from our studies showed differences in the implementation status of FSMS, related to food safety governance, market and supply chain structure (chapters 4 and 6). These suggest a need for collaboration between organisations, for instance, agricultural development and food safety agencies or ministries, to develop stratified enforcement strategies and policy tools that address the specific needs of companies with different sizes, located in differently organised supply chains and sectors. Moreover, these need to consider the impact of confounding (policy) measures (chapter 4). Achieving this is very much related to improving measurement of results and accountability, not only in monetary terms, but also in view of safety and quality.

A number of recommendations for improvement to respond to climate change in view of food safety were generated in chapter 7. These were differentiated for companies and support organisations at community level, in terms of coping and adaptation.

Based on the overall list of responses we can conclude that:

- The first response to the pressures to food safety due to climate change will be realised by the control activities implemented in companies and the response strongly depends on their current state (i.e. level of implementation and operation). There is a need to strengthen the core control activities and some of their elements, such as water control (including water treatment and quality monitoring), irrigation methods, pesticide management (and pre-harvest intervals), personal hygiene requirements and (cold) storage control.
- It is important to support the right implementation and operation of core control activities by validation for the changed circumstances, training and guidance to farmers, especially small-scale in less integrated supply chains.
- Additional responses can be applied (beyond the core control activities) and specific to the pressure for farms to cope with the pressures immediately after occurring
- Long-term adaptation of companies and their FSMS needs support and contingency planning provided at community level (by e.g. sector organisations, NGOs).

8.7. Future perspectives

Lots of efforts have been put into implementation and improvements of FSMS in the food sector. Nevertheless, problems are frequently reported, often attributed to shortcomings in other systems (e.g. enforcement and governance) or human behaviour (e.g. adulteration). Studying particular events leading to failures in FSMS limits the understanding about complexity of processes behind, and understanding systemic risk factors related to, for instance, management or organisational deficiencies, technological shortcomings, failures in the food safety culture. New approaches, frameworks and theories are still needed to analyse the systemic risks occurring at the intercept with other systems, and to generate adequate improvements at a company and policy level.

8.7.1. Interaction between systems and their influence on FSMS

FSMS are the result from enforcement, and are a part of a larger suprasystem of food safety governance in a country and sector. These can be affected by other social systems such as market and public policy (figure 8.1.; chapter 4). Systems interact with each other, connected via causal relationships and (complex) feedback loops. These need to be studied further to determine most effective policy measures and tools to ensure quality and safety in the supply chain without impeding economic growth.

Important changes in the global governance, regulation and trade as driven by dynamic economic, social, and ecological processes can lead to changes in FSMS activities such as pesticide application *(161)*. This can happen due to application of certain targeted policy measures such as subsidies or taxes *(405, 406)*, or due to changes in the requirements of importers *(102)*. However, the reasons for changes are not always that straightforward and may result from indirect influence of the market environment, legislation, ideology and culture, as discussed regarding Chinese food suppliers by Roth, Tsay, Pullman, & Gray *(390)*. Such problems fit into the scope of agroecology, which is a discipline that conceptualises agriculture within the global context including natural and social processes *(446)*. However, food safety is mainly addressed when in conflict with environmental issues *(*e.g. *39)* or in terms of pesticides management *(162, 163)*. It fails to consider quality and safety management systems implemented in companies, and the complexity of their coupling with other social systems.

8.7.2. Supply chain food quality management

Aggressive and competitive environments put lots of stress on cost and productivity and play a primordial role in supply chain management decisions on a short, mid or long-term. Studies suggest that there is a synergy between quality management and supply chain management, and defined the concept of supply chain quality management *(147, 387)*. Supply chain quality management is an approach for improving performance by increasing linkages with suppliers and customers *(151)*. Research in the food sector was focused on the (long-term) alignment between supply chain structures and quality assurance schemes *(378, 478)*, but without investigating the actual activities performed to promote and realise supply chain safety and quality management. Chapter 5 of this thesis investigated the effect of cooperatives, as a form of supply chain integration in fresh produce chains, on FSMS at farms. What is more, it gave (some) insight about the activities used by cooperatives for supply chain safety and quality management. Nonetheless, many questions are still open: What is the state of the art of supply chain quality and safety control in different food sectors, especially in the beginning of the chain? How are different strategic supply chain management decision affecting food quality management and the final food quality? What is the effect of mid- and short-term decisions?

8.7.3. Co-regulation

There is a shift towards co-regulation as governmental agencies are facing budget cuts. Enforcement of food safety is increasingly put into the hands of private parties. Various standards are put into place, differing not only in their public or private character, but also in the way they are set-up. Some authors mention the so called baseline standards, which aim at assuring the minimum requirements for addressing food safety, focusing core activities from a public health perspective *(141)*. In the same time, stringent (mostly private) standards put additional requirements on specific elements of the FSMS, thus, creating high entry costs *(199)*. Henson & Humphrey *(200)* raise the issue that previous studies do not address the institutional form of the standards. This topic was included in chapter 4 of this thesis, where we studied public and private enforcement and resulting governance structures (chapter 4). Furthermore, different types of standards were linked to differences in the status of FSMS (chapter 6). Further insights are needed into institutional mechanisms leading to different forms of food safety governance, and how this interplay between public and private parties can affect the set-up and operation FSMS and their food safety output. More research is needed to determine the most effective and efficient institutional arrangement to deliver safe food, and the role of the public sector as a regulator.

8.7.4. The human factor

Food safety management has been researched from the perspective of natural and organisation sciences, but further insights are needed into the psychological factors that underlie human behaviour. People are involved in all steps of the production and distribution processes, over each stage of the global supply chain. FSMS are put into place to assure food safety, however, compliance of people operating in these systems can vary and be determined by variety of factors *(489)*. Recent studies highlighted the role of the food safety culture in organisations *(e.g. 187, 370)*. The latter refers to the view of management and employees of a company on food safety *(489)*. People are motivated by economic gain, and problems persist regarding food fraud and counterfeiting *(409)*. The overall food safety governance, setting enforcement strategies and executing the enforcement practices can also be affected by human motives and cultural models *(43, 425)*. Audit agencies and public bodies already struggle with lack of resources *(409)*, and further research is necessary to inform targeted cost-effective (e.g. risk-based) control approaches.

8.7.5. Complexity of systems

Traditional approaches to food safety management are based on controlling critical points in the production process, where contamination can occur. Nowadays, new technological and social factors affect the etiology of risks *(381)*. This requires a new approach to food safety management and the research in this area, which is going beyond analysis of cause and consequences, but including also the complex interdependencies and relationships between systems that may affect FSMS or the overall system of food safety governance (figure 8.1).

Complexity of systems comes in many forms. Decompositional complexity is related to inconsistencies between structural and functional decomposition. This type of complexity was addressed in the principles behind the diagnostic tool, as activities of the system and their output are measured (chapters 2 and 3). Interactive complexity (between components of a system and between systems) was the focus of this thesis, as we investigated the main factors and activities that define the status of FSMS. Moreover, we studied the influence of other systems, such as agro-climatic, market and public policy environments. The models described in this thesis can be further tested and validated with data, for example, from audits and inspections, market data.

Our approach used deductive and inductive reasoning, and was based on the diagnostic tool, which provides a snap-shot picture of the FSMS. Therefore, it failed to address the dynamic complexity (changes over time), which may provide further insights about trends and dynamic changes in the factors affecting the systems. Another type of complexity that was not explicitly addressed was the nonlinear one. It is related to cases when cause and effect are not related in an obvious or direct way. Such complexity in FSMS can be related to implicit factors, for instance the food safety culture of the organisation. The latter gained attention in the last years, but with scant empirical evidence. Both dynamic and nonlinear complexity problems are studied by system dynamics *(433)*, which uses modelling approaches to predict future changes of systems. System dynamics models can address the problems of simultaneous causation of several factors and their change over time by updating all variables with positive and negative feedbacks and by including time delays *(432)*. These are based on abductive reasoning approaches. Commonly used methods are Bayesian belief networks, stochastic programming, and agent-based modelling. These methods allow simulation based on existing data(sets) to unravel the most likely explanation of a certain problem or phenomenon.

8.8. Conclusions

The research described in this thesis demonstrated that FSMS are influenced not only by the narrow FSMS context of a company, including type of product, production, organisation and chain, but also by systems in the broad context of a country and sector. There are strong interconnections between these different systems and systemic risks can occur at the junction between them. The systems in the broad context have been identified to include the agro-climatic, market and public policy environments that can affect the overall food safety governance. Food safety governance includes different public, private or hybrid organisations aimed at enforcing standards and guidelines into companies' specific FSMS.

Market and particularly supply chain integration play an important role for capacity building and maturation of the FSMS. The highest degrees of integration are driven by private interests imposed by private standards, and result in advanced FSMS. Baseline standards putting minimum requirements from a public health perspective result in basic FSMS, not adapted and tested for own production circumstances.

Vertical integration in the supply chain is particularly important in developing and emerging economies, where the institutional environment is sometimes weaker, with less produce and sector organisations, and shortcomings in the set-up and enforcement of legislation. In developed economies in the European Union, cooperatives play an important role to support farmers. However, their expansion may have negative impact on FSMS due to loss of social capital and members' motivation.

Last but not least, FSMS need to continuously evolve and adapt to new pressures like the ones triggered by climate change. However, this is not always within the capabilities of a single farm or company, and the adaptive capacity depend on the other systems in the broad context of the countries and sectors.

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Summary
in English and Dutch

Background and aim

This research was a part of a project of the European Commission called VEG-i-TRADE, aimed at identifying possible impacts of climate change and globalisation on safety of fresh produce. VEG-i-TRADE formed a multidisciplinary team of scientists from different disciplines, representatives from the food industry and other stakeholders from the European Union and third party countries. The objective of this research was to investigate the influence of context on status of food safety management systems (FSMS) in the fresh produce chain. Under context, we aimed to study the broad context in which companies operate, including food safety policy, supply chain, and climate that may directly and indirectly influence the actual set-up and operation of FSMS. Therefore, an interdisciplinary approach was employed to link concepts from different fields, and to provide scientific evidence about the possible role of the systems in the broad context in setting and operating FSMS in companies. The scientific challenge was to employ an interdisciplinary approach and bridge the gap between disciplines such as food technology, quality management, political economy, and supply chain management. The approach that was used could also be defined as transdisciplinary, as it was problem-oriented and involved companies, sector organisations and academia, thus, relating stakeholders/problem owners and scientists.

Findings

Chapters 2 and 3 of this thesis describe the development of a diagnostic tool to assess the status of FSMS and riskiness of their company specific context. The tool allows assessment of the FSMS activities, FSMS output and context factors that affect decision-making in the FSMS (so called, FSMS context). The latter include product, production, organisation, and chain characteristics. The tool allows assessment that is independent from implemented legislation, guidelines, or standards. Moreover, the tool provides for mapping of FSMS and their context over supply chains, different countries, and sectors.

The diagnostic tool was applied in three case studies of leafy greens production regions in Belgium, Norway, and Spain (chapter 4). Moreover, a theoretical framework was developed to explore the broad context in which companies operate. The latter was defined as including the sub-systems of: food safety governance, agro-climatic, market and public policy environments. The companies operating in favourable broad context, including favourable climate, big companies in integrated market, and stringent standards as a result of

market self-regulation, have demonstrated advanced FSMS, good information about the output and supporting organisational characteristics. The FSMS of the companies that were operating in less favourable broad context, either in fragmented market with small companies or in less favourable climate, have demonstrated less mature FSMS. As a conclusion, we postulate that the FSMS output is a function of the broad context in a country and sector, the FSMS context in a company, and implemented food safety management system.

Market and supply chain governance were further investigated in chapter 5, with a special focus on cooperatives. Case studies were performed in four cooperatives, with different supply chain governance of transactions. Results suggested that high vertical integration has a positive influence on FSMS. However, when cooperatives become too large and complex, horizontal collaboration decreases and may negatively influence FSMS.

Chapter 6 dove into the factors determining differences between companies operating under the European Union laws, and companies in emerging and developing countries exporting to the EU. Data analysis revealed that the main factor that was determining the differences between companies was not their location, but the availability of information, expertise, and collaboration within the supply chain, which was linked to the increased integration of supply chains triggered by the stringent requirements of private standards. Another important factor was linked to the support by sector organisations and NGOs for small and medium companies, in cases when supply chains are less integrated and only national standards or GlobalGAP are followed. The companies with lowest scores of their FSMS were linked to lack of support in supply chain or country, and no standards or guidelines implemented. These companies were only small ones located in developing and emerging countries.

The pressures of climate change on safety management in fresh produce farms were explored in a Delphi study (chapter 7). The experts were from countries in the global North - with industrialized food systems, and in the global South - with structured and traditional food systems. The identified pressures were linked to contamination of water resources and production environment with microorganisms, pesticide residues, mycotoxins and heavy metals. Response strategies were defined for each pressure, including coping strategies immediately after a pressure occurs, and adaptation strategies to increase adaptive capacity. The insights from the study revealed that a first response to climate change will be realised by the FSMS activities implemented in companies. The experts stressed the need to strengthen some of the activities, and validate their effectiveness for the changed circumstances. Likelihood of the most pressures was assessed as higher for the countries from the global south, which was explained by existing adaptations in the global north. It was proposed that the adaptive and coping capacities of companies, regions and sectors are determined by the currently available adaptation and coping strategies.

The role of the broad context for the food safety management research and practice is discussed in chapter 8. It is highlighted that systemic risks can occur at the junction between different social, political and natural systems, and they need to be taken into account in the overall food safety governance. Systems thinking approaches are advocated to explain the relationships between systems and their synergic effects.

Conclusions

The research described in this thesis demonstrated that FSMS are influenced not only by the narrow FSMS context of a company, with its product, production, organisation, and chain, but also by the broad context in a country and sector. The broad context involves the agro-climatic, market and public policy environments that can affect the overall food safety governance. Food safety governance includes different public, private or hybrid organisations aimed at enforcing standards and guidelines into companies' specific FSMS.

Market and particularly supply chain integration play an important role for capacity building and maturation of the FSMS. The highest degrees of integration are driven by private interests imposed by private (brand) standards, and result in advanced FSMS. Baseline standards putting minimum requirements from a public health perspective result in basic FSMS, not adapted, and tested for own production circumstances. Vertical integration in the supply chain is particularly important in developing and emerging economies, where institutional environments are sometimes weaker – struggling with the set-up and enforcement of legislation, lacking produce, and sector organisations to support farmers. In developed economies in the European Union, cooperatives play an important role to support farmers. However, their vertical expansion may have negative impact on FSMS possibly related to loss of social capital and members' motivation.

Last but not least, FSMS need to continuously evolve and adapt to new pressures like the ones triggered by climate change. However, this is not always within the capabilities of a single farm or company, and the adaptive capacity dependents on the other systems in the broad context of the countries and sectors.

Achtergrond en doel

Dit onderzoek maakte onderdeel uit van een project van de Europese Commissie, genaamd VEG-i-TRADE, dat gericht was op het identificeren van de mogelijke gevolgen van klimaatverandering en globalisering voor de veiligheid van groente- en fruitproducten. VEG-i-TRADE bestond uit een multidisciplinair team van wetenschappers, vertegenwoordigers van de voedselindustrie en andere belanghebbenden uit de Europese Unie, en derde landen. Het doel van de PhD studie was om de invloed van context op de status van de voedselveiligheid systemen (voedselveiligheidssystemen?) in groente- en fruitketens te onderzoeken. Onder context verstaan we: de brede context waarbinnen bedrijven opereren, inclusief voedselveiligheidsbeleid, de leveringsketens en het klimaat, zaken die direct maar ook indirect invloed kunnen hebben op het ontwerp en de uitvoering van de voedselveiligheid systemen. Daarom is een interdisciplinaire benadering gebruikt om concepten van verschillende vakgebieden te koppelen, en om wetenschappelijk bewijs te leveren voor de mogelijke rol van de brede context voor het ontwerpen en beheren van de voedselveiligheidssystemen in bedrijven. De wetenschappelijke uitdaging was om een interdisciplinaire benadering te gebruiken, die een brug kon slaan tussen disciplines zoals voedseltechnologie, kwaliteitsmanagement, politieke economie, en ketenmanagement. Deze aanpak kan ook gedefinieerd worden als transdisciplinair omdat hij probleemgericht was en bedrijven, brancheorganisaties en universiteiten erbij betrok; belanghebbenden/ probleemeigenaren en wetenschappers werden met elkaar in verbinding gebracht.

Resultaten

De hoofdstukken 2 en 3 van dit proefschrift beschrijven de ontwikkeling van een diagnostisch instrument om de status van voedselveiligheid systemen en de risicokenmerken van de bedrijfsspecifieke context te beoordelen. Dit instrument maakt het mogelijk om de prestatie van het systeem (output) en cruciale beheers- en borgingsmaatregelen te beoordelen in het licht van de inherente risicokenmerken van de systeemcontext. Deze context factoren omvatten: product-, productie-, organisatie- en ketenkenmerken die de besluitvormingsactiviteiten in het systeem kunnen beïnvloeden en daarmee de systeemuitkomst. De diagnose is niet gekoppeld aan specifieke wetgeving, richtlijnen of normen maar richt zicht op hoe cruciale beheers- en borgingsmaatregelen ontworpen zijn en geïmplementeerd. Het instrument kan gebruikt worden op bedrijfsniveau, keten maar ook op wereldwijd niveau.

Het diagnose-instrument is toegepast in drie casestudies met telers in bladgroenten in de productieregio's België, Noorwegen en Spanje (hoofdstuk 4). Bovendien is een theoretisch kader ontwikkeld om de brede context waarin bedrijven opereren te verkennen. Naast de directe context zijn de bedrijfsvoedselveiligheidssystemen onderdeel van andere subsystemen, deze omvatten: het voedselveiligheidsbeleid, de agro-klimatologische kenmerken, de marktomgeving en de publieke beleidsomgeving. De bedrijven die actief waren in een brede context, met een gunstig klimaat, in een geïntegreerde markt en met strengere beleidsnormen als gevolg van zelfregulering door de markt, hebben aangetoond te beschikken over geavanceerde voedselveiligheidssystemen, goede informatie over de systeemoutput en ze hebben ondersteunende organisatorische kenmerken. Bedrijven die actief waren in een minder gunstige brede context, hetzij werkzaam in een gefragmenteerde markt met kleine bedrijven of in een minder gunstig klimaat, hebben aangetoond te beschikken over een minder geavanceerd voedselveiligheidssysteem. We kunnen concluderen dat het voedselveiligheidssysteem het resultaat is van de brede context in een land en sector, de context in een bedrijf, en het werkelijke voedselveiligheidssysteem.

De markt en integraal ketenbeheer zijn verder onderzocht in hoofdstuk 5, met speciale aandacht voor coöperaties. Casestudies zijn uitgevoerd in vier coöperaties, met een verschillend ketenbeheer van de transacties. De resultaten suggereren dat een grote verticale coördinatie een positieve invloed heeft op het voedselveiligheidssysteem. Als coöperaties echter te groot en complex worden, dan is de horizontale samenwerking minder en zijn de gevolgen negatief voor het systeem.

In hoofdstuk 6 zijn de factoren beschreven die de verschillen bepalen tussen bedrijven die onder de wetgeving van de Europese Unie handelen, en bedrijven uit ontwikkelingslanden en opkomende landen die naar de EU exporteren. Uit de data-analyse is gebleken dat de belangrijkste factor die de verschillen tussen de bedrijven bepaalt niet afhankelijk is van hun locatie, maar van de beschikbaarheid van informatie, expertise en samenwerking binnen de ketens, gekoppeld aan de toenemende integratie van de ketens door de strenge eisen van private kwaliteitsstandaarden en normen. Een andere belangrijke factor is gekoppeld aan de steun van sectororganisaties en NGO's (niet-gouvernementele organisaties) voor kleine en middelgrote bedrijven als ketens minder geïntegreerd zijn en als alleen nationale normen of GlobalGAP worden nageleefd. De bedrijven met de laagste scores voor de voedselveiligheidssystemen werden in relatie gebracht met een gebrek aan ondersteuning in de ketens of het land, en beschikken niet over geïmplementeerde normen of richtlijnen ten aanzien van voedselveiligheidssystemen of best practices. Het betreft hier alleen kleine bedrijven in ontwikkelingslanden en opkomende landen.

De pressie ten gevolge van klimaatverandering op het veiligheidsmanagement in groente- en fruitboerderijen is onderzocht in een Delphi-studie (hoofdstuk 7). De deskundigen waren afkomstig uit landen in het noordelijk halfrond - met geïndustrialiseerde voedselsystemen, en het zuidelijk halfrond - met gestructureerde en traditionele systemen. De geïdentificeerde pressiefactoren ten gevolgen van klimaatverandering zijn gekoppeld aan de besmetting van waterbronnen en een productieomgeving met micro-organismen, residuen van bestrijdingsmiddelen, mycotoxinen en zware metalen. Responsstrategieën zijn gedefinieerd voor elke druk, inclusief coping-strategieën direct nadat de druk optreedt, en aanpassingsstrategieën om het adaptief vermogen te verhogen. Uit het onderzoek blijkt dat de eerste reactie op klimaatverandering gerealiseerd zal worden door de activiteiten die bedrijven hebben geïmplementeerd in het voedselveiligheid systeem. De experts benadrukten de noodzaak van de versterking van een deel van die activiteiten, en het valideren van de effectiviteit ervan voor de gewijzigde omstandigheden. Waarschijnlijk is de druk van klimaatverandering hoger in de landen uit het zuidelijk halfrond, omdat in het noordelijk halfrond diverse aanpassingsstrategieën al zijn geïmplementeerd. Er wordt verondersteld dat het aanpassings- en coping-vermogen van bedrijven, afhangt van de regio en sector, en mede bepaald wordt door de beschikbare aanpassings- en coping-strategieën.

De rol van de brede context voor het beheer en de praktijk van het voedselveiligheidsonderzoek wordt besproken in hoofdstuk 8. Er wordt benadrukt dat systeemrisico's kunnen optreden op de kruising tussen de verschillende sociale, politieke en natuurlijke systemen. Hiermee dient rekening gehouden te worden in het totale voedselveiligheidsbeleid. Benaderingen van systeemdenken worden bepleit om de relaties tussen systemen en zijn synergistische effecten te verklaren.

Conclusies

Het onderzoek beschreven in dit proefschrift heeft aangetoond dat de voedselveiligheidssystemen niet alleen beïnvloed worden door de directe context van een bedrijf, namelijk product-, productie-, organisatie- en ketenkenmerken, maar ook door de brede context in een land en sector. De brede context betreft het agro-klimaat, de markt en de publieke beleidsomgevingen die het totale beleid van voedselveiligheid kunnen beïnvloeden. Voedselveiligheidsbeleid komt tot stand door de inzet van verschillende publieke, private of hybride organisaties die gericht zijn op het handhaven van normen en richtlijnen in het bedrijfsspecifieke voedselveiligheid systeem.

De markt, maar vooral de ketenintegratie, spelen daarin een belangrijke rol bij de capaciteitsopbouw en ontwikkeling van voedselveiligheidssystemen. De hoogste mate van integratie wordt bepaald door particuliere belangen, opgelegd door particuliere (merk)normen, en resulteert in geavanceerde voedselveiligheid systemen. Baseline standaarden die minimale eisen stellen vanuit het oogpunt van de volksgezondheid resulteerden in meer basale voedselveiligheid systemen, die gebaseerd zijn op ervaringen en niet op kennis en ook niet aangepast zijn aan de bedrijfsspecifieke productieomstandigheden. Verticale integratie in de keten is vooral belangrijk voor ontwikkelingslanden en opkomende landen, waar institutionele omgevingen soms zwakker zijn en die worstelen met de opstelling en handhaving van wetgeving en het ontbreken van producent- en brancheorganisaties om boeren te ondersteunen. In de ontwikkelde economieën in de Europese Unie spelen coöperaties een belangrijke rol om boeren te ondersteunen. Hun verticale uitbreiding kan echter een negatieve invloed hebben op de voedselveiligheidssystemen, mogelijk vanwege het verlies van sociaal kapitaal en motivatie van de leden.

Tot slot, voedselveiligheidssystemen moeten continue geëvalueerd en aangepast worden aan nieuwe pressiefactoren, zoals die geïnitieerd worden door klimaatverandering. Dit valt echter niet altijd binnen de mogelijkheden van een boerderij of bedrijf: het aanpassingsvermogen is afhankelijk van de andere subsystemen in de brede context van de landen en sectoren.

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-Klementina-

Overview of completed training activities

International Conferences & Meetings

- The 29th International Horticultural Congress: Horticultural Economics & Management (17th International Symposium) & Supply Chain Management (5th International Symposium), International Society for Horticultural Science, Brisbane, Australia (**oral presentation**) 2014
- Hybridisation of Food Governance: Trends, Types and Results, Nijmegen University, Nijmegen, The Netherlands (**oral presentation**) 2014
- VEG-i-TRADE Closing Event: Bringing Food Safety of Fresh Produce to the Next Level, European Commission, FAVV-AFSCA & Fresh Trade, Brussels, Belgium (**oral presentation**) 2014
- Food Sovereignty Conference: Global Perspectives in the Fresh Produce Supply Chain, VEG-i-TRADE, Pretoria, South Africa 2014
- Six consortium meetings of VEG-i-TRADE project 2010-2014
- Reshaping Trade in Fresh Foods, Nyenrode Business University & Start People, Breukelen, The Netherlands 2013
- EFFoST Annual Meeting: A Lunch Box For Tomorrow: An Interactive Combination of Integrated Analysis and Specialized Knowledge of Food, EFFOST & INRA, Montpellier, France (**oral presentation**) 2012
- Fifth International Conference: Quality and Safety in the Food Production Chain, Wroclaw, Poland (**poster presentation**) 2011
- International Symposium: Measuring Food safety and Comparing Self-Checking Systems, Federal Agency for the Safety of the Food Chain (FASFC), Brussels, Belgium 2010

Workshops with stakeholders

- Food Compass Bijeenkomst 2014, NBC Congrescentrum, Blokhoeve 1, Nieuwegein, The Netherlands 2014
- Three workshops with companies in South Africa, VEG-i-TRADE & Pretoria University, South Africa 2013
- Test your horticulture safety management system – A diagnostic instrument, CEBAS & VEG-i-TRADE, Murcia, Spain 2012
- Veiligheid in de groenten en fruit ketens: update en stand van zaken, VEG-i-TRADE & Ghent University, Lokeren, Belgium 2012
- Toets uw voedselveiligheids-systeem, Wageningen University, Wageningen, the Netherlands 2012

Courses and trainings

- Summer school food security, safety and quality, Global Challenges University Alliance, Swedish University of Agricultural Sciences, Uppsala, Sweden — 2014
- Improve your writing, Wageningen University — 2014
- Workshop presentation skills, Wageningen University — 2013
- Training in application of the Horticultural Assessment Scheme, VEG-i-TRADE, National Veterinary Institute, Oslo, Norway — 2012
- Applied statistics course, VLAG, Wageningen University — 2012
- Techniques for writing and presenting a scientific paper, Wageningen University — 2012
- Bayesian statistics course, PE&RC, Wageningen University — 2010

Optional activities

- Organising PhD discussion groups — 2012-2014
- Participating in the PhD trip to UK — 2012
- Organising a PhD trip to UK — 2011
- Writing a research proposal — 2010
- PhD introduction week — 2010

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