Performance of Food Safety Management Systems in the Fresh Produce Export Processing Sector in Kenya

By

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Declaration

I, Chemutai Tonui Sawe, hereby declare that this dissertation is my original work and that it has not been presented for a degree in any other University.

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This dissertation has been submitted for examination with our approval as University Supervisors.

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Dedication

To my husband, Naftali Sawe and children: Edwin, Victor and Joy for their support, patience and encouragement.
Acknowledgement

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To Him who directs and establishes our steps: All glory and honour.
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### Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BRC</td>
<td>British Retail Consortium</td>
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<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>CCP</td>
<td>Critical control point</td>
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<td>CP</td>
<td>Critical point</td>
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<td>CSL</td>
<td>Critical Sampling Location</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>EU</td>
<td>European Union</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>FAOSTAT</td>
<td>Food and Agriculture Organization Statistics</td>
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<tr>
<td>FSMS</td>
<td>Food Safety Management System</td>
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<tr>
<td>GAP</td>
<td>Good Agricultural Practices</td>
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<td>GHP</td>
<td>Good Hygiene Practices</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<tr>
<td>HACCP</td>
<td>Hazard analysis and critical control point</td>
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<tr>
<td>HCDA</td>
<td>Horticultural Crops Development Authority</td>
</tr>
<tr>
<td>ICMSF</td>
<td>International Commission on Microbiological Specifications for Food</td>
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<td>IFS</td>
<td>International Food Standard</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>KEPHIS</td>
<td>Kenya Plant Health Inspectorate</td>
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<td>MAP</td>
<td>Modified atmosphere packaging</td>
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<tr>
<td>MAS</td>
<td>Microbial Assessment Scheme</td>
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<tr>
<td>MRL</td>
<td>Maximum Residue Level</td>
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<tr>
<td>MSLP</td>
<td>Microbial safety level profile</td>
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<tr>
<td>QA</td>
<td>Quality Assurance</td>
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<tr>
<td>RASFF</td>
<td>Rapid Alert System on Food and Feed</td>
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<tr>
<td>SPS</td>
<td>Sanitary and phyto-sanitary</td>
</tr>
<tr>
<td>TNS</td>
<td>Tesco Nature Source</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Abstract

Food producers are required to implement different food safety and quality assurance standards and guidelines. This may result in variable food safety performance or output due to differences in technological development, resource access, food safety legal framework and the dynamic environment in which they operate. Despite developments in food safety management systems (FSMS), food-borne outbreaks linked to fresh and minimally processed vegetables and fruits continue to be reported. Commonly used approaches such as inspections, audits and sampling for testing do not provide systematic information on distribution and dynamics of microbial contamination.

The aim of this study was to evaluate the performance of FSMS in the fresh produce processing sector in Kenya using a FSMS diagnostic instrument (FSMS-DI) and a microbial assessment scheme (MAS). The FSMS-DI based on a questionnaire with 71 indicators with level descriptions for context factors, control and assurance activities and food safety output was used to evaluate thirteen fresh produce exporting processors in Kenya. The MAS was also used to assess the microbial performance of core control and assurance activities of five of the thirteen processors. *Listeria monocytogenes, Salmonella* (food safety indicators), *Enterobacteriaceae, Escherichia coli, Staphylococcus aureus* (hygiene indicators), *Coliforms, E.coli* and *Enterococci* (water quality indicators) were analysed at critical sampling locations (CSLs). CSLs included the initial and final products, food contact surfaces, personnel hands and/or gloves and water. Based on compliance to criteria, food safety levels of either 0, 1, 2 or 3 was attributed to each parameter analysed at the various sampling locations and microbial safety level profiles (MSLPs) constructed from the sum of scores at each sampling location.
The FSMS diagnosis indicted that majority of the processors (≥7) operate at moderate level in most (74 %) of the context riskiness indicators. Seven out of the 13 processors indicated that susceptibility of initial material to microbial contamination posed the highest risk with respect to product characteristics. Even though majority (61 %) of the companies had advanced level core control activities performance for 6 out of 29 of the activities, they showed a moderate performance in 48 % of the activities and 24 % control activities were not applied. Core assurance activities for majority of the companies also performed moderately in 89 % of the indicators. FSMS performance was poor for 53 % and good for 37 % of the processors. All the processors had advanced scores for monitoring of pesticide residues but 38 % lacked sampling and criteria for microbial analysis. The FSMS implementation for 77 % of the companies was poor to moderate and, given the moderate context riskiness, this therefore resulted in moderate FSMS-output.

MAS results indicated that only two processors attained the maximum MSLP for the initial product, while only one processor achieved the maximum MSLP for the final product. None of the processors attained the maximum MSLP for the hygiene indicators. *Salmonella* and *Listeria monocytogenes* was not detected in products of all the processors. *E. coli* was detected in 5 out of 6 of the sampling locations, including the final product. *E. coli* was positive in final products in instances where it was negative in initial products for 3 out of 5 processors, an indication of cross contamination due to poor cleaning and sanitation or inadequate intervention in processing. *E. coli* was positive in final products in instances where it was negative in initial products for 3 out of 5 processors, an indication of cross contamination due to poor hygiene or inadequate cleaning and sanitation. MAS results revealed that the levels at which FSMS activities had been translated
in individual companies had a direct impact on the outcome of microbiological performance at selected control points.

The levels- whether basic, moderate or advanced- at which FSMS activities have been translated in a company therefore had a direct impact on the outcome of microbiological performance at selected control points. In this way, weaknesses in the system were identified. The mostly moderate FSMS activity levels when assessed in the context riskiness lower the food safety performance of the fresh produce sector. Several recommended control and assurance activities in fresh produce sector should be improved to advanced levels in order to realize a stable and predictable safety output subject to the riskiness of context situation.

**Key words:** Food Safety Management System, Microbial Assessment Scheme, fresh produce industry, context characteristics, control activities, assurance activities, Microbial Safety Level Profile.
Chapter 1
1.0 General Introduction

Food safety management system (FSMS) consists of food safety and its management system. Food safety can be considered as a specific aspect of food quality (Luning and Marcelis, 2009), and is defined as the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (CAC, 2003; ISO 22000:2005).

A FSMS is the result of the implementation of relevant quality assurance guidelines such as Codex Alimentarius HACCP principles, British Retail Consortium (BRC) food safety standard, ISO 22000:2005, GlobalGAP and legislative guidelines, among others. It consists of safety control activities aimed at realizing food safety, and assurance activities focused on providing confidence that safety requirements will be met, both of which contribute to the overall performance of a FSMS (Luning et al, 2008, 2009a).

Established and emerging food safety hazards coupled with technological advances in food production, marketing and distribution, rejections and bans and increased consumer awareness has enhanced the rise of food safety as a public and political issue as well as a scientific and technical one (FAO, 2007a). However, fresh produce was only recently recognized as an emerging vehicle of food borne illnesses compared to food from animal origin (Jacxsens et al., 2010; Ilic et al., 2008). A recent report on microbiological hazards in fresh fruits and vegetables indicated that leafy vegetables and fresh herbs currently present the greatest concern in terms of hazards such as pathogenic bacteria, viruses and protozoa (FAO, 2008; Baert et al., 2008).

Consequently, food authorities in many developed countries have introduced new mandatory standards and regulations for previously unknown or unregulated hazards in fruits and vegetables (FAO 2007b) such as the recent case of E. coli O157 in Europe, and/or increased the stringency
of existing standards such as for pesticide and veterinary drug residues and mycotoxins (EFSA, 2011). This is in response to better knowledge about the sources and consequences of food-borne diseases and increased consumer concerns (Jacxsens et al., 2010).

Food safety and quality management has therefore assumed great importance as a key driver for organization and management of food production systems in the agribusiness and food industry (Luning et al., 2009b). However, typical characteristics of food production, such as microbiological and chemical food safety risks, limited shelf life, seasonal harvesting, heterogeneity of raw materials, and complexity of supply chains, put high demands on control and assurance of food quality and safety (Luning and Marcelis, 2009; Luning et al., 2009b). Therefore, there is need to evaluate and improve the performance of FSMS in the fresh produce processing sector in light of new and modified safety control measures and production techniques (Luning et al., 2008; 2011).

1.1 Problem statement

Many Kenyan processors/exporters are certified to standards such as the International Food Standard (IFS) or GlobalGAP and the BRC food safety standard (Mithofer et al, 2008). However, the degree to which these approaches can guarantee safety and quality is not known as studies on reliability of third-party certification and those addressing auditors’ independence and objectiveness are few (Albersmeiret al., 2009). It has been found that most producers in developing countries get certified or comply with private voluntary standards not because of the perceived benefits, but because their buyer demands it (MacGregor, 2009).

As a result, food processing companies are obliged to direct more efforts and resources towards designing and implementing effective and efficient food safety management systems in order to comply with requirements and to deliver safe food products (Jacxsens et al, 2011). The producers
are also challenged in attempts to combine requirements from different stakeholders e.g. government, retailers and consumers in designing and implementing the FSMS (Jacxsens et al., 2010). Developing countries are also becoming more and more integrated in the global high income fresh food markets and this means that their FSMSs must adapt to the stringent quality and safety standards and regulations in these markets (Unnevehr, 2000; Trienekens and Zuubier, 2007).

Performance of currently implemented FSMS also not yet effective (Stuart, 2008) as food borne outbreaks due to contaminated fresh or minimally processed fruits and vegetables have been reported recently (Olaimat and Holley, 2012). Alerts, interceptions and rejection rates due to safety concerns also appear to be increasing in export markets. For instance, the Kenya Plant Health Inspectorate Service (KEPHIS) 2009/2010 annual report indicated that a total of 112 interceptions of fruits and vegetables were communicated to KEPHIS from export destinations compared to 63 in the previous year, and most of these were in the European Union (KEPHIS, 2010). Consequently, questions on the effectiveness of currently applied FSMSs in preventing and controlling food safety hazards have been raised (Jacxsens et al., 2010; Luning et al., 2011; 2013). Methods of FSMS evaluation commonly used focus on verification of actual microbiological safety output and audit of an implemented FSMS against specified requirements. Even though these FSMS evaluation techniques presuppose safer food when control and assurance activities are properly executed, they do not assess actual activities in the FSMS (Luning et al., 2011). Assessing the performance of implementation of FSMS in fresh produce is therefore necessary in order to determine the effectiveness of the interventions used to control hazards and assure safety and to identify bottlenecks for further improvement of the FSMS (Fraser and Monteiro, 2009; Luning et al., 2009b).
1.2 Justification

Fruits and vegetables are often eaten raw or minimally processed, yet elimination of contamination is limited due to the nature of the products, their intended use and interventions that can be applied (Kirezieva et al., 2013). Consequently, food-borne outbreaks associated with fresh produce appear to be on the increase as recent reports indicate (Jacxsens et al., 2010; EFSA, 2011). This suggests inadequacies in implementation of FSMS in companies along the fresh produce supply chain (Ilic et al., 2008; 2012). However, information related to these inadequacies is restricted by a lack of in-depth understanding of activities and factors that are crucial in FSMS performance, and little is known about the status of the FSMS as current methods of evaluation do not assess actual activities in the FSMS (Luning et al., 2008).

In export sectors, often more than one FSMS are used concurrently and within countries, there are rarely uniform standards for processors and distributors (Henson and Mitullah, 2004; FAO, 2007c). In addition, food safety and quality issues are more likely to be a concern in fresh food products (unlike processed food products) because handling at all points in the chain can influence its safety and quality (Unnevehr, 2000). As such, considerable efforts have been made in the development and implementation of FSMS in horticultural production chains in preventing and anticipating safety concerns (Jacxsens et al., 2009; Da Cruz et al., 2006). The translation of these requirements into a product-specific system remains a challenge because requirements and guidelines are often generic and producers may lack guidance, information, resources and knowledge for effective implementation in their own circumstances (Pachepsky et al., 2011; Hatanaka et al., 2005). Therefore an understanding of critical factors influencing performance of FSMS in fresh produce and horticultural production chains would ensure food safety in the short and long term.
This study therefore, is aimed at using the principles and demonstrating the usefulness of FSMS assessment tools that have been developed under European Union (EU) projects (PathogenCombat and Veg-i-Trade), in outlining the status of the FSMS in the Kenyan fresh produce export processing sector. This aims at enhancing knowledge in assessment of the performance of fresh produce food safety management systems using a FSMS diagnostic tool (FSMS-DI) (Luning et al., 2008;2009b) and a microbial assessment scheme (MAS) (Jacxsens et al., 2009). The FSMS-DI is a structured questionnaire with situational and level descriptions for assessment of FSMS context and activities. The MAS tool facilitates a systematic analysis of microbial counts in order to evaluate the microbiological performance of an implemented FSMS. The tools have recently been tested in case studies performed in the European meat and dairy industries (and the on-going Veg-i-trade project). The measurement of the set-up and performance of the FSMS will lead to roadmaps for improvement of the safety and quality of fresh produce.

1.3 Broad/main objective
To assess the performance and options for improvement of the fresh produce safety and quality management systems in Kenya

1.4 Specific Objectives
1. To evaluate the performance of the fresh produce core control activities, core assurance activities and food safety output amongst selected fresh produce export processors given the context in which they operate.

2. To assess the actual food safety output (microbiological performance) of the fresh produce safety management system for selected fresh produce processors.
3. To relate the actual food safety output (microbiological performance) with the food safety management system for selected fresh produce processors.

1.7 Hypotheses

1. Fresh produce safety management systems performing on a higher level are more predictable and are better able to achieve a desired safety outcome.

2. The food safety output of fresh produce safety management system does not depend on the safety management system.

3. Low numbers of microorganisms and low variations in counts in the analyzed samples indicate an effective FSMS and increased food safety output.
Chapter 2

Literature Review

2.1 Introduction

The food industry has adopted management practices that focus on prevention and control of food safety hazards. Hazards are expensive to test for and may enter food products at several points in the production process. Therefore, documented production practices, that are verified to prevent and control hazards, are becoming accepted as the most cost-effective means of reducing food safety hazards. While testing and verification are essential for establishing good process controls, testing can never be practical as the only means of monitoring safety (Unnevehr, 2000; FAO, 2007a).

At the same time, exports of non-traditional food and agricultural commodities especially fresh and minimally processed products from developing to developed countries have increased, driven by changing consumer tastes and advances in production, transport and supply chain technologies (Uyttendaele et al., 2010; Jacxsens et al, 2010; FAO, 2007b). Fresh fruit and vegetables, fish, meat, nuts and spices now account for more than 50 percent of the total agro-food exports of developing countries (FAOSTAT, 2013). Compliance with food safety regulations has therefore become a ticket for accessing the global food value chain as the past few decades have seen significant new developments that have tightened controls in different countries (Mensah and Julien, 2011).

Kenya exports fresh and minimally processed vegetables such green beans (French and runner beans), peas (snow peas and sugar snaps), a variety of leafy vegetables, squash, aubergines, chilli peppers, sweet corn, herbs and tropical fruits (mango, avocado, papaya and passion fruit) (Legge et al., 2008). The Horticultural Crops Development Authority (HCDA) annual statistics indicates
that Kenya exported about 32,000 and 75,000 metric tonnes of fresh fruits and vegetables respectively in 2009 and 2010 (HCDA, 2011).

However, it has been established that developing countries’ producers face challenges and pressures related to food safety and quality compliance due to weak financial capacity to implement food safety compliance aspects, limited access to information on standards and increased cost of production (Nanyunja et al., 2013). On the international food market, developing countries face stiff competition due to price and quality of products from other countries and majority being small economies, the volume of production destined for the global market is relatively small (Okello et al., 2007; Nanyunja et al., 2013).

2.2 Food Safety Management Systems

The development of food safety management systems that supplement and/or replace traditional end-product inspection and testing procedures, and their extension to all steps of the food chain has been one of the major developments in the last 15 years (FAO, 2007a). The systematic adoption and use of these systems, including Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), Good Hygienic Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) have accompanied the development of the farm to table approach. These approaches are now recognized as the most effective way to achieve maximum consumer protection. This is done by ensuring that regulatory and non-regulatory measures are applied at the most outcome-effective points in the food chain, from primary production practices to the point of sale or distribution to consumers (Trienekens and Zuurbier, 2007; FAO, 2007a)

FSMSs comprise various preventive and performance-based measures that allow greater flexibility to achieve the desired level of protection most efficiently. They are now frequently
required for domestic and/or international trade. The widespread adoption of these systems by the food retail and commercial sectors has led to a proliferation of such systems, each with its own standards, accreditation, auditing and certification processes (Mensah and Julien, 2011; Albersmeier et al., 2009).

There is also shift in thinking about the roles of stakeholders from farm to table and direct responsibility for food safety control is passing from governments to producers, processors and other entities in the food chain (FAO, 2007a). Food producers and enterprises are recognized as best placed to devise and manage systems for ensuring that the food they supply is safe and as such have legal responsibility for meeting the food safety requirements established by governments and customers (Jacxsens et al., 2011).

As global trade in fruits and vegetables continues to expand, developing countries such as Kenya make efforts to seize the opportunities in the global fresh produce markets. However, this comes along with food safety demands by importing countries such as the EU market. Attention therefore needs to be focused on assessing the capacity of Kenya’s processors and exporters to guarantee supplies of high quality and safety. It is therefore important to diagnose the performance of their implemented food safety management systems for the purpose of determining their food safety output as well as identifying key areas for improvement (Jacxsens et al., 2011).

2.3 Performance measurement of a food safety management system

Food processing companies dedicate much effort and resources in designing and maintaining their food safety management systems and thus it is necessary to evaluate and improve the performance of the implemented FSMS in order to assure food safety and meet consumer and stakeholder requirements (Luning et al., 2011; Jacxsens et al., 2011). Methods of evaluation
commonly used focus on analyzing actual microbiological safety output and analysis of activities in an implemented FSMS against preset requirements with the assumption that fulfilled requirements results in a good food safety output. However, these methods do not give insight on the actual activities in the FSMS (Luning et al., 2008; Jacxsens et al., 2010a). It is therefore necessary to systematically analyze and evaluate performance of food safety control and assurance activities, taking into account present and anticipated contextual situations in order to assure safety of fresh produce in the short and long term (Jacxsens et al., 2010a). This kind of assessment gives insight in weaknesses and strengths of a FSMS and can serve as basis for discussion about possible solutions for improvement and changing of quality assurance (QA) requirements of currently implemented systems.

2.3.1 Food Safety Management System Diagnostic Instrument

Luning et al. (2008, 2009, and 2011a) presented the FSMS-diagnostic instrument (FSMS-DI) to assess context, safety control and assurance activities in a food safety management system. The tool has also been extended to FSMS in fresh produce, taking into account activities that are pertinent to fresh produce across the supply chain (primary production, processing and trade) (Kirezieva et al., 2013). The FSMS-DI enables a systematic analysis and differentiated assessment of levels at which core control and assurance activities are executed in a company in order to realize and ensure that food safety requirements are met. This is independent of the quality assurance standards and guidelines that have been implemented (Luning et al., 2008; 2009). It also enables a systematic and differentiated assessment of contextual factors to judge the vulnerability, uncertainty and ambiguity of the circumstances wherein the system has to operate (Luning et al., 2011a). A context factor is defined as structural elements of a situation that affect decision-making activities in the FSMS, and its food safety output. The four factors
included in FSMS context are product, process, organisational, and chain environment characteristics. (Luning et al., 2011). The principle behind it is that FSMS that operate in a more vulnerable, uncertain, and ambiguous situation should have a FSMS with more specific and scientifically-underpinned control and assurance activities that are critically analysed, structured, procedure-based and independent (Luning et al., 2009). The assessment of FSMS applied in fresh produce processing will be important in establishing the level at which FSMS activities have been translated by Kenyan fresh produce processors and exporters with a view of obtaining insight on activities that are crucial for FSMS performance, given the level at which they are implemented.

2.3.2 Microbiological Assessment Scheme

In addition to the FSMS-DI, a Microbiological Assessment Scheme (MAS) to support a systematic FSMS microbiological performance analysis has been elaborated. The MAS tool facilitates a systematic analysis of microbiological counts in order to evaluate the microbiological performance of an implemented FSMS (Jacxsens et al., 2009). MAS is a protocol that supports in the identification of critical sampling locations, the selection of microbiological parameters, the assessment of sampling frequency, the selection of sampling method and method of analysis, results interpretation criteria and data processing (Jacxsens et al., 2009; Luning et al., 2011b; Lahou et al., 2011). Based on MAS, microbiological safety level profiles can be derived indicating microorganisms and the extent to which they contribute to food safety for a specific company. The assumption is that low numbers of microorganisms and small variations in microbiological counts indicate an effective FSMS (Jacxsens et al., 2009).

The combined assessment using both FSMS-DI and MAS tools provide insight in weak and strong points in the system and can serve as basis for strategic decisions on FSMS
improvements. The ongoing climate change and complex international supply chains (due to globalization and increasing fresh produce consumption) are expected to become crucial contextual factors that could affect performance of FSMS in the near future (Jacxsens et al., 2010a; Holvoet et al., 2012). Large scale assessment using both tools (quantitative assessment) over the whole fresh produce chain can assist in mapping and analyzing weaknesses in the systems which in turn will facilitate the formulation of solutions to enhance FSMS performance.

2.4 Case studies illustrating the usefulness of the diagnostic tools

The usefulness of the diagnostic tools (FSMS-DI and MAS) applied singly or concurrently have enabled the profiling of FSMS output and provided specific information on FSMS activities in meat and poultry processing (Sampers et al., 2010; Oses et al., 2012; Luning et al., 2011), food service establishments (Luning et al., 2013; Lahou et al., 2011), dairy processing (Opiyo et al., 2013; Sampers et al., 2012) and in water management practices in fresh produce processing (Holvoet et al., 2012).

Sampers et al. (2010) studied two Belgian poultry processing firms using the FSMS-DI and MAS. The study was conducted to obtain insight into control and QA activities as addressed in an implemented FSMS in relation to the prevalence and distribution of *Campylobacter* spp. in poultry meat preparations, as previously established in a Belgian nationwide survey in 2007. The MAS and FSMS-DI were used to objectively evaluate the performance of the FSMS of the two poultry companies. The MAS results revealed differences in the distribution of *Campylobacter spp.* counts in both companies. MAS also reflected the difference in the overall microbial performance. With respect to the contextual situation of the companies, one company had organization characteristics that created a lower risk of inadequate decision making in the FSMS compared with the other company. Nevertheless, both companies had to deal with high-risk
product and process characteristics, which put high demands on the level of design and actual operation of the crucial control and quality assurance (QA) activities in their FSMS. The in-depth analysis of the MAS results and FSMS diagnosis enabled the derivation of possible interventions to reduce the riskiness of the context and/or improve the levels of certain control and safety assurance activities.

In another study to demonstrate the usefulness of a concurrent analysis of FSMS performance and food safety (FS) output, Luning et al. (2011b) analysed three companies (small, medium and large-sized) that processed meat. All companies had a food safety management system in place based on the same regulatory requirements but their food safety output differed. The results of the FSMS diagnosis also revealed differences and insufficiencies in the core control and assurance activities for two of the companies. In one company, the activity and context diagnosis did not indicate problems, while the output diagnosis showed high total viable counts (TVC), which could only be solved through supplier measures. Also, in one of the companies, the diagnosis output showed various contamination problems, and the activity and context diagnosis showed various low activity levels. This is an indication that problems are not always directly related to a lower activity levels in the FSMS, but also depends on context situation.

A combined assessment of FSMS in three slaughter houses, one processing plant and nine butcher shops in Spanish lamb chain indicated the FSMS activities that needed to be performed at higher levels in order to improve the food safety output. The study also revealed from a chain perspective that high contamination at the initial stages of slaughter persisted to the subsequent actors in the chain due to differences in FSMS organization (Oses et al., 2012).

Opiyo et al. (2013) applied the MAS protocol to assess the microbial performance FSMS of fourteen Kenyan dairy processors. The results established that poor implementation of pre-
requisite programmes in some processing plants led to poor microbial quality end products due to cross contamination from either handlers’ hands or dirty product contact surfaces.

Microbial performance of water management practices in fresh produce processing assessed in some Belgian lettuce processing companies using MAS provided insight on the degree of microbial contamination in the processing chain (Holvoet et al., 2012). The MAS protocol was adapted to fresh-cut processing to gain information on water management practices as an important potential source of microbial contamination, washing being an intervention step in fresh produce processing (ICMSF, 2011). The study established that washing produce with water of poor quality led to cross-contamination and an increase in microbial load. Results of the study also indicated that the washing step in the production process of fresh-cut lettuce and water may act as vehicle for dispersion and introduction of micro-organisms via cross-contamination to the end product rather than an intervention step to reduce microbial contamination (Holvoet et al., 2012).

2.5 Kenyan fresh produce sector

The fresh produce sector in Kenya is associated with significant smallholder involvement, especially at the farm level. It has been estimated that three-quarters of fruit and vegetable for export comes from smallholders (Okello et al., 2007). However, it is acknowledged that smallholder involvement has significantly declined due to pressures from GlobalGAP compliance (Legge et al., 2008).

In addition, many exporting processors are certified to standards such as the International Food Standard (IFS) and the BRC food safety standard (Mithofer et al, 2008). However, the degree to which these approaches can guarantee safety and quality is not known as studies on reliability of third-party certification and those addressing auditors’ independence and objectiveness are
limited (Albersmeir et al., 2009). It has been found that most producers in developing countries get certified or comply with private voluntary standards not because of the perceived benefits, but because their buyer demands it (MacGregor, 2009).

Kenyan fresh produce processing and exporting companies therefore need to systematically analyse their FSMS in order to improve their food safety output and meet the food safety assurance needs of customers and other stakeholder. This will enhance the competitiveness of Kenyan produce in exports markets, thereby contributing to the country’s economic growth. The assessment of FSMS activity levels and context riskiness in relation to the actual microbiological output provides insight on causes of safety problems. This indicates distinct directions for improvements towards higher FSMS activity or lower risk levels in context characteristics (Luning et al, 2011).
Chapter 3

Performance of current food safety management systems applied in fresh produce exporting industry in Kenya: a case study

Abstract

Food producers are required to implement different food safety and quality assurance standards and guidelines which may result in variable food safety performance or output due to differences in technological development, resource access, food safety legal framework and the dynamic environment in which they operate. The aim of this study was to evaluate the performance of food safety management systems (FSMS) in the fresh produce processing sector in Kenya. The risk posed by the context in which they operate was assessed. A FSMS diagnostic instrument based on indicators and descriptive grids for context factors, control and assurance activities and food safety output was used to evaluate thirteen fresh produce exporting processors in Kenya.

Majority of the processors (≥7) operate at moderate level in most of the context riskiness indicators (74 %). Seven out of the 13 processors indicated that susceptibility of initial material to microbial contamination posed the highest risk with respect to product characteristics. Even though majority of the companies had advanced level core control activities performance for 6 out of 29 of the activities, they showed a moderate performance in 48 % of the activities and 24 % control activities were not applied. Core assurance activities for majority of the companies also performed moderately in 89 % of the indicators. FSMS performance was poor for 53 % and good for 37 % of the processors. All the processors had advanced scores for monitoring of pesticide residues but five lack sampling and consequent criteria for microbial analysis. The FSMS implementation for 77 % of the companies was poor to moderate and, given the moderate context riskiness, this therefore resulted in moderate FSMS-output.
The mostly moderate FSMS activity levels when assessed in the context riskiness lower the food safety performance of the fresh produce sector. Several recommended control and assurance activities in fresh produce sector should be improved to advanced levels in order to realize a stable and predictable safety output subject to the riskiness of context situation.

**Key words:** Food Safety Management System, Diagnostic Tool, fresh produce industry, context characteristics, control activities, assurance activities

### 3.1 Introduction

One of the major developments of the last two decades has been the advancement of food safety management systems (FSMS) that supplement and/or replace traditional end-product inspection and testing procedures and their extension to all rungs of the food chain (FAO, 2007a). These FSMSs address food safety hazards that ‘are reasonably expected to occur’ at different points in the food chain, or are difficult to monitor (ISO 22000:2005, 2005). The progressive adoption and use of these Hazard Analysis and Critical Control Point - based (HACCP) systems in combination with the farm to table approach provides the most effective way to achieve maximum consumer protection by ensuring that regulatory and non-regulatory measures are applied at specific points in the food chain. (CAC, 2003; Trienekens and Zuurbier, 2007; FAO, 2007a).

At the same time, trade in fresh food products has grown in comparison to traditional processed products. This has been attributed to, among others, the perceived health benefits associated with fruits and vegetables, air transport, as well as advances in maintenance of the cold storage throughout the supply chain (Jacxsens et al., 2009). Many countries have experienced growth in exports of non-traditional agricultural specialty food products, such as fruits and vegetables (Unnevehr, 2000). However, fresh food products have greater potential for food safety risks with
sanitary and phyto-sanitary (SPS) measures assuming greater importance in determining market access (Roberts, 1998; Okello et al., 2007; Henson et al., 2011; Stanton and Wolff, 2008).

To reduce safety risks, food safety and quality management has therefore assumed great importance as a key driver for organization and management of food production systems in the agribusiness and food industry (Luning et al., 2009). Substantial investments and efforts have been made in the development and implementation of FSMS (da Cruz et al., 2006; Jacxsens et al., 2010) to prevent introduction of and control food safety hazards along the supply chain (Jacxsens et al., 2009). These FSMSs comprise various preventive and performance-based measures that allow flexibility to achieve the desired level of protection most efficiently and are now frequently required for domestic and/or international market access through third party certification to one or more standards (Stanton and Wolff, 2008).

However, the effectiveness of these FSMS vary widely due to differences in interpretation (Ropkins and Beck, 2000), and there have been concerns in terms of both cost to industry and public health benefit (Unnevehr and Jensen, 1999). Moreover, governments are concerned about the fact that safety measures in place have been ineffective in reducing food-borne illnesses (Motarjemi and Kaferstein, 1999; Warriner et al., 2009). Recent years have witnessed an increase in hazards associated with fresh produce (Olaimat and Holley, 2012), for example, the recent outbreak of E. coli O104:H4 in Germany. In January 2011, a workshop organized by the European Union (EU) Veg-i-Trade project to capture opinions of stakeholders on food safety issues in the global fresh produce supply chain identified bacterial pathogens, viruses and pesticide residues as three most important concerns (van Boxstael et al., 2013). Fresh produce from tropical regions with pesticide residues exceeding European Union’s maximum residue limits (EU MRLs) are also common place (EFSA, 2011).
In addition, the widespread adoption of these FSMS by the food retail and commercial sectors has led to a proliferation of such systems, each with its own standards, accreditation, auditing and certification processes (Albersmeier et al., 2009). Food producers may therefore be required to combine and implement different safety and quality assurance standards and guidelines into their FSMS such as British Retail Consortium (BRC), ISO 22000, Tesco Nature Source (TNS) and Carrefour (Luning et al., 2009; 2011b) depending on customer requirements. This results in variable implementation and safety output of the systems due to differences in access to information on standards, food safety legal framework and resource constraints (FAO, 2007a).

Furthermore, food business operators also aim to enhance returns on their investments as these systems require huge technological, financial and managerial inputs and to determine the aspects of FSMS that need improvement (Jacxsens et al., 2010).

Moreover, third party audits and inspection systems, in their current form, have limitations in improving food safety as food-borne illness outbreaks have been linked to farms, processors and retailers that went through some form of certification audit (Albersmeier et al., 2009). There is also constant pressure on these systems due to the dynamic environment wherein the systems operate due to such factors as established and emerging food-borne hazards, high-profile bans and rejections of food products in export markets due to safety concerns, technological changes in food production, marketing and distribution, and increasing consumer awareness (FAO, 2007a).

Need for tools to empower food producers in the diagnosis of their FSMS to assess weaknesses and identify potential areas for improvement therefore arose (Luning et al., 2008). Luning et al. (2008; 2009; 2011) and Jacxsens et al. (2011) recently reported on an FSMS diagnostic instrument (FSMS-DI) to diagnose the performance of a FSMS, independent of quality and
safety assurance standards and legislative guidelines being implemented. The instrument has been developed and validated under the European Union (EU) project, PathogenCombat, and allows a system analysis based on indicators and situational description of context factors, core control and assurance activities and food safety performance of a FSMS (Luning et al., 2008, 2009, 2011; Jacxsens et al., 2010, 2011). Similarly, a diagnostic tool has been developed for the fresh produce sector and tailored for the global context under the EU Veg-i-Trade project (Kirezieva et al., 2013). The diagnostic tool covers the fresh produce supply chain from primary production to trade.

The fresh produce sector processing tool comprises seventy one indicators with different levels of descriptions to assess: 1) risk levels of context factors affecting the FSMS performance (Luning et al., 2011), 2) core control activities (Luning et al., 2008), 3) core assurance activities addressed in the FSMS (Luning et al., 2009) and 4) FSMS output level measured by food safety performance indicators (Jacxsens et al., 2010).

Context factors are structural elements of a situation that affect decision- making activities in the FSMS and consequently, its food safety output. It includes product and production process characteristics as well as the organization’s set-up and the environment in which it operates (Luning et al., 2011). For each context indicator a matrix giving three descriptions of level of riskiness corresponding with a low, moderate and high-risk is given (Luning et al., 2009; 2010). Food safety management system control and assurance are aimed at realising food safety and providing confidence that safety requirements will be met (Luning and Marcelis, 2007), both activities contributing to the overall performance of a food safety management system. The control activities comprise preventive measures, intervention processes and monitoring systems and their operation. Each control and assurance activity indicator comprises a matrix with four
situational descriptions representing activities and the levels at which they are implemented, which may be ‘not applied’, basic, average or advanced.

Food safety output, on the other hand, measures the ability of an implemented FSMS to control and prevent food safety hazards (Jacxsens et al., 2010). Internal and external food safety performance indicators have also been described along with four different situational levels of performance that give an indication of the level of food safety output of a FSMS. They include evaluation of FSMS through audits and inspections and type of non-conformances, nature of complaints and how they are addressed, frequency of sampling for chemical and microbial analysis and the criteria used for interpretation of results (Jacxsens et al., 2009; 2010). The objective of this study was therefore to assess the performance of FSMSs implemented by some fresh produce processing export companies subject to the contextual pressure. Strengths and weaknesses and potential areas for improvement were identified.

3.2 Materials and Methods

3.2.1 Characterization of firms

The FSMS diagnosis was carried out in 13 Kenyan export-oriented fresh produce processing companies coded P1 to P13 for confidentiality. All the companies obtained their initial materials from own farms or from subcontracted out-growers based in various growing regions. The farms were Global GAP certified. The companies process various vegetables including various green beans, peas, leafy vegetables, spring onions, broccoli, herbs and stir-fry mixes. Most of the companies are certified to the British Retail Consortium (BRC) food safety management system, and customer based-standards such as Tesco Nature Source. Table 1 gives a summary of the characteristics of the assessed firms.
Table 1. Characteristics of the vegetable processing exporters studied

<table>
<thead>
<tr>
<th>Processor</th>
<th>No. of employees</th>
<th>No. in QA department</th>
<th>Products</th>
<th>FSMS certified standard</th>
<th>Tonnes exported per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>50-249</td>
<td>N/A</td>
<td>F, V</td>
<td>N/A</td>
<td>1500</td>
</tr>
<tr>
<td>P2</td>
<td>50-249</td>
<td>20</td>
<td>F, V</td>
<td>BRC</td>
<td>8000</td>
</tr>
<tr>
<td>P3</td>
<td>&gt;249</td>
<td>20</td>
<td>F, V</td>
<td>BRC</td>
<td>3000</td>
</tr>
<tr>
<td>P4</td>
<td>50-249</td>
<td>30</td>
<td>V, H</td>
<td>BRC, CBS</td>
<td>9000</td>
</tr>
<tr>
<td>P5</td>
<td>50-249</td>
<td>20</td>
<td>V</td>
<td>BRC</td>
<td>1200</td>
</tr>
<tr>
<td>P6</td>
<td>50-249</td>
<td>11</td>
<td>V</td>
<td>BRC</td>
<td>2000</td>
</tr>
<tr>
<td>P7</td>
<td>50-249</td>
<td>6</td>
<td>V</td>
<td>N/A</td>
<td>500</td>
</tr>
<tr>
<td>P8</td>
<td>&gt;249</td>
<td>33</td>
<td>V, H</td>
<td>BRC, CBS</td>
<td>7800</td>
</tr>
<tr>
<td>P9</td>
<td>&gt;249</td>
<td>35</td>
<td>V, F</td>
<td>BRC, CBS</td>
<td>5000</td>
</tr>
<tr>
<td>P10</td>
<td>50-249</td>
<td>7</td>
<td>F, V</td>
<td>N/A</td>
<td>500</td>
</tr>
<tr>
<td>P11</td>
<td>50-249</td>
<td>4</td>
<td>V</td>
<td>ISO 22000</td>
<td>1000</td>
</tr>
<tr>
<td>P12</td>
<td>&gt;249</td>
<td>50</td>
<td>V</td>
<td>BRC, CBS</td>
<td>8000</td>
</tr>
<tr>
<td>P13</td>
<td>50-249</td>
<td>120</td>
<td>V, H</td>
<td>BRC, CBS</td>
<td>7000</td>
</tr>
</tbody>
</table>


3.2.2 Food Safety Management System Diagnosis

The FSMS diagnosis involved interviews and in-depth discussions with quality assurance personnel of the respective companies using the structured questionnaire (Appendix 1). For each indicator, the interviewees had to choose which level of risk (context) or FSMS activity was most representative for their situation. Each question had supporting statements to guide the interviewee in selecting the company’s most typical situation as described in the questionnaire. With this assessment, an insight on the context riskiness and levels at which FSMS activities were implemented in each company was obtained.
3.2.3 Diagnosis of riskiness in context
The first part of the diagnosis involved the assessment of the FSMS context which encompasses product characteristics (5 indicators), process characteristics (3 indicators), organization characteristics (7 indicators) and chain characteristics (8 indicators). For each risk or context indicator, the respondent had to choose the matrix that best suited or described their situation. These were: situation 1 (low risk), situation 2 (moderate risk) and situation 3 (high risk).

3.2.4 Diagnosis of control and assurance activities
FSMS control and assurance indicators comprised 29 and 9 indicators respectively. For each control and assurance activity, the respondents also had to choose the level or situation that best described their activities’ performance levels, whether ‘not conducted or applied’ (situation 1), basic (situation 2), average (situation 3) or advanced (situation 4). Situation 1 means the activity is not implemented or not conducted (score 0). The basic level (situation 2) for control activities is typified by use of own experience, general knowledge, ad-hoc analysis, incomplete descriptions or registration or programmes, not bench-marked, instability and/or regular problems. The basic level (situation 2) for assurance activities is characterized by problem-driven situations which are only checked when problems arise, rarely reported and lack of independence. The average level (situation 3) for control activities makes use of expert (supplier) knowledge, sector or governmental guidelines, best practices and standardized methods with occasional problems. The average level for assurance activities corresponds with active translation of stakeholder requirements, extra analysis and documentation of the system, regular reporting of status, and input of experts. The advanced level (situation 4) means that the control or assurance activity is characterized by use of specific information, science-based knowledge, critical and in-depth analyses, systematic methodology and autonomous positions (Luning et al, 2009).
3.2.5 Diagnosis of food safety output

Similarly for the food safety output, the interviewees had to select the grid that best depicted their FSMS performance or output for the 10 food safety performance indicators. These were ‘not done’ (situation 1), poor (situation 2), moderate (situation 3) and good food safety output (situation 4). These situational levels of performance correspond with scores of 0, 1, 2 and 3 respectively and were thus scored (Kirezieva et al., 2013; Jacksens et al., 2010). Level 0 means no indication of food safety performance and refers to absent, not present or not conducted. It means that the FSMS evaluation is not done, and/or that the specific food safety performance information is not known. Level 1 means poor performance and is associated with aspects like ad-hoc sampling, minimal criteria used for FSMS evaluation, and existence of various food safety problems due to different problems in the FSMS. Level 2 represents moderate performance and refers to regular sampling; several criteria used for FSMS evaluation, and restricted food safety problems mainly due to one (restricted) type of problem in the FSMS. Level 3 which mean good performance portrays a systematic evaluation of the FSMS using specific criteria and existence of no safety problems (Jacxsens et al., 2010).

To obtain an indication of the microbiological performance as judged by the external evaluation, the indicator ‘seriousness of remarks’ has been defined. Level 3 implies that all requirements of the stakeholders have been met and no major remarks and/or only minor remarks on aspects of the FSMS are observed, and hence, a good food safety performance.

3.3 Data Analysis

The FSMS assessment resulted in a total of 71 indicators with differing scores for each processor. The scores for level of risk ranged from one (low risk) to three (high risk). The scores for context riskiness indicators for each processor were then added and a mean obtained. The FSMS activity
and food safety output scores ranged from zero (not applied or done) to three (advanced for FSMS activities and good for food safety output). Similarly, these scores were added up and means obtained for both FSMS activities and food safety performance of each processor. These were done using Excel Spreadsheet (Microsoft Corporation). Because the scores represented qualitative descriptions, the scores were then transformed to assigned scores according to Luning et al. (2011; 2013) and Sampers et al. (2012)(Table 2). The assigned scores represent the range wherein the mean falls and provide an indication of the overall level of context riskiness and FSMS performance.

Table 2. Overall mean values and the corresponding assigned scores of food safety management system activities and context indicators

<table>
<thead>
<tr>
<th>Mean activities</th>
<th>FSMS</th>
<th>Assigned score</th>
<th>Mean scores Context</th>
<th>Assigned score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 1.2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 – 2.2</td>
<td>2</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2.3 – 2.7</td>
<td>2- 3</td>
<td></td>
<td>1.3-1.7</td>
<td>1-2</td>
</tr>
<tr>
<td>2.8 – 3.2</td>
<td>3</td>
<td></td>
<td>1.8-2.2</td>
<td>2</td>
</tr>
<tr>
<td>3.3 – 3.7</td>
<td>3 -4</td>
<td></td>
<td>2.3-2.7</td>
<td>2-3</td>
</tr>
<tr>
<td>3.8 – 4.0</td>
<td>4</td>
<td></td>
<td>2.8-3.0</td>
<td>3</td>
</tr>
</tbody>
</table>

FSMS- food safety management systems

3.3 Results and discussion

3.3.1 Context factors

 Majority of the companies operate under low risk from contextual pressure by climatic conditions (69 % of companies), water supply (all companies), extent of management commitment (69 % of companies) and extent of power in supplier relationships (all companies) (Table 3).
Table 3. Risk level amongst fresh produce export processors as defined by product, production process, organization and chain characteristics.

<table>
<thead>
<tr>
<th>Context Indicators</th>
<th>Risk level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (1)</td>
</tr>
<tr>
<td><strong>Product characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Risk of initial materials- microbial contamination</td>
<td>0</td>
</tr>
<tr>
<td>Risk of initial materials-pesticide contamination</td>
<td>0</td>
</tr>
<tr>
<td>Risk of initial materials-mycotoxins contamination</td>
<td>0</td>
</tr>
<tr>
<td>Risk of final product- microbial</td>
<td>0</td>
</tr>
<tr>
<td>Risk of final product-pesticide</td>
<td>0</td>
</tr>
<tr>
<td><strong>Production Process characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Risk of production system- microbial</td>
<td>0</td>
</tr>
<tr>
<td>Climate conditions</td>
<td>69</td>
</tr>
<tr>
<td>Water supply</td>
<td>100</td>
</tr>
<tr>
<td><strong>Organization characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Presence of technological staff</td>
<td>8</td>
</tr>
<tr>
<td>Variability in workforce composition</td>
<td>0</td>
</tr>
<tr>
<td>Sufficiency of operator competencies</td>
<td>8</td>
</tr>
<tr>
<td>Extent of management commitment</td>
<td>69</td>
</tr>
<tr>
<td>Degree of employee involvement</td>
<td>0</td>
</tr>
<tr>
<td>Level of formalization</td>
<td>15</td>
</tr>
<tr>
<td>Sufficiency supporting information systems</td>
<td>46</td>
</tr>
<tr>
<td><strong>Chain environment characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Severity of stakeholder requirements</td>
<td>46</td>
</tr>
<tr>
<td>Extent of power in supplier relationships</td>
<td>100</td>
</tr>
<tr>
<td>Food safety information exchange</td>
<td>23</td>
</tr>
<tr>
<td>Condition of logistic facilities</td>
<td>0</td>
</tr>
<tr>
<td>Inspections by food safety authorities</td>
<td>0</td>
</tr>
<tr>
<td>Variability of initial material suppliers</td>
<td>23</td>
</tr>
<tr>
<td>Specificity of external support</td>
<td>0</td>
</tr>
<tr>
<td>Food safety legal framework specificity</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: The figures are percentage of processors with low (1), moderate (2) or high (3) risk.
Eighty three percent of the companies operated at moderate risk for 74% of the context riskiness indicators. All 13 companies operated at moderate risk for 8 of the indicators.

Majority of companies (7 out of 13) operated at high risk of microbial contamination for initial materials (Table 3). The 13 companies worked with almost similar products (whole or minimally processed vegetables) mainly green beans, snow peas, sugar snaps and runner beans. However, the seven companies are bigger exporters who handle additional products such as leafy vegetables (e.g. pakchoi, baby spinach, and cabbage), broccoli, herbs, baby corn, butternut, a variety of onions such as chives and leeks. These products are susceptible to microbial contamination due to surface characteristics that provide good conditions for microbial growth (Olaimat and Holley, 2012) hence the high risk (situation 3) on risk of initial material to microbial contamination. The initial materials have different characteristics which support different micro-organisms, as survival of micro-organisms on fresh produce is affected by nutrient availability, toxic compounds released by the plant, competition from other microorganisms and hydration levels (Olaimat and Holley, 2012). These processors also have prepared products such as ready-to-cook vegetable and stir-fry mixes which consists of various cut and shredded vegetables with applied partial physical intervention such as washing with chlorinated water (up to 80 parts per million of chlorine). The susceptibility in final products is affected by the product’s intrinsic properties (water activity, pH, presence of preservatives) as well as the applied intervention (Luning et al., 2011).

The six processors who scored a moderate risk in susceptibility of initial material to microbial contamination deal mainly in green beans, sugar snaps, snow peas, chilies and runner beans which have surface characteristics that may hinder microbial adherence and growth. However, the six processors scored a high risk (situation 3) in terms of risk of final products with respect to
microbial contamination. This may be because the products are either packed whole or with ends trimmed and no intervention is applied. For these six processors, their production process only entails sorting, grading and trimming which is carried out under ambient conditions and with no intervention, therefore relies on preventive measures such as good hygiene practices. Portable water is available in the production premises but the product is not washed prior to packing.

All the thirteen processors reported a moderate risk (score 2) with respect to pesticide contamination in both initial and final products. This is because the processors source their initial materials from GlobalGAP-certified farms in which minimum requirements on good agricultural practices and hygiene requirements are a must (GlobalGAP, 2012). Additionally, only approved pesticides and proper application (rates, methods) is required by the farm assurance, GlobalGAP system hence the moderate risk associated with pesticide contamination. However, for processors with no partial physical intervention, the risk of pesticide contamination on final product was apparently higher because there was no possibility of residual pesticide removal during handling.

Six processors scored a high risk (situation 3) for the contextual factor production process characteristics. This is due to absence of intervention steps. Process characteristics provide an indication about the susceptibility of survival of undesired micro-organisms relative to the applied intervention processes (Luning et al., 2011). The seven other processors operate at situation 2 with respect to this indicator though they handle both pre-packed and prepared products. This is because their processing conditions differ as they have more advanced/rigorous systems due to their capacity. They also process additional products such as ready-to-cook vegetables which are packed in retail-size units ready for shipping to various supermarket chains in Europe. Additionally, these processors are also certified to customer-based standards such as
BRC, Tesco Nature Source (TNS), Woolworths and Marks & Spencer which are deemed more stringent due to the due diligence required by EU food safety laws on retailers. These standards are HACCP-based and are integrated in practice. These processors also have intervention steps such as washing using chilled chlorinated water and production carried out under controlled conditions (lower temperatures) which suppress micro-organisms. Some of their final products such as stir-fry mixes are susceptible to microbial contamination and growth due to cut surfaces despite the partial intervention by washing due to exudates which may support microbial growth (Olaimat and Holley, 2012).

All firms have a quality assurance (QA) department but with varying expertise and level of competence. The number of personnel in the QA department also varies from processor to processor. This may be attributable to size of the firm as well as the requirements of the implemented system and capital outlay or investment. Some companies are large in scale with annual exports of up to 9000 tonnes (P4) while others only export about 1000 tons annually (P10, P11). All the processors have a common turnover of employees (1-5 years) with engagement of temporary operators during the peak seasons, but minimal to high and specific requirements on competence put the risk associated with operators at low to moderate risk. The workforce composition, competence and stability are important for proper execution of food safety controls (Luning et al., 2011).

With the exception of one processor, there was top management commitment and food safety policies in place, providing insight on the degree of top management commitment to food safety and customer requirements. Top management commitment is a fundamental requirement for an effective FSMS, as priorities in food safety management decisions such as investment in
appropriate equipment and setting food safety policy and objectives is influenced by top management (CAC, 2003; ISO 22000:2005, 2005).

The chain environment characteristics are represented by 7 indicators for which all processors clustered around low or moderate risk. None of the processors scored a high risk for these contextual factors. This may be attributable to traceability requirements (CAP 319) as well as the organization of the sector and vertical integration (Okello et al., 2007). The first indicator is severity of stakeholder requirements in which seven of the processors indicated additional stakeholder requirements while for the rest, only general recognized QA standards are required. The indicator ‘severity of stakeholder requirements’ represents the various demands different stakeholders (such as customers and regulators) may indirectly exact on a FSMS in ascertaining that their safety or regulatory needs are being met (Luning et al., 2011). The EU which is the main market for Kenya’s fresh produce is characterized by stringent food safety regulations which places the responsibility for ensuring safety on retailers, and in turn have their own food safety standards. Consumers are also knowledgeable on food safety issues (Okello et al. 2007). The processors are therefore challenged by these requirements (Unnevehr, 2000).

All 13 companies indicated being explicitly involved in supplier relationships, including product specifications. The processors can therefore influence the FSMS and/or quality management systems of their major suppliers through audits. Initial materials are sourced from own farms or subcontracted farmers who are GlobalGAP-certified and get technical advice from their buyers (Okello et al., 2007). Supplier control is an important activity that segregates safe suppliers from unsafe ones, and leads to a higher confidence in the safety of purchased initial materials (Kirezieva et al., 2013).
3.3.2 Core Control Activities

Seventeen percent of the companies operated at advanced level in 21% of the core control activities. However there was a moderate performance by 33% of companies in 48% of core control indicators and 41% (12 out of 29) of the indicators were not applied. There was either basic level application or lack in FSMS of 6 indicators in all 13 companies especially those related to physical intervention and packaging intervention equipment (Table 4).

Packaging is mostly done manually with personnel putting the final product in the packages before sealing using simple induction sealing machines. Punnets are wrapped with clear film using over-lay machines. All the 13 processors placed personnel hygiene requirements at an advanced level (situation 4) which places high and specific requirements for all food operators on clothing, personal care and health, specific training and hygiene instructions which are implemented in daily practice. Additionally, all food handlers have to comply with national public health legislation requirements on communicable diseases (CAP 319, 2008). Equipment and facilities meet basic hygiene requirements (situation 2) in all companies assessed.

All the 13 processors did not apply full physical intervention but make use of partial physical interventions methods. Such methods include sorting and chemical decontamination techniques aimed at enhancing food safety through the reduction of physical contaminants and microbial load (FAO, 2010). Five companies applied basic partial physical intervention where the products are sorted, graded and packed either when whole or trimmed. These are generic processes which can be applied to any product and whose efficacy in reducing food safety hazards cannot be measured and are therefore considered as basic interventions (Kirezieva et al., 2013). The other eight processors applied ‘best standard’ intervention equipment hence the moderate level for this indicator.
Table 4. Performance levels for core safety control activities amongst fresh produce processors

<table>
<thead>
<tr>
<th>FSMS ACTIVITIES</th>
<th>Performance levels (number of companies)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not applied</td>
</tr>
<tr>
<td>Core safety control activities</td>
<td></td>
</tr>
<tr>
<td>Design of preventive measures</td>
<td></td>
</tr>
<tr>
<td>Sophistication of hygienic design of facilities</td>
<td>0</td>
</tr>
<tr>
<td>Adequacy of maintenance and calibration program</td>
<td>8</td>
</tr>
<tr>
<td>Sophistication of storage facilities</td>
<td>0</td>
</tr>
<tr>
<td>Adequacy of sanitation program</td>
<td>0</td>
</tr>
<tr>
<td>Extent of personnel hygiene requirements</td>
<td>0</td>
</tr>
<tr>
<td>Adequacy of in-coming material control</td>
<td>0</td>
</tr>
<tr>
<td>Packaging equipment</td>
<td>0</td>
</tr>
<tr>
<td>Extent of supplier control</td>
<td>0</td>
</tr>
<tr>
<td>Extent of water control</td>
<td>38</td>
</tr>
<tr>
<td>Design of intervention processes</td>
<td></td>
</tr>
<tr>
<td>Adequacy of full physical intervention equipment</td>
<td>100</td>
</tr>
<tr>
<td>Adequacy of partial physical intervention equipment</td>
<td>38</td>
</tr>
<tr>
<td>Adequacy of chemical intervention strategies</td>
<td>0</td>
</tr>
<tr>
<td>Design of monitoring system</td>
<td></td>
</tr>
<tr>
<td>Appropriateness of CCP analysis</td>
<td>0</td>
</tr>
<tr>
<td>Standards and tolerances design</td>
<td>0</td>
</tr>
<tr>
<td>Adequacy of analytical methods-pathogens</td>
<td>31</td>
</tr>
<tr>
<td>Adequacy of analytical methods-pesticides</td>
<td>0</td>
</tr>
<tr>
<td>Adequacy of measuring equipment to monitor CP</td>
<td>31</td>
</tr>
<tr>
<td>Specificity of sampling plan-microbial assessment</td>
<td>31</td>
</tr>
<tr>
<td>Specificity of sampling plan-pesticide assessment</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Score 0</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Extent of corrective actions</td>
<td>0</td>
</tr>
</tbody>
</table>

**Operation control strategies**

- Actual availability of procedures: 0 8 62 30
- Actual compliance to procedures: 0 8 54 38
- Actual hygienic performance of facilities: 8 22 8 62
- Actual storage/cooling capacity: 0 0 100 0
- Actual process capability of full intervention processes: 100 0 0 0
- Actual process capability of partial physical intervention: 31 0 69 0
- Actual process capability of packaging intervention equipment: 0 100 0 0
- Actual performance of measuring equipment: 31 8 23 38
- Actual performance of analytical equipment: 0 0 0 100

Note: The figures are percentages representing proportion of processors with: Not applied (score 0), basic (score 1), moderate (score 2) and advanced level (score 3) core control activity levels.

The moderate level is associated with equipment with capability that is described in specifications by equipment suppliers but equipment is neither adapted nor tested for the company’s specific circumstances (Luning et al., 2008). It has previously been reported that majority of food processors delegate the responsibility for setting up of the food safety control systems to third parties such as equipment suppliers and consultants who have little understanding of the importance of effectiveness of company specific process (Ilyukhin et al., 2001). When intervention equipment performs at advanced level, the equipment is specifically selected, modified and/or tested to meet a company’s food production specifications (Luning et al., 2011).

All processors analysed their products for pesticide residues in accredited laboratories hence they all placed at an advanced level for this indicator. This is because of the stringent requirements on
maximum residue levels (MRL) set by the EU, which is the major market for Kenya’s fresh vegetables. The criteria for interpretation and/or acceptance of results were established in internal guidelines for processors P2, P4 and P8 but legal documents and customer specifications especially EU MRLs are crucial in determining compliance to requirements for all 13 processors. All the processors scored a low level (situation 1) in standards and tolerances design as tolerances were not clearly specified. The processors had equipment for monitoring process or product status that are offline and not tested for accuracy and consisted mainly of pH meters, metal detectors and hand-held refractometers. This is because the products consist of whole fresh or minimally processed vegetables which are not transformed. However, it has been shown that deficiencies in standards and tolerances can cause safety problems as it is one of the factors that influence the ability of a monitoring system to adequately provide information about the product or process status (Luning et al., 2008).

Twelve firms acknowledged having up-to-date and accessible procedures and majority of operators were aware of the existence of procedures at designated locations hence moderate to high performance for these indicators. The advanced level describes a situation where procedures are readily accessible and with accurate, easy-to-understand and up-to-date content (Luning et al., 2008). Studies have found availability and compliance to procedures useful in dealing with variability of sanitary behavior among fresh produce workers (Kirezieva et al., 2013). Procedures are aimed at directing peoples’ decision-making behavior to obtain certain safety goals but studies have shown that they are often not properly followed leading to undesired safety outcomes (Luning and Marcelis, 2007). Compliance is affected by knowledge of procedures, the right attitude towards their execution (Azanza and Zamora-Luna, 2005; Panisello and Quantick, 2001) and monitoring. A high level of actual compliance corresponds with operators who check
their own compliance, have a comprehensive understanding of safety control tasks and procedures, and with internalized safety control activities (Luning et al., 2008).

The thirteen firms obtained a moderate score for actual storage or cooling capacity. The storage or cooling equipment was indicated to be stable with automatic conditions though no systematic analysis of deviations done. Only temperature and humidity levels were monitored.

No full intervention processes were applied by all the assessed firms due to the technology employed. Full intervention processes include heat treatment processes such as blanching, pasteurization, sterilization and drying, which are not usually applied in fresh cut and minimally processed produce (Kirezieva et al., 2013) though such processes as irradiation have been developed elsewhere (Goodburn and Wallace, 2013).

Actual process capability of partial physical intervention (washing) was at moderate level for nine of the processors, while four firms do not apply any intervention (Table 4). Stability of the processes cannot be determined due to the nature of processing techniques (sorting, trimming, peeling, shelling, washing, spinning etc) used and the varying nature of vegetables.

Packaging was carried out manually by all the assessed firms, therefore the score for actual performance of packaging equipment was basic (situation 2). Whole products such as green bean and sugar snaps were packed loose in cartons as pre-packs while prepared products such as mixed vegetables were packed in smaller units such as punnets and polythene bags which create modified atmosphere conditions (MAP) conditions but the gases in the packages are not monitored. The packs are sealed manually then passed through a metal detector prior to bulking for air freighting. Packaging is an important control activity in fresh produce and therefore its operational capability is crucial (Chua et al., 2008).
3.3.3 Core Assurance activities

Seventy percent of the assessed processors had their assurance activities at moderate level in 89% of the indicators (Table 5). This can be attributed to the currently applied FSMS where 77% of the companies have BRC and ISO 22000 FSMS certification (Table 1) in which assurance activities such as validation, verification and documentation are mandatory (BRC, 2011; ISO 22000, 2005). Assurance activities implemented at higher levels ensures an effective and predictable FSMS and consequently provides confidence that food safety requirements will be achieved (Luning et al., 2009). The Kenyan processors therefore need to advance the level at which assurance activities are executed in order to improve the performance of the FSMS.

The first aspect of core assurance activities is defining system requirements which entail translation of stakeholder requirements into a FSMS and the systematic use of feedback information to modify FSMS. All the processors responded positively to translating stakeholder requirements and systematically using feedback to modify their FSMS. However the smaller processors performed at the basic levels (situation 2) while the bigger processors performed at moderate and advanced levels (situation 3 and 4).

The translation process is vital in aligning, capturing and incorporating stakeholder requirements when designing and implementing a FSMS (Jacxsens et al., 2009). Subsequently, information derived from feedback is used in the updating and modification of the FSMS. Both activities are considered crucial in meeting the assurance sought and compliance criteria set by stakeholders (Luning et al., 2009). The results therefore show that the processors are keen on adapting their FSMS so as to comply with the needs and requirements of their stakeholders.
Table 5. Performance levels for core assurance activities amongst the fresh produce processors

<table>
<thead>
<tr>
<th>FSMS ACTIVITIES</th>
<th>Performance levels</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not applied (0)</td>
<td>Basic (1)</td>
<td>Moderate (2)</td>
<td>Advanced (3)</td>
</tr>
<tr>
<td>Core assurance activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defining system requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Translation of stakeholder requirements into FSMS</td>
<td>0</td>
<td>16</td>
<td>46</td>
<td>38</td>
</tr>
<tr>
<td>Systematic use of feedback to modify FSMS Validation</td>
<td>0</td>
<td>7</td>
<td>62</td>
<td>31</td>
</tr>
<tr>
<td>Extent of validation of preventive measures</td>
<td>0</td>
<td>8</td>
<td>84</td>
<td>8</td>
</tr>
<tr>
<td>Extent of validation of intervention measures</td>
<td>0</td>
<td>0</td>
<td>92</td>
<td>8</td>
</tr>
<tr>
<td>Extent of validation of monitoring system</td>
<td>0</td>
<td>23</td>
<td>62</td>
<td>15</td>
</tr>
<tr>
<td>Verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verification of people related performance</td>
<td>0</td>
<td>15</td>
<td>77</td>
<td>8</td>
</tr>
<tr>
<td>Verification of facilities and methods related</td>
<td>15</td>
<td>8</td>
<td>69</td>
<td>8</td>
</tr>
<tr>
<td>Verification of record-keeping system</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentation system</td>
<td>0</td>
<td>8</td>
<td>62</td>
<td>30</td>
</tr>
<tr>
<td>Record keeping system</td>
<td>0</td>
<td>8</td>
<td>69</td>
<td>23</td>
</tr>
</tbody>
</table>

Note: The figures are percentages representing proportion of processors with: Not applied (score 0), basic (score 1), moderate (score 2) and advanced level (score 3) core assurance activity levels.

For verification of people-related performance, the processors mostly indicated a moderate level (situation 3) in which verification of procedures and compliance is carried out by independent internal staff such as through internal audits. Verification activities include verification of people-related performance, verification of facilities and methods and record-keeping system (Luning et al., 2009). Verification is an important activity as it confirms that food safety hazards are within identified acceptable levels and demonstrates conformity to planned arrangements such as implementation of prerequisite programmes such as good hygiene and sanitation.
practices). It also forms a basis for identifying need for updating or improving the FSMS (ISO 22000, 2005).

About 79% of the assessed processors had their validation activities at moderate level where these activities were achieved with the assistance of an external consultant. Only 10% of the processors had their validation activities at an advanced level, which includes own experimental trials. With respect to verification, 73% of the firms scored moderately for these activities while about 11% were at a basic level. Validation is obtaining evidence that the food safety control measures managed by the HACCP plan are capable of being effective, while verification is confirmation through the provision of objective evidence that specified requirements have been fulfilled (ISO 22000, 2005). Therefore, validation and verification are two very important core assurance activities in a FSMS which provide evidence and confidence to stakeholders that safety requirements will be met. Validation and verification both give insight on the performance of the control system and must be evaluated on its principal effectiveness and proper execution (CAC, 2008). The level at which validation and verification activities are executed in a company gives credence to the control measures in place.

3.3.4 Food safety output
The firms registered FSMS performance scores ranging from poor to good (Table 6). However, majority of the companies operated at moderate levels for most (60%) of the FSMS output indicators. Chemical safety-related complaints were registered by all processors with 54% of the processors operating at level 2 (situation 3) which is indicative of restricted complaints on one specific chemical hazard. This may be due to sector guidelines and EU regulations on MRLs.

The rigorousness of sampling for pesticide residue analysis was placed at an advanced level (situation 4) for all the processors (Table 6) because the Agricultural Produce (Export) Act (CAP
places the responsibility of residue monitoring on the producer and/or exporter. Due to the numerous alerts (Rapid Alert System on Foods and Feed (RASFF) issued by the EU, the frequency of testing for pesticide residues has been intensified on a sector level. Criteria used to interpret pesticide testing results are mainly the EU and Codex MRLs. In this regard, the processors scored a moderate level due to reliance on specifications set by external parties.

Sampling for microbiological analysis was variable among the companies assessed with five companies not carrying out microbial analysis (score of zero) (Table 6). The rest of the companies conduct structured sampling on initial product, final product and environmental samples and therefore obtained a score of 3. Additionally, a combination of legal criteria and customer specifications are used to interpret results hence a moderate score.

Fifty three percent (53 %) of the assessed firms therefore had their food safety output at a moderate level, while only 37 % had a good food safety output (Table 6).

External food safety performance contributed more to the food safety output compared to internal food safety performance. A higher number of processors had either moderate or good scores in external food safety performance indicators (Table 6). Only 15 % of processors had a poor performance in FSMS evaluation and 8 %, a score of zero on registration of microbial-related complaints, whereas in internal food safety performance, five processors did not carry out sampling for microbial analysis. This could be because implementation of FSMS is largely customer or stakeholder-driven, with the processors aiming at meeting customer and regulatory requirements. This is apparent from the scores on ‘translation of stakeholder requirements and systematic use of feedback to modify FSMS’ which indicate presence of a mostly active and pro-active translation of external assurance requirements and regular use of feedback to modify FSMS (Table 5).
Table 6. Food Safety performance levels for fresh produce processors

<table>
<thead>
<tr>
<th>Food Safety performance</th>
<th>Performance levels</th>
<th>Not applied (0)</th>
<th>Poor (1)</th>
<th>Moderate (2)</th>
<th>Good (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External food safety performance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extent of FSMS evaluation</td>
<td>0</td>
<td>16</td>
<td>46</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Seriousness of FSMS evaluation remarks</td>
<td>0</td>
<td>0</td>
<td>31</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>Extent of hygiene and microbial-related complaints</td>
<td>8</td>
<td>0</td>
<td>69</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Extent of chemical-related complaints</td>
<td>0</td>
<td>0</td>
<td>54</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Extent of (visual) quality-related complaints</td>
<td>0</td>
<td>0</td>
<td>85</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td><strong>Internal food safety performance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigorousness of sampling- microbial</td>
<td>38</td>
<td>0</td>
<td>0</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>Criteria used to interpret micro analysis results</td>
<td>38</td>
<td>0</td>
<td>62</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Rigorousness of sampling-pesticide</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Criteria used to interpret pesticide analysis results</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Type of non-conformities</td>
<td>0</td>
<td>0</td>
<td>85</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

Note: The figures are percentages representing proportion of processors with: Not applied (score 0), poor (score 1), moderate (score 2) and good (score 3) scores for food safety output activities.

MacGregor (2008) reported that most producers in developing countries get certified or comply with private voluntary standards such as BRC, not because of the perceived technical efficiencies, but because their buyer demands it. Renewal of export licenses as well as issuance of phyto-sanitary certificates is also determined by compliance to regulations and extent of non-conformities as well as incidences relating to interceptions at export entry points. Equally, frequent offenders are faced with threats of total bans in export markets (CAP 318, 2008). Processors with a moderate food safety (FS) output obtained higher scores in external
performance (57%) in comparison with internal FSMS performance (49%). For those with a good food safety output, 38% of the firms scored better in external food safety performance compared to 35% for internal food safety performance.

Sampling for microbial analysis had the least contribution to the overall food safety output with 38% of the firms not carrying out this crucial activity. However, 69% of the processors obtained moderate and 23% had advanced performance in the indicator ‘extent of hygiene and microbial related complaints’ despite five of them (P1, P5, P6, P7 and P10) not carrying out microbial analysis. This may be attributed to design and operation of preventive and control measures such as personnel hygiene requirements and sanitation programmes, incoming material and supplier control as well as storage facilities of the five companies. Personnel hygiene requirements and sanitation programs was at an advanced level whereas incoming material and supplier control and storage facilities were at moderate level. According to Luning et al. (2008), full-steps and tailored sanitation program with appropriate cleaning agents, supported with appropriate instructions better prevents contamination, while higher and more specific personal hygiene requirements with specific instructions reduce chances of contamination, both positively contributing to food safety. Stable cooling facilities equally contributes to a higher level of food safety by preventing growth of pathogenic and spoilage micro-organisms (Luning et al., 2008).

Sampling for chemical analysis and the criteria used to interpret results had the highest contribution to internal and the overall FSMS performance. All the assessed firms obtained the advanced score of level 3 in rigorousness of sampling for residue analysis. Criteria set by external parties (EU) are used to determine compliance to specifications hence the moderate score (situation 3).
A relationship can be established between the context factors and FSMS performance and the level at which the FSMS (control and assurance) activities were translated in a company’s FSMS (Table 7). The values shown are assigned scores derived from the means of context, FSMS activities and food safety performance scores for each processor.

The processors operated in a moderate risk context with 15% registering a slightly lower context riskiness of 1-2 (Table 3). Context riskiness combines product, production process, organization and chain environment characteristics which together give an indication of the riskiness of the context in which a firm operates and thereby determines the probability of food safety problems. A higher risk (2-3) therefore, corresponds with an increased probability of food safety problems (Luning et al., 2011). These in turn influence control and assurance activities in a FSMS and ultimately, the food safety output. Though 31% of the processors were operating in a moderate risk context, the level at which FSMS activities are implemented (1-2 or basic to moderate) gave a poor to moderate food safety output (Table 6). For 54% of the processors, the moderate risk context and FSMS activities at a moderate to advanced level resulted in a moderate to good food safety output (2-3). Processors P8 and P13 had a low to moderate context riskiness but the FSMS activities were at moderate to advanced levels hence a moderate to good FS output. Given the moderate context riskiness and the moderate level at which control and assurance activities have been translated in the company-specific FSMSs, a lower level food safety performance can be predicted as these activities have an impact on the outcome of food safety performance indicators and in turn, an indication of the FS output (Jacxsens et al., 2010; 2011).
Table 7. Relationship between overall context, food safety management activities and food safety output of the assessed fresh produce processing companies

<table>
<thead>
<tr>
<th>Processor</th>
<th>Context</th>
<th>FSMS Activities</th>
<th>FSMS output</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>2</td>
<td>2</td>
<td>1-2</td>
</tr>
<tr>
<td>P2</td>
<td>2</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>P3</td>
<td>2</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>P4</td>
<td>2</td>
<td>3 - 4</td>
<td>2-3</td>
</tr>
<tr>
<td>P5</td>
<td>2</td>
<td>2</td>
<td>1-2</td>
</tr>
<tr>
<td>P6</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>P7</td>
<td>2</td>
<td>1</td>
<td>1-2</td>
</tr>
<tr>
<td>P8</td>
<td>1-2</td>
<td>3</td>
<td>2-3</td>
</tr>
<tr>
<td>P9</td>
<td>2</td>
<td>2-3</td>
<td>2-3</td>
</tr>
<tr>
<td>P10</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>P11</td>
<td>2</td>
<td>3</td>
<td>2-3</td>
</tr>
<tr>
<td>P12</td>
<td>2</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>P13</td>
<td>1-2</td>
<td>3-4</td>
<td>2-3</td>
</tr>
</tbody>
</table>

FSMS: Food safety management systems

3.3.5 Conclusion

The FSMS diagnosis revealed the factors and activities that are crucial in obtaining an insight on the performance of FSMSs for the fresh produce chain. From the study, it was evident that the processors are operating in an overall moderate risk with majority of the processors indicating moderate risk for seventeen out of the twenty three (74 %) context riskiness indicators. There was high risk posed by susceptibility of initial materials and final product to microbial contamination which may be as a result of the production environment, absence of interventions and the possibility of contamination at the packing step. Developments in the sector together
with a legal requirement for traceability have contributed to lowering context riskiness associated with supplier relationships.

Control and assurance activities have been adapted differently by each of the thirteen processors due to differences in organizational and production process characteristics, such as extent of management commitment and risk of production system to microbial hazards. This resulted in varying food safety performance which ranged from poor to good.

All the processors placed the FSMS control activity ‘extent of personnel hygiene requirements’ at the advanced level. The other control activities such as hygienic design of equipment, storage facilities, sanitation programme, supplier and incoming material control, CCP analysis and maintenance of the cold chain have been optimized by the processors as these are critical towards controlling food safety hazards. However, it is necessary to undertake a structured microbial assessment to establish the actual microbiological performance of the FSMSs.

Pesticide residues are monitored on a sector level and analysis carried out in accredited laboratories a factor which is largely driven by the market and regulatory requirements. On the other hand, sampling for microbial analysis, a critical food safety verification activity was not being carried out by five out of the thirteen diagnosed processors. This represents a potential risk to food safety because food-borne outbreaks can be more far-reaching and may further compound the hurdles already being experienced with EU MRLs.

FSMS activity levels and context riskiness in relation to the food safety output provided an insight on FSMS activities which have an impact on the food safety output or FSMS performance. It is therefore necessary for several FSMS activities to be applied at higher or more advanced levels. These include partial physical intervention equipment, standards and tolerances design, packaging interventions, pathogen analytical methods, CCP monitoring, sampling for
microbiological analysis and criteria for interpretation of results and verification of facilities and methods-related performance.
Chapter 4
Microbial performance of food safety control and assurance activities in fresh produce processing sector

Abstract
Despite developments in food safety management systems food-borne outbreaks linked to fresh and minimally processed vegetables and fruits continue to be reported. Approaches such as inspections, audits and sampling for testing are commonly used to evaluate food safety management systems (FSMS). This system of evaluation does not provide systematic information on distribution and dynamics of microbial contamination. A microbial assessment scheme (MAS) was used to systematically assess the microbial performance of core control and assurance activities in five fresh produce processing and exporting companies. MAS involved the selection of six critical sampling locations (CSLs), microbiological parameters, sampling frequency, sampling and analytical method and criteria for interpretation of results. Based on compliance to criteria, food safety levels of either 0, 1, 2 or 3 was attributed to each parameter analysed at the various CSLs and microbial safety level profiles (MSLPs) constructed from the sum of scores at each CSL. A total of 280 samples comprising personnel swabs, food contact surface swabs, initial and final products and water were analysed. The maximum MSLP were as follows: Six for the initial product (two microbial parameters each with a maximum safety level of 3), 9 for final product, 6 for food contact surfaces, 6 for personnel samples and 9 for both incoming and final rinse water. Two companies attained the maximum MSLP of 6 for the initial product, while only one attained the maximum MSLP of 9 for the final product. None of the processors attained the maximum MSLP for environmental samples, with the best performing company achieving a MSLP of 5 out of 6. *Salmonella* and *Listeria monocytogenes* was not detected in products of all the processors. *E. coli* was detected in 5 out of 6 of the sampling
locations, including the final product. Majority (60%) of the assessed companies received a low food safety level for *Escherichia coli* in their end product. *E. coli* was also detected in hand swabs of operators in 80% of the processors. Four out of five (80%) of the assessed processors had poor to unacceptable results for *Enterobacteriaceae* with results ranging from 0 to 3.2 log CFU/cm$^2$ against a maximum limit of 2.5 CFU/cm$^2$. *E. coli* was positive in final products in instances where it was negative in initial products for 3 out of 5 processors, an indication of cross contamination due to poor hygiene or inadequate cleaning and sanitation.

Improved performance of preventive and intervention measures will therefore be dependent on cleaning and sanitation programme specific for fresh produce as well as personnel hygiene and hygienic design of equipment and facilities.

**Key Words**: Food safety management system, Microbial assessment scheme, critical sampling location, microbial safety level profile, contamination.

### 4.1 Introduction

Food safety hazards in fresh and fresh-cut vegetables include microorganisms acquired as a result of the production environment (soil, manure, irrigation water), handling during harvesting, processing (trimming, cutting, peeling, washing, spinning) and packing (Ijabadeni et al., 2011; WHO, 1998; ICMSF, 2011). These microorganisms are associated with farm workers, harvesting, transportation and the production and processing environments and may contaminate the product at various points in the production process. Studies have established that many vegetables support the growth of micro-organisms, including human pathogenic bacteria. Additionally, cutting, slicing or peeling causes tissue damage releasing nutrients which facilitates further growth of the microorganisms (ICMSF, 2011; Harris et al., 2003; Olaimat and Holley, 2012). Given that fruits and vegetables receives minimal or no processing before consumption,
pathogen contamination along the chain can pose a serious risk to consumers. Control of bacterial growth is therefore critical for quality and safety of such products (FAO/WHO, 2008; ICMSF, 2011).

Producers and processors in the fresh and minimally processed fresh produce chain are therefore required to design and implement effective food safety management systems (FSMS) according to the general principles of food hygiene of the Codex Alimentarius. Codex Alimentarius principles incorporate hazard analysis and critical control point (HACCP) and prerequisite programmes such as cleaning and sanitation and good hygiene practices. The most commonly used FSMS standards and quality assurance guidelines include ISO 22000: 2005 and British Retail Consortium (BRC) (Jacxsens et al., 2009; Luning and Marcelis, 2009). These FSMS standards and guidelines combine both performance-based approaches such as inspection and sampling for testing to evaluate the food safety control system and performance of prerequisite programs like good hygiene and sanitation programs (Jacxsens et al., 2009; Brown et al., 2007). It also includes integrated process-based approaches like food safety management which combines both control and assurance activities (Luning et al., 2009; Mensah and Julien, 2011).

However, despite these developments, bacterial pathogens, viruses and pesticide residues is still a major concern (van Boxstael et al., 2013) and food-borne outbreaks linked to fresh and minimally processed vegetables and fruits have continued to be reported (FAO/WHO, 2008; EFSA, 2011; Warriner et al., 2009). This apparent ineffectiveness of FSMS in controlling food safety hazards has been attributed to differences in the translation and implementation of FSMS in the different sectors in the food chain (primary production, processing and trade) (Jin et al, 2008; Konecka-Matyjek et al, 2005; Ropkins and Beck, 2000). The disparities in the translation and implementation of FSMS have been shown to be influenced by technological development,
resource availability as well as access to information on standards (FAO, 2007). Situational
elements that create risk in decision-making processes and impact design, implementation and
operation of a FSMS have also been found to influence food safety output (Luning et al., 2011;
Sampers et al., 2010).

Consequently, stakeholders in the agri-food chain such as consumers, sector organizations,
regulatory agencies and/or food safety authorities require information on the performance of
FSMSs in their effort of evaluation of implemented interventions to improve the microbiological
food safety output (Jacxsens et al., 2010; Luning et al., 2008; 2011). The most common method
of FSMS evaluation commonly entails checking compliance to specific requirements, which
does not provide any insight on FSMS performance especially with respect to microbiological
hazard levels. Different FSMS standards and guidelines like ISO 22000, BRC and Codex
HACCP guidelines recommend evaluation of critical control points (CCPs) and prerequisite
programmes through microbial testing to confirm that selected control measures are effective in
eliminating and/or reducing microbial hazards to defined acceptable levels (BRC, 2011; CAC,
2003; Jacxsens et al., 2009). However, this system of verification may not provide systematic
information on distribution of microbial contamination as well as dynamics of microbial
contamination (Jacxsens et al., 2009). By tracking proximate indicators such as rates or levels of
contamination before and after control points, the impacts of particular control measures can be
determined (ICMSF, 2006). Jacxsens et al. (2009) presented a Microbial Assessment Scheme
(MAS) tool that can be used to systematically assess the microbial performance of core control
and assurance activities in an implemented FSMS.

The MAS protocol enables a methodical analysis of actual microbiological performance of a
FSMS as an indication of its food safety output and provides an overview on microbial quality,
hygiene and safety levels of products and processes. The MAS tool therefore supports FSMS performance analysis. The protocol involves the analysis of selected microbial parameters in certain critical locations on a food establishment over a time interval, usually several months. Microbial safety level profiles are then assigned according to extent to which criteria are met at the critical sampling locations (Jacxsens et al., 2009).

The usefulness of MAS in assessing FSMS performance has been demonstrated in various studies including the dairy sector in Kenya (Opiyo et al., 2013), meat processing and slaughter houses in Europe (Luning et al., 2011; Oses et al., 2012; Sampers et al., 2010), water management in fresh produce processing (Holvoet et al., 2012) and food service establishments in Europe (Luning et al., 2013; Lahou et al., 2011). The microbial profiles obtained in these studies provided insight on improvements needed in FSMS activities. However, the protocol has not been applied in fresh produce processing.

The MAS protocol was therefore applied in this study to assess the microbiological performance as food safety output of FSMS (control and assurance activities) of fresh produce export processing and exporting companies. The aim was to obtain insight on the effectiveness of the FSMS control activities in preventing or reducing microbial contamination or hazards and to recommend aspects towards improvements in fresh produce safety.

**4.2 Materials and methods**

**4.2.1 Characterization of firms**

The assessment was carried out in five randomly selected Kenyan fresh produce export processing companies based in Nairobi. All five had been involved in the FSMS diagnosis using the FSMS diagnostic tool (Chapter 3). They process various vegetables including various green beans, peas, leafy vegetables (spinach, pakchoi), spring onions, chives, broccoli, herbs and stir-
fry mixes (mixed vegetables) etc which are destined for export markets (Table 8). They obtained their produce mostly from own farms and from subcontracted out-growers with GlobalGAP certification. The companies were certified to the British Retail Consortium (BRC) food safety management system standard and processors 3 had additional certification to customer-based standards such as Tesco Nature Source, Woolworths and Marks and Spencer.

Table 8. Characteristics of fresh produce processors where microbial performance of safety management systems was assessed

<table>
<thead>
<tr>
<th>Processor</th>
<th>P3</th>
<th>P8</th>
<th>P9</th>
<th>P12</th>
<th>P13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of employees</td>
<td>&gt;249</td>
<td>&gt;249</td>
<td>&gt;249</td>
<td>&gt;249</td>
<td>50-249</td>
</tr>
<tr>
<td>No. of personnel in QA Dept</td>
<td>20</td>
<td>33</td>
<td>35</td>
<td>50</td>
<td>120</td>
</tr>
<tr>
<td>Products</td>
<td>F, V</td>
<td>V, H</td>
<td>F, V</td>
<td>V</td>
<td>V, H</td>
</tr>
<tr>
<td>QA standard certified</td>
<td>BRC</td>
<td>BRC, CBS</td>
<td>BRC, CBS</td>
<td>BRC</td>
<td>CBS</td>
</tr>
<tr>
<td>Tonnage exported per annum</td>
<td>3000</td>
<td>7800</td>
<td>5000</td>
<td>7000</td>
<td>7000</td>
</tr>
</tbody>
</table>

Note: F- fruits; V- vegetables; H- Herbs; BRC- British Retail Consortium; CBS- Customer-based Standards; QA- Quality Assurance.

4.2.2 Food safety output assessment

A modified sampling plan based on the MAS protocol described by Jacxsens et al. (2009) was used to determine the microbiological food safety output of the FSMS of the five firms. The protocol involves the selection of: 1) critical sampling locations, 2) microbiological parameters or indicators, 3) sampling frequency, 4) sampling and analytical method and 5) criteria for interpretation of results (Jacksens et al., 2009; Sampers et al., 2010; Oses et al., 2012).

4.2.2.1 Selection of critical sampling locations

Critical sampling locations (CSL) are defined as locations where sampling for microbial analysis provides information about the performance of core control activities outlined by the FSMS. It is
a location at which contamination, growth, and/or survival of micro-organisms can occur if the intervention or preventive strategy is not working effectively, or where specific controls and correction/corrective actions have to be carried out to achieve the desired output (Jacxsens et al., 2009).

Product samples included initial materials (CSL 1) and finished products/packaged vegetables (CSL 2). The food contact surface samples collected and analyzed included swabs of working tables/chopping boards, conveyer belt, spinning baskets, holding crates and washing troughs (CSL 3), and hands/gloves swabs of personnel (CSL 4). Both CSL 3 and 4 are potential sources of cross contamination and provide insight on microbial performance of FSMS preventive measures. These CSLs were selected following discussion with quality assurance personnel in the respective processors on what they identified and had been documented as critical control points and the control activities addressed in their FSMS (Jacxsens et al., 2009). Washing water quality was also assessed as the use of water of poor microbial quality can lead to cross-contamination and an increase in microbial load in the end product (Holvoet et al., 2012; Allende et al., 2008). Water samples were drawn at inlet to holding tank/washing trough (CSL 5) and at the final rinse water trough (CSL 6). Sampling was also accompanied by observations on execution of tasks and other pertinent operations (operational prerequisites) and state of facilities. The in-coming water was drawn from the inlet into holding tanks from either borehole or municipal lines. The final rinse water was sampled from the rinsing troughs or flume tanks after addition of chlorine and before introduction of the product. This was aimed at establishing the microbial quality of water used and the effectiveness of the added chlorine in controlling/eliminating the selected microbial indicators at CSL 6.


4.2.2.2 Selection of microbiological parameters

Conditions at the growing location and the cultivation system have been shown to impact the microbial safety of fresh produce (Kirezieva et al., 2013). The pathogens *E. coli*, *Salmonella spp.* and *Listeria monocytogenes* were therefore selected as food safety indicators. These microorganisms are indicative of pre-harvest contamination of vegetables either from the production environment, from human or animal sources as well as from inputs such as manure and irrigation water as well as equipment (ICMSF, 2011; WHO/FAO, 2008; Johnston et al., 2005). *Escherichia coli* and *Enterobacteriaceae* were analysed as environmental hygiene indicators as safety is dependent on adequate hygiene and sanitation during harvesting and processing (ICMSF, 2011). *E. coli* and *Staphylococcus aureus* were selected as indicator of personnel hygiene (Soon and Baines, 2012; Aarnisalo et al., 2006). Only personnel handling the final product or working in the packaging area were swabbed. Coliforms, *E. coli* and Enterococci were selected as indicators of water quality as these are associated with faecal contamination (WHO, 2006)

4.2.2.3 Sampling frequency

Samples were drawn three times from each firm at different periods between October 2012 and June 2013. Vegetables (runner bean, fine bean, baby spinach, pakchoi, tender stem broccoli etc) at receiving (initial material), final products (packaged vegetables) and water samples were collected once per sampling visit. Different food contact surfaces and hands of operators were also swabbed during each visit. Three visits were made to each firm during the sampling period. Product lines were followed from start to packaging to ensure that samples drawn were all from the same batch and being handled by the same personnel. A total of 280 samples were analysed as follows: 60 each for the initial and final product and food contact surface swabs; 80 personnel hand swabs and 10 each for the initial and final rinse water.
4.2.2.4 Sampling and analytical methods

Samples were drawn and microbiological parameters analyzed using International Organization for Standardization (ISO) methods and/or standards. Destructive sampling was performed on fresh-cut vegetables. A sample 250 g of fresh produce (one crop type for the raw material) was taken by means of sterile tweezers and put aseptically into a stomacher bag. Finished product samples were sampled from the packaged units. Non destructive sampling was performed for the food contact surfaces and hands/gloves by swabbing using horizontal methods for sampling techniques using cotton swabs on surfaces in accordance with ISO 18593: 2004. A sterile steel template was used to delineate an area for sampling. An area covering 50 cm\(^2\) or 25 cm\(^2\) for the food contact surfaces and hands/gloves of the personnel respectively was swabbed by using a sterile cotton swab pre-moistened in 10 ml sterile nutrient broth. All samples were stored and transported to the laboratory in a cool box at \(\leq 4^\circ C\). Sample preparation was done in accordance with ISO 6887-4:2003. Detection and enumeration of the various microorganisms was done as shown in Table 9. For enumeration and qualitative detection purposes, 25g of product sample was weighed in a stomacher bag and homogenized for 1 min in 275ml of buffered peptone water (BPW). This also served as primary enrichment for detection of *Salmonella* spp. Serial dilutions were done where applicable. Swab samples were vortexed for 10 seconds, and the solution incubated in the primary enrichment medium for detection of pathogens or serially diluted for enumeration purposes. The limit of detection for *E. coli* in weighed samples was 10 while that for *Salmonella* was 1.

Water samples were collected into sterile one-litre bottles and tested using Colilert\textsuperscript{TM} and Enterolert\textsuperscript{TM}, rapid method for the detection of Coliforms and *E. coli* and Enterococcus respectively (Idexx Laboratories, Westbrook, Maine). The sample with Enterolert was incubated
at 41°C and Colilert at 37°C for 24 hours. The samples were then observed under ultra violet (UV) light to detect fluorescence (green or blue) that indicates presence of the microorganisms.

All analyses were done using analytical grade reagents and media (Oxoid) in an ISO 17025 accredited laboratory at the Kenya Bureau of Standards.

4.2.2.5 Microbiological criterion

Currently, no microbiological guidelines exist for non ready-to-eat vegetables. Guidelines that exist are for ready-to-eat vegetables. Many of the vegetables sampled (fine bean, runner bean, tender stem broccoli) are not eaten in the same state as they are sold but are typically cooked before consumption. Therefore to provide a comparative reference the microbiological results for product samples were interpreted against the criteria given in European Commission (EC) Regulation 1441/2007 and ICMSF Book 8 for ready to eat vegetables. The microbiological guidelines established by the Laboratory of Food Microbiology and Food Preservation, Ghent University (LFMFP-UGhent) were used to evaluate food contact surfaces due to absence of legal criteria (Debevere et al., 2006; Uyttendaele et al., 2010). Recommendations by Herbert et al. (1990) were used to evaluate personnel hand swabs. Results for water samples were interpreted against the requirements of Kenya Standard Specification for potable water, part 1, KS 459-1:2007. Table 9 gives the summary of the CSLs, parameters analysed and their test methods as well as criteria for interpretation of results.
Table 9. Critical sampling locations, microbiological parameters analysed, test method and criteria for interpretation of results

<table>
<thead>
<tr>
<th>CSL</th>
<th>Description</th>
<th>Parameters</th>
<th>Test method</th>
<th>Criteria</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial products</td>
<td>E. coli</td>
<td>ISO 7521: 2005</td>
<td>m&lt;10^2, M&lt;10^3</td>
<td>EC 1441/2007</td>
</tr>
<tr>
<td>2</td>
<td>Final product</td>
<td>E. coli</td>
<td>ISO 7521: 2005</td>
<td>m&lt;10^1,M&lt;10^2</td>
<td>ICMSF 8</td>
</tr>
<tr>
<td>3</td>
<td>Food contact</td>
<td>E. coli</td>
<td>ISO 7521: 2005</td>
<td>≤0.7 log CFU/50 cm² (below detection limit)</td>
<td>LFMFP, UGhent</td>
</tr>
<tr>
<td></td>
<td>surfaces</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enterobacteriaceae</td>
<td>ISO 21528-2:2004</td>
<td>≤1.7 log CFU/25 cm² (below detection limit)</td>
<td>LFMFP, UGhent</td>
</tr>
<tr>
<td>4</td>
<td>Hand/glove swabs</td>
<td>S. aureus</td>
<td>ISO 6888-3:2003</td>
<td>≤0.7 log CFU/25 cm² (below detection limit)</td>
<td>LFMFP, UGhent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. coli</td>
<td>ISO 7521: 2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Water at inlet</td>
<td>Coliforms</td>
<td>ISO 9308-1:2000</td>
<td>Absent/100ml</td>
<td>KS 459</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. coli</td>
<td>ISO 9308-1:2000</td>
<td>Absent/100ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enterococci</td>
<td>ISO 7899-2:2000</td>
<td>Absent/100ml</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Final rinse water</td>
<td>Coliforms</td>
<td>ISO 9308-1:2000</td>
<td>Absent/100ml</td>
<td>KS 459</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. coli</td>
<td>ISO 9308-1:2000</td>
<td>Absent/100ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enterococci</td>
<td>ISO 7899-2:2000</td>
<td>Absent/100ml</td>
<td></td>
</tr>
</tbody>
</table>

LFMFP- Laboratory of Food Microbiology and Food Preservation, Ghent University, Belgium; EC- European Commission Regulation; KS- Kenya Standard.
4.2.2.6 Data analysis and interpretation of results

MAS data was compiled and interpreted for compliance based on criteria given in 4.2.2.5 above and a food safety level attributed to each parameter analysed on a scale of 1 to 3. Level 3 represents a good safety performance, where legal criteria or guidelines are not exceeded; no improvement is required and the current level of the FSMS seems adequate to control the respective hazard. Level 2 indicates a moderate safety performance in which improvement is required on a specific control activity in the FSMS. Level 1 represents a poor safety performance where legal criteria or guidelines are exceeded, and improvements are needed on several control activities in the FSMS (Jacxsens et al., 2009; Sampers et al., 2010 and Luning et al. 2011). The sum of the food safety levels per CSL gave the MSLP score. A score of 0 was also attributed to the presence of a microorganism (pathogen) in a test sample. Table 10 gives the summary of criteria for assigning the food safety levels.

Table 10. Criteria for attribution of food safety level scores

<table>
<thead>
<tr>
<th>Food safety level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>( R \leq m ) or organism absent in x grams, millilitres or 50 cm(^2) or 25 cm(^2)</td>
</tr>
<tr>
<td>2</td>
<td>( m &lt; R &lt; M )</td>
</tr>
<tr>
<td>1</td>
<td>( R = M )</td>
</tr>
<tr>
<td>0</td>
<td>( R &gt; M ) or organism present in x grams, millilitres or 50 cm(^2) or 25 cm(^2)</td>
</tr>
</tbody>
</table>

Note: \( R \)- Results; \( m \)- maximum level of organism in a test sample considered acceptable; \( M \)- maximum level of organism in a test sample considered unacceptable.

The attributed food safety levels for the microbial parameters were used to derive MSLPs in order to obtain an overview of the FSMS output for each processor. Microsoft Office Excel 2007 (Microsoft, Redmond, WA) was then used to construct bar graphs and scatter plots to visualize microbial safety level profiles and microbial distribution between the companies and over CSLs.
The evaluation of each microbiological parameter in a specific CSL gave insight on the actual microbiological status or performance of the FSMS control activities (Luning et al., 2011).

**4.3 Results and discussion**
The attributed food safety level (0, 1, 2 or 3) for each parameter analysed at the various CSLs shows the contribution of each CSL to the overall food safety output. These are depicted in the MSLPs (bar graphs) in Figure 1. FSMS performance was variable and none of the processors attained the maximum score when all CSLs were considered per processor, an indication that their FSMS are not operating at optimum and that some improvements need to be made in FSMS control and assurance activities to achieve a better output. The MAS results can be related to various control activities in the FSMS such as preventive and intervention measures (Luning et al., 2008). It also gives insight of the actual operation and efficacy of these measures in controlling and/or reducing selected microbial hazards to acceptable levels (Jacxsens et al., 2009).

All the processors attained a food safety level of 3 for *Salmonella* and *Listeria monocytogenes*. This indicates that the FSMS appears sufficient in controlling the selected pathogens. However, various studies have recommended caution in interpreting results as these bacteria are associated with low prevalence in fresh produce (<0.1 to 1 %) and low defect rates in lots (Holvoet et al., 2012; ICMSF, 2011). *E. coli* was detected in 5 out of 6 of the CSLs including the final product (CSL 2) thereby making the most contribution to lower food safety levels. There was variation in *Enterobacteriaceae* counts on food contact surface swabs over the sampling period with two firms (P3 and P12) not meeting the criteria on all the samples analysed. The other processors had poor to average performance while P13 met the criteria for *Enterobacteriaceae*, an indication that its cleaning and sanitation program is effective in achieving the intended outcome.
*E. coli* was detected in the initial product (CSL 1) from all five processors at various times during the sampling period, though the counts were within the specification of $10^2$-$10^3$ colony forming units (CFU) per gram (Fig 1. a). An average food safety level of 2 was therefore attributed to this CSL. This may be an indication that preventive measures such as good agricultural practices, farm hygiene and personnel hygiene during harvesting were able to limit contamination. All the processors sourced their initial materials from GlobalGAP certified farms where minimum food safety assurance activities are practiced. This is a prerequisite for initial materials of good microbial quality (Jacxsens et al., 2009). The presence of *E. coli* in the initial material of all the processors represents a moderate to high risk context which requires more rigorous FSMS controls to ensure that the microbial quality of the end product meets food safety criteria (Jacxsens et al., 2009). The total MSLP for CSL 1 was 6 with all the processors attaining an average of 5. This good performance for the initial product was due to the absence of *Salmonella* in the initial product. The results for CSL 1 for both *E. coli* and *Salmonella* indicate good preventive measures that minimized the risk of poor microbial quality initial materials which may put a strain on the FSMS controls at processing (Luning et al., 2008). Microbiological performance of initial materials provides information on potential safety risks associated with raw materials such as levels of microbial contamination which in turn determine the rigorousness of FSMS interventions (Kirezieva et al., 2013; Jacxsens et al., 2009; Luning et al., 2008).

Performance at CSL 2 (final product) was unsatisfactory with respect to *E. coli* as 60% of the assessed processors had a poor performance with a food safety level of 1 assigned at this CSL (Fig 1.b). One processor had a moderate level of 2 while another had a level of 3. The poor performance is indicative of inadequate decontamination processes or represents contamination...
from the processing environment, equipment or human handling. A general lack of efficacy of sanitizers in removing or killing pathogens on raw fruits and vegetables has partly been attributed to structures and tissues that may harbor pathogens (Beuchat, 2002). The microbial quality of end products gives an indication of the effectiveness of applied interventions in preventing and/or reducing microbial hazards to acceptable levels and the overall performance of the FSMS (Luning and Marcelis, 2006; 2007). Microbiological performance at this CSL therefore provides information on the effectiveness of intervention measures addressed in a company’s FSMS, such as adequacy of hygiene and sanitation and the decontamination processes. The most prevalent method of decontamination among the assessed processors was successive washing followed by rinsing with chilled chlorinated water (40-80 ppm for 5 minutes on average, at 4-8°C). However, there was no indication that pH and concentration of chlorine was being checked to ensure maintenance of concentrations which have been found effective in decontaminating the product. For chlorine to be effective, a combination of its concentration, pH and contact time with product is important (WHO, 1998). Microbial cells present in the initial product might therefore persist to the end product due to the absence of monitoring of active ingredient needed to inactivate them. The risk posed by low level contamination can be enhanced by cross-contamination during washing, surface moisture and temperature variation (Danyluk and Schaffner, 2011). Factors such as hydrophobicity of plant surfaces and biofilm formation by bacterial cells have also been shown to limit the effectiveness of post-harvest washing in reducing the microbial load (Whipps et al., 2008; Frank, 2001). In addition, water flumes used during processing have been demonstrated to spread initial spot contamination (ICMSF, 2011). Johnston et al. (2005) reported that the level of Coliforms in parsley and cilantro increased after washing with the most increase occurring at the rinsing step. Furthermore, contamination can
originate or increase at the processing/packing phase (Gagliardi et al., 2003; Castillo et al., 2004; Prazak et al., 2002). This might therefore explain the presence of *E. coli* on the final product despite it not being detected in the initial products in some instances, for example, P9 and P12 during first sampling.

The product contact surfaces (CSL 3) consisting of produce holding crates, bowls, spinning baskets and liners, conveyor belts, chopping boards and work tables had total MSLP of 6. None of the processors achieved the maximum level for this CSL (Fig 1.c). The results for *E. coli* and *Enterobacteriaceae* at the CSL were variable over the sampling period. Processor P3 had the lowest MSLP due to the presence of *Enterobacteriaceae* counts above the maximum limit. *E. coli* was detected in food contact surface swabs of P3 and P9. This was mainly in crates used to hold the product after spin-drying prior to packaging. The crates are made from plastic and its construction may facilitate adherence of micro-organisms due to the presence of perforations and may be difficult to clean. It is recommended that containers coming into contact with products should be designed and constructed in a way that makes them easy to clean, disinfect and maintain to avoid contamination of product (CAC, 2003). On the other hand, 80 % of the assessed processors had poor to unacceptable results for the indicator *Enterobacteriaceae*. The results ranged from 0 to 3.2 log CFU/ 50 cm$^2$ against a maximum of 2.5 CFU/ 50 cm$^2$ as per the guidelines. This indicates inadequate cleaning and sanitation procedures which are not effective in reducing microbial contamination to acceptable levels. It may also be attributed to microorganisms adhering to food contact surfaces in form of biofilms even after sanitation (Schlegelova et al., 2010; Frank, 2001; Evans et al., 2004). The poor performance at CSL 3 can therefore compromise food safety through cross contamination. Verification after cleaning and sanitation was said to be carried out at defined intervals, however, the frequency appears
unsatisfactory in determining the effectiveness of the programmes. It may also be as a result of failure to follow procedures and instructions while cleaning. Sanitation programs which are tailored and supported with appropriate instructions and verified to be effective in eliminating hazards should be implemented and modified when results of verification show deviations from specifications (CAC, 2003; Luning et al., 2008).

*S. aureus* was detected in one hand swab of personnel (CSL 4) from P12 on one sampling occasion hence a food safety level of 2 at this CSL. *E. coli* was detected in hand swabs of 80% of the assessed processors hence food safety levels of 1-2 for the indicator. *S. aureus* was absent in majority of the samples and therefore contributed to the average to good performance of this CSL as MSLPs of 4-5 out of a maximum of 6 were recorded (Fig 1. d). Only one processor had the least MSLP of 4 while the rest had 5. The poor performance at the CSL with respect to *E. coli* might have resulted from contact with environment which has been known to contaminate hands with transient flora such as *E. coli* and *Salmonella* (Dijk et al., 2007). The CSL is a critical control point in the FSMS as most operations are manual and inadequate compliance to hygienic practices may compromise the safety of end products. Personnel hygiene is therefore addressed in FSMS in order to prevent direct and indirect contamination of food as hands can contaminate food through flora of the skin such as *Staphylococci* (Aarnisalo et al., 2006; Dijk et al., 2007). However, no relationship was established between the detection of E. coli on personnel hands and in the final product. For example, *E. coli* was not detected in any personnel swabs of P12 but the indicator was detected in the final product on two occasions. This means that contamination of end product with *E. coli* may have originated from other sources in the processing environment. Both CSL 3 and 4 are potential sources of cross contamination and provide insight on microbial performance of FSMS preventive measures such as hygienic design of equipment.
Another aspect that was addressed in the FSMS assessment was water which comprised CSL 5 (initial water) and 6 (final rinse water), each with a total MSLP of 9. Washing is an intervention step in fresh produce processing. However, washing has been identified as a potential step through which microbial hazards can be introduced and especially if microbial quality of the water is unsatisfactory (Holvoet et al., 2012). Fresh cut produce washing being a critical step that may reduce microbiological contamination and also removes some of the cell exudates at cut surfaces which support microbial growth (CAC/RCP, 2003) requires use of potable water in order to prevent the transfer of contamination from water to the produce (FAO, 2010). Processor P3 had a food safety level of 0 for CSL 5 due to the detection of Coliforms, *E. coli* and *Enterococci* in their incoming water (Fig 1.e). P9 also had a poor performance at the CSL due to the presence of Coliforms and *E. coli* in the incoming water. Processor P12 had a MSLP of 7 for the CSL while P8 attained a MSLP of 8. For P13, *Enterococci* was detected in the incoming water on all samples drawn hence a MSLP of 6. These results might suggest contamination of water at source or the presence of biofilms in the piping system (Hallam et al., 2001). Processors P3 and P13 sourced their water from boreholes while the rest used municipal water. A better output was recorded at CSL 6 (Fig 1. f) because all the firms treated their water with chlorine prior to using it to rinse the product. Processor P3 despite having a MSLP of 0 at CSL 5 attained the maximum MSLP of 9 at CSL 6. Processor P12 also had a safety level of 9 for CSL 6 while P8, P9 and P12 had lower scores due to detection of *Enterococci* in the final rinse water which may be as a result of poor cleaning of flume tanks or ineffective water treatment.
No contamination build-up from one CSL to the next was observed but the contamination as depicted by the indicator *E. coli* appeared random and may be attributed inadequate cleaning and sanitation and cross contamination. *Enterobacteriaceae* counts for CSL 3 were poor to unsatisfactory as 80% of the firms had a food safety level of 0 or 1 attributed to this indicator. However, processor P13 had a good food safety compared to the other companies. Its final product met the criteria throughout the sampling period and cleaning and sanitation seems effective with either no or low variation in *E. coli* contamination when present (Fig. 2). *Enterobacteriaceae* counts were also within the guidelines. *E. coli* was detected on only one personnel swab (out of 12) The FSMS control and assurance activities for P13 therefore seem effective in controlling microbial hazards though water quality monitoring needs to be enhanced to ensure compliance with specifications. Processor P3 had the least performing FSMS as depicted by the MAS results (Fig. 1 and 2) in which the food safety levels at some CSLs showed unsatisfactory performance of control activities and the prerequisite programs in preventing and/or controlling microbial hazards to acceptable levels. This poor output was mainly contributed by CSL 3 (food contact surfaces) and CSL 5 (incoming water) The processor therefore needs to improve on cleaning and sanitizing processes to minimize the risk of cross contamination from equipment and facilities to product and thereby achieve a better FSMS output.

All the processors need to verify the effectiveness of cleaning and sanitation through appropriate means such as swabbing cleaned surfaces to confirm that cleaning and disinfection achieves the desired outcome.
Figure 1. Microbial safety level profiles for critical sampling locations for fresh produce processing firms (a) CSL 1, initial products; (b) CSL 2, final products; (c) CSL 3, product contact surfaces; (d) CSL 4, personnel hands and/or gloves; (e) CSL 5, incoming water; (f) CSL 6, final rinse water. P3, P8, P9, P12, P13 - processors 3, 8, 9, 12 and 13.
Figure 2. Variation in *E. coli* food safety level profiles of fresh produce processors at critical sampling locations. CSL 1, initial products; CSL 2, final products; CSL 3, product contact surfaces; CSL 4, personnel hands and/or gloves; CSL 5, incoming water; CSL 6, final rinse water.

**4.4 Conclusion**

The analysis of microbiological parameters at the selected critical points (CSL) in the fresh produce production process provided an insight of the performance of FSMS control and assurance activities. Majority of the assessed companies received a low food safety level for *E. coli* in their end product. Though no pathogenic microorganisms were detected, the presence of E. coli (an indicator organism) in the end product indicates the ineffectiveness of FSMS control measures. This may render resultant products unsafe especially if pathogenic micro-organisms with low infective dose are present and because microbiocidal treatments at the point of consumption (such as cooking) are usually not adequate for fresh produce.

Where the indicator *E. coli* was not detected in the initial product or food contact surfaces, the same was detected in the final product in 3 out of the 5 processors. This is an indication of
cross-contamination due to either spread of spot contamination during washing or due to poor cleaning and sanitation (preventive measures) of flume tanks and inadequate intervention processes (decontamination) and monitoring systems.

FSMS performance and microbial safety will therefore be contingent upon preventive measures such as high and specific cleaning and sanitation programs, personnel hygiene, hygienic equipment and facilities as well as frequent training and evaluation of effectiveness of such trainings. Re-evaluation of intervention processes coupled with adequate monitoring methods are also necessary to assure food safety.
Chapter 5

5.1 General Discussion

The horticultural sector is important to Kenya’s economic and technological development. However, the sector is faced with numerous challenges, the main one being inadequate food safety assurance. Assurance of fresh and minimally processed produce is key in accessing the economically important but safety stringent EU markets (Okello et al., 2007). Through the assessment of FSMS of selected fresh produce processors using both the FSMS-DI and MAS, an insight on FSMS performance in fresh produce processing was obtained. The assessment tools consider both technological and managerial factors (Luning and Marcelis, 2006; 2009; Jacxsens et al., 2009) which allowed an analysis of the FSMS context, control and assurance activities and food safety performance. This section therefore aims at providing a combined insight on FSMS of fresh produce processing companies from both FSMS-DI and MAS.

The assessment of context indicated that the processors were operating in an overall moderate risk, with 54 % scoring moderate risk for seventeen out of the twenty three context riskiness indicators. There was high risk posed by susceptibility of initial materials and final products to microbial contamination which may be due to the production environment, limited control interventions applicable to fresh produce and the possibility of contamination and growth at the processing and packing step. FSMS diagnosis conceptualizes that companies operating in a high risk context (overall score 3) need to implement FSMS activities at the advanced level (overall score 3) in order to realize a good food safety output (overall score 3). Similarly, a moderate risk context (overall score 2) would require an average FSMS (score 2) in order to achieve a good food safety output. Under a low risk situation (overall 1) a basic FSMS would be adequate in achieving a good performance (Luning et al., 2011a; 2009). For the assessed companies, FSMS activities performed at moderate to advanced levels (2-3) were therefore necessary to mitigate the risk associated with the context. However, majority of the assessed
companies (77%) had FSMS activities at basic to moderate levels (1-2) which might have been insufficient in addressing the risk of microbial contamination. In the study of FSMS performance in meat processing companies, Luning et al. (2011b) found that inadequate performance of FSMS was attributable to activity level taking into account the risk context. An analysis of FSMS activities in conjunction with context characteristics is therefore necessary in order to obtain further insight on causes of insufficient performance.

The context riskiness of the five processors involved in microbial assessment was moderate (average score of 2). However, the risk of microbial contamination for initial and final products was moderate to high (2-3) (Chapter 3, Table 4). The processors therefore needed to have their FSMS activities at a moderate to an advanced level for them to achieve a good food safety output given the overall moderate risk context. Water analysis presented a moderate to high risk to processor P3, P9 and P13 as Coliforms, *E. coli* and *Enterococci* were detected in the initial water but this risk was reduced by treating the water prior to use though analysis of the same water after treatment indicated inadequacy of the method as some indicator organisms especially *Enterococci* persisted in the water (P8, P9 and P13). These are depicted in the microbial safety level profiles (MSLPs) derived from MAS in chapter 4 (Figure 1e and 1f). The risk posed by ineffective water treatment can therefore be reduced further by selecting the most appropriate water treatment technique tailored specifically for fresh produce processing, accompanied by improvements in the produce wash process.

FSMS control activities were assessed using MAS by selecting critical sampling locations (CSL) at points in the production process that may point to sources of poor performance in the FSMS. The five processors had moderate to high levels (2-3) for risk associated with initial material of poor microbial quality but this risk was reduced by adequate incoming material control and supplier control in which majority of the firms had moderate to advanced scores (Chapter 3, Table 4). This finding was supported by the results of microbial analysis.
on initial material as the pathogen *Salmonella spp.* was not detected whereas *E. coli* counts showed moderate to good (2-3) food safety output for this indicator (Chapter 4, Figure 1 a). According to the FSMS diagnosis, requirement on personnel hygiene was at an advanced level for all five companies. However, actual microbial analysis (MAS) showed presence of *S. aureus* and *E. coli* in hand swabs of personnel at various times during the sampling period resulting in varying food safety levels (Chapter 4, Figure 1d). This shows that though personnel hygiene requirements are high and specific and with accessible procedures, actual compliance to procedures are not satisfactory and further training and evaluation is needed to achieve better performance (Oses et al., 2012, Lahou et al., 2011). Soon and Baines (2012) reported that visual demonstrations of procedures enhances compliance as a result of relational experience. Visual methods could therefore be used to improve personnel hygiene towards higher levels in order to prevent cross-contamination of products and processing facilities.

The FSMS diagnosis results indicated that the hygienic design of equipment and facilities performance was advanced (level 3) for all five processors (Chapter 3, Table 4). However, MAS results for food contact surfaces swabs were variable as *E. coli* was detected in sample of P3 and P9 hence an average food safety level. Processors P8, P12 and P13 obtained a good food safety level for *E. coli* (Figure 1c). *Enterobacteriaceae* counts on food contact surfaces were unsatisfactory for four processors, an indication that their cleaning and sanitation programmes were not effective despite the score of advanced levels in FSMS diagnosis. Only P13 obtained a better food safety for this parameter. Equipment and facilities hygiene is crucial in prevention of cross-contamination throughout the processing environment. Practices such as insufficient washing of wash or flume tanks have been found to increase the potential to transfer *E. coli* contamination to the end product (ICMSF, 2011; Johnston et al., 2005). Hygienic design of equipment and facilities is supported by adequate cleaning and
sanitation programmes with performance tests done on a regular basis (Luning et al., 2008). Effectiveness of cleaning therefore requires re-validation in order to improve general hygiene and reduce the possibility of cross-contamination. This will facilitate development of more effective sanitation programmes adapted for various production zones that will counter risk of cross contamination.

The FSMS diagnosis showed partial physical and chemical intervention activities at moderate to advanced levels (2-3) which means ‘best standard’ interventions and modified for the company’s specific situation (Chapter 3, Table 4). MAS results for final products indicated absence of the pathogens Salmonella spp. and Listeria monocytogenes but E. coli was detected in some of the final products of the processors except those of company P13 (Chapter 4, Figure 1 b). The MAS results also revealed instances in which E. coli was absent in the initial product but was detected in the final product. This pointed to contamination from either handling as operations are manual or from processing facilities. E. coli can therefore be used as an indicator to determine the effectiveness of FSMS interventions in inactivating or reducing microbiological hazards to acceptable levels. The interventions employed by the assessed processors were mainly several washing steps with potable water before finally rinsing with chilled treated (chlorinated) water. This method has been shown to reduce microbial load by 1-2 logs (ICMSF, 2011; Goodburn and Wallace, 2013) but washing can also spread spot contamination (Johnston et al., 2005). This might explain the detection of E. coli on final product, which could also be due to cross contamination from product contact surfaces as well as handling.

To improve the performance of the FSMS, the monitoring systems which include critical control point (CCP) analysis, standards and tolerances design, sampling plan and analytical methods to assess pathogens and adequacy of measuring equipment to monitor CCPs need to be improved towards advanced levels (Chapter 3, Table 4). Processor P3 and P12 had
moderate scores (level 2) for CCP analysis while the rest had advanced scores, meaning that CCPs had been adequately identified and documented in their HACCP plans. However for fresh produce, critical limits cannot be set, and efforts are mainly directed towards the reduction of potential contamination (Kirezieva et al., 2013). This reduction can be achieved through operational pre-requisite programmes such as washing with potable water supported by the more general pre-requisite programmes like cleaning and sanitation (da Cruz et al., 2006; BRC, 2011) which are tailored for the different equipment and facilities. In addition, cleaning and sanitizing agents use should be tested for efficacy.

All five firms had basic scores (level 1) for standards and tolerances design (Chapter 3, Table 4). This means that standards for critical product and process parameters are specified but tolerances not clearly specified and assessment based on historical data and company experience. In addition to this, measuring equipment to monitor CCP was also at a basic level for all the processors. FSMSs requires establishment of monitoring systems to demonstrate that CCPs are in control including monitoring devices used (ISO 22000, 2005; BRC, 2011). These findings indicated inadequacies in standards and tolerances and monitoring systems which are crucial in FSMS performance as they enable corrections and corrective actions when set parameters are out of specifications. Studies aimed at obtaining insight on prevalence and distribution of microbial contamination in lettuce processing emphasized the importance of monitoring in fresh produce production as inadequacies in the monitoring systems can cause food safety problems (Holvoet et al., 2012). The weaknesses in monitoring of CCPs and verification of pre-requisite programmes may have contributed to the problem of *E. coli* contamination that was revealed by MAS results (Chapter 4, Figure 1). Therefore, FSMS monitoring activities need to be enhanced towards advanced levels to enable detection of non-compliances in good time to facilitate corrective actions.
Since chlorine is the most commonly used chemical in water treatment and equipment disinfection or sanitization, parameters such as oxidation-reduction potential, total and free chlorine can be easily monitored and can be used to develop operation specific procedures (WHO, 1998). This will in turn facilitate modifications and validation of the control measures in the FSMS and therefore provide assurance that safety requirements will be met and that the performance of the FSMS will be stable. This will ultimately contribute to a higher FSMS performance and the overall food safety output of the companies.

The findings from this study using both the diagnostic tool and the microbial assessment scheme indicated insufficiencies in FSMS performance in the fresh produce processing sector. Other studies on FSMS assessment using both tools, either singly or concurrently have also provided insight on FSMS activities in various food sectors. The tools are therefore useful in identification of possible causes of poor food safety output, thereby providing clear directions on areas where improvements are needed.

### 5.2 Conclusion
FSMS activity levels and context riskiness in relation to the food safety output provided an insight on FSMS activities which have an impact on the food safety output or FSMS performance. A relationship was also established between the results obtained through FSMS diagnosis and microbiological performance at specific CSLs, indicating whether the respective control activities achieved the desired output or needed to be improved. The levels- whether basic, moderate or advanced- at which FSMS activities have been translated in a company had a direct impact on the outcome of microbiological performance at selected control points. In this way, weaknesses in the system were identified. These included monitoring system design and certain aspects of preventive measures and intervention processes. Weaknesses in monitoring systems including standards and tolerances design and product status monitoring as well as inadequate cleaning and sanitation led to low safety level
for majority of the processors despite preventive measures rated at moderate to advanced levels. Recommendations for improvement in these areas have been suggested.

The FSMS diagnosis revealed varying food safety performance which ranged from poor to good with 53% of the processors having a moderate food safety output whereas only 37% had a good output. These results were corroborated by microbial analysis in which majority of the assessed companies received a low food safety level for *E. coli* in their end product. Though no pathogenic microorganisms were detected, the presence of *E. coli* (an indicator organism) in the end product indicated inadequacies in FSMS preventive and intervention measures.

The study also established that stakeholder requirements play a key role in translation and implementation of FSMS. This was reflected by pesticide residues monitoring where analysis is carried out in accredited laboratories, a factor which is largely driven by the market and regulatory requirements (EU MRLs). This was also reflected in the score levels on the assurance activity, ‘translation of stakeholder requirements’, where 85% of the assessed companies had average to advanced score levels. On the other hand, sampling for microbial analysis, a critical food safety verification activity was not being carried out by 38% of the processors. This may render end products unsafe especially if pathogenic micro-organisms with low infective dose are present and because microbiocidal treatments at the point of consumption (such as cooking) are usually not adequate for fresh produce. This represents a potential risk to food safety because food-borne outbreaks can be more far-reaching and may further compound the hurdles already being experienced with EU MRLs.

The results from this study showed weaknesses in monitoring systems (standards and tolerances design and product status monitoring). Ineffective intervention processes and inadequate cleaning and sanitation also led to lower safety levels for majority of the processors despite moderate to good preventive measures. Where *E. coli* was not detected in
the initial product or food contact surfaces, the same microorganism was detected in the final products of 60% of the processors involved in MAS. This is an indication of cross-contamination due to either spread of spot contamination during washing or due to poor cleaning and sanitation (preventive measures) of flume tanks and inadequate intervention processes (decontamination) and weak monitoring systems.

The combined assessment of a FSMS using both the FSMS-DI and MAS tools therefore provided pertinent information on FSMS performance. The tools enabled an understanding of FSMS activities aimed at certain food safety goals at specific steps in processing. Deficiencies in these activities can therefore be addressed and corrected as outlined in the recommendations below.

5.3 Recommendations

The assessment of FSMS context, control and assurance activities and the overall food safety output using both the FSMS-DI and MAS gave clear direction for the enhancement of FSMS performance of fresh produce processing companies. These include improvement in production climate conditions to controlled, climatized conditions for processors deficient on this aspect. This will reduce the risk associated with temperature and humidity associated with ambient conditions that favors growth of microorganisms, occurrence of pest and/or mycotoxin production. Enhancement of management commitment, technological expertise, formalization, operators’ knowledge, skills and level of involvement on food safety issues by all processors is also recommended to reduce the high risk context associated with these administrative conditions that can lead to lower food safety levels of a FSMS. Lack of commitment and support for food safety from the top management may lead to a shift of priorities, and low involvement among workers. Sensitization and training of management to enhance knowledge and management commitment will reduce the impact of lack of technological expertise.
It is also necessary to provide support and resources to all processors so that their FSMS is product and production system specific as well as science-based. Specificity of external support which relates to assistance available in setting FSMS, presented a high risk level to all the processors as the current institutions and resources are currently geared towards primary production.

Improvement is needed towards integrated hygienically designed equipment and facilities which are modified for company specific production characteristics. Equipment and facilities just met basic hygiene requirements for all processors. This should be coupled with verification of performance and complete cleaning and sanitation programmes tailored for the different equipment and facilities in order to augment prerequisite programmes towards better safety performance.

All processors need improvement in packaging from general packaging equipment whose capability is not known to equipment that is modified and adapted for fresh produce and whose capability is known, tested and documented. This will reduce the chances of cross contamination associated with the current manual packaging operations.

Application of partial physical interventions such as washing produce with potable water by six of the processors together with sampling for microbial analysis would improve their FSMS performance to at a higher level. Even though no definite inactivation can be applied in fresh produce processing, food safety hazards should be addressed through control points. This will require design and implementation of a monitoring system which entails clear documentation of standards and tolerances, application of appropriate monitoring of control points, statistical sampling plans and corrective actions based on systematic causal analysis. This will result in higher performance in actual operation of preventive and intervention measures leading to a good food safety output. There is also need to develop microbiological criteria and sampling plans for non-ready to eat vegetables. This will further assist in the
development of appropriate intervention measures for a wider variety of fresh-cut and minimally processed vegetables.

Validation and verification of core assurance activities need to be based on scientific sources and own experimental trials before and after system modifications. This is because more demands are expected on FSMS in the fresh produce sector as a result of increasing consumption due to perceived health benefits accompanied by increased safety concerns.
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Appendix 1:

FSMS-DI Questionnaire (Fresh Produce Processing)

Part 0: Introduction

Part I: Assessment contextual factors
A. Assessment of product characteristics (01-05)
B. Assessment of process characteristics (06-08)
C. Assessment of organization characteristics (09-15)
D. Assessment of chain environment characteristics (16-23)

PART II: Assessment core safety control activities
E. Assessment of preventive measures design (24-32)
F. Assessment of intervention processes design (33-35)
G. Assessment monitoring system design (36-43)
H. Assessment of operation of preventive measures, intervention processes and monitoring systems (44-52)

PART III: Assessment core assurance activities
I. Assessment of setting system requirements activities (53-54)
J. Assessment validation activities (55-57)
K. Assessment of verification activities (58-59)
L. Assessment of documentation and record-keeping to support food assurance (60-61)

PART IV: Assessment of food safety performance
M. EXTERNAL Food Safety Performance indicators (62-66)
N. INTERNAL Food Safety Performance indicators (67-71)

Part 0: Introduction questions

(All company specific information is made anonymous for data processing).

01. Is your company part of a larger (inter/national) company*
   ☐ Yes
   ☐ No

02. Name (mother) company ........................................

92
03. Location of your company ................................

04. Total number of employees in your company (in this location)
   □ 1-9
   □ 10-49
   □ 50-249
   □ >249

05. Which production sector (i.e. type of fruits, vegetables) are you in?
   ........................................................................................................

06. Which Quality Assurance (QA) standards/guidelines have been implemented?
   □ PRP (GMP, GHP, GDP)
   □ HACCP
   □ ISO 9001
   □ ISO 22000
   □ BRC
   □ IFS
   □ SQF 2000
   □ National standard, please specify........................................
   □ Other.................................
   □ None

07. For which QA standards is your company certified?
   □ ISO 9001
   □ ISO 22000
   □ BRC
   □ IFS
   □ SQF 2000
   □ National standard, please specify.................................
   □ Other.................................
   □ None

08. Do you have a QA manager?
   □ Yes
   □ No

09. Do you have a QA department*?
   □ Yes
   □ No

10. How many people are working in the QA department? ....................
011. Which specific product is made in this production unit?

012. Who are the major customers of this specific product group? (e.g. wholesalers, retailers, food processing companies, catering, etc.)

013. What are the initial materials that you use for these products? (e.g. fresh raspberries, lettuce, herbs, etc.)

014. What is packaging concept used for this product group? (e.g. no packaging, Equilibrium Modified Atmosphere Packaging (EMAP), Controlled Atmosphere (CA), carton, etc.)

015. Who are major suppliers of initial materials? (e.g. local farms, local wholesalers)

016. What are major production steps to make this product (e.g. washing, cutting, mixing, packaging, etc.)

017. What are major facilities (rooms/areas) used for this product group (e.g. cooling zones, production zone, assembling areas, packaging rooms, storage rooms)

018. What are major equipment/machines used for this product group (e.g. shredder, mixer, packaging machine, etc.)?
I. ASSESSMENT OF CONTEXTUAL FACTORS

A. ASSESSMENT OF PRODUCT CHARACTERISTICS

A1. In which situation would you place the initial materials of your RPU in respect to microbiological contamination?

☐ No association of final products with microorganisms and pathogen contamination

Surface properties completely protect the edible part and/or will be removed e.g. citrus fruits, bananas.

☐ Occasional association of final products with microorganisms and pathogen contamination

Product has natural protection that hinders microorganisms (e.g. waxy skin) e.g. apples, tomatoes, cucumber, pears, peaches, melons, mango.

☐ Common association of final products with microorganisms and pathogen contamination

Lack of protective skin or surface properties that create good conditions for microorganisms (e.g. complex surface, porosity, downy skin) e.g. berries, spinach, lettuce, fresh herbs, seed sprouts.

A2. In which situation would you place the initial materials of your RPU in respect to pesticide contamination?

☐ Initial materials are not associated with pesticide contamination; No pesticides are used during cultivation.

☐ Initial materials are associated with pesticides, only officially approved pesticides.

☐ Initial materials are associated with pesticides; likely to contain also unapproved pesticides.

A3. In which situation would you place the initial materials of your RPU in respect to mycotoxins contamination?

☐ No association of initial materials with mycotoxins; Initial materials are resistant to fungal development.
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 toxin production e.g. lettuce, spinach, herbs, mango, mushrooms.

Common association of initial materials with mycotoxins; Initial materials are susceptible to fungi development, which are associated with toxin production e.g. apples, tomatoes, berries, grapes.

A4. In which situation would you place the final product of your RPU in respect to microbiological contamination?

- 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. washing, peeling, packaging after pasteurization)
- Products with no intervention applied, growth of microorganisms is possible (e.g. cut, shredded, etc. products).

A5. In which situation would you place the final product of your RPU in respect to pesticide contamination?

- No association of final products with pesticides; No pesticides are used during production.
- Occasional association of final products with pesticides; Possibility of pesticides removal during processing and/or handling (e.g. peeling of fruit skin)
- Common association of final produce with pesticides; Lack of possibility to remove pesticides during processing and/or handling (e.g. washed products)

B. ASSESSMENT OF PRODUCTION PROCESS CHARACTERISTICS

B6. In which situation would you place susceptibility for microbial contamination of the production system of your RPU?
☐ 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)

B7. In which situation would you position the **climate conditions** (temperature and humidity conditions) in which your RPU operates, in respect to microbiological and chemical contamination?

☐ Production in controlled or climatized conditions that do not favor micro-organisms survival and growth, and/or pest occurrence

☐ Production in ambient conditions in moderate climate zones that occasionally favor microorganisms survival and growth, occurrence of pests and/or mycotoxin production

☐ Production in ambient conditions in subtropical and tropical climate zones that favor growth of microorganisms, occurrence of pests and/or mycotoxin production

B8. In which situation would you position the **water supply** of your RPU in respect to microbiological and chemical contamination your RPU?

☐ 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.)
C. ASSESSMENT OF ORGANISATION CHARACTERISTICS

C9. In which situation would you place your company with regards technological staff?

☐ Industrial company with a significant QA department with own staff and experts in food safety areas (e.g. food microbiologists, food quality management expert, etc.); Own research lab for all microbial and/or chemical analyses, safety controls

☐ Company which has a QA manager (and or small department) with restricted number of people with expertise in food safety; collaboration with external experts (e.g. University); Research facilities for routine analyses, complex analyses at external labs

☐ Company has one person responsible for QA with no specific food safety expertise, expertise is hired from outside (e.g. HACCP consultant) or company has no person responsible for QA at all; Microbial and/or chemical analyses, safety controls at external labs

C10. In which situation would you place the variability of workforce composition with respect to your RPU?

☐ Low turnover of employees (> 5 years); Occasionally temporary operators

☐ Common turnover of employees in food industry (1-5 years); Temporary operators at specific seasons

☐ High turnover of employees (< 1 year); Temporary operators at whole year around

C11. In which situation would you place operator competences with respect to your RPU?

☐ High and specific requirements on competence level of operators: medium/ professional education level in agri-food; Broad experience in food safety control (minimal 3 years); Specific requirements on language skills; Specific food safety and FSMS training on regular basis

☐ Minimal requirements on competence level of operators; low professional education level not necessarily in agri-food; Some experience in food industry (minimal 1 year); No specific requirements on language skills, ability to speak current language; Basic food safety training at start then ad-hoc follow up training
☐ No specific requirements on competence level of operators; No specific requirements on experience; No requirements on language skills; Basic training (instructions) in food safety control at start but no follow up training or only basic instructions about control activities

C12. In which situation would you place management commitment in your company?

☐ Company has detailed food safety policy with clear measurable objectives; It has an official food safety team, with formalized meetings and own budget

☐ Company has general food safety policy (e.g. introduced by retailer or produce organization); It has an official food safety team, with regular meetings and restricted budget

☐ Company has no written food safety policy; It has no food safety team; Only meetings on safety control in case of recalls, problems, no specific budget

C13. In which situation would you place employee involvement with respect to your RPU?

☐ Operators are explicitly involved in design and modifications of FSMS; They are expected to bring in their knowledge to improve systems

☐ Operators’ opinions are considered in design and modifications of FSMS; They are stimulated to provide ideas/ suggestions for improvements (e.g. typically use suggestion boxes) ☐ Operators are only informed about modifications in FSMS by production or QA manager; They are not asked to provide ideas/suggestions for improvements

C14. In which situation would you place formalization (as the degree to which organization’s procedures, rules, personnel requirements, and information systems are written down and enforced) to support decision-making in your company?

☐ All activities are described in SOPs (standard operating procedures)/procedures; Formalized meetings for all different issues; Structured documentation of minutes of meetings available via central system

☐ Procedures and meetings are restricted to crucial processes typically related to the food safety management system (FSMS); Regular meetings; structured documentation of minutes of meetings available via QA department/QA person
No (few) procedures, people are not used to work with it; Working instructions are communicated via informal meetings or direct communication; No (structured) documentation of meetings

C15. In which situation would you place information systems to support food safety (management system) decisions in your company?

☐ Company has a specific Quality Information Management (QIM) to support decisions in control, assurance, design, and improvement of product safety and quality; Accessible for all people to support execution of food safety control activities (i.e. all have authority of use, user friendly, at right location)

☐ Company has production information system, from which some information sources are suitable to support decisions in product safety control; System is only accessible to authorized people

☐ Company has standard information system for bookkeeping (incoming and outgoing materials); No standard information system for food safety control decisions or company has a very simple book keeping system (often paper based).

D. ASSESSMENT OF CHAIN CHARACTERISTICS

D16. In which situation would do you place requirements of stakeholders with respect to your RPU?

☐ General world-wide recognized QA requirements (Codex Alimentarius

☐ Additional QA requirements (e.g. ISO, SQF) but similar for major stakeholders

☐ Additional QA requirements, which are different for major stakeholders

D17. In which situation would you place supplier relationships with respect to the major suppliers of critical materials for your RPU?

☐ Company is explicitly involved in development of product specifications of major suppliers and; Can influence their horticulture safety management system (FSMS), quality management system (QMS) (e.g. via audits)
☐ Company can discuss about product specifications of major supplier but has no influence on their FSMS/QMS

☐ Company has no influence on product specifications nor the FSMS/QMS of major suppliers; Only a possibility to check specifications and or measure raw materials

D18. In which situation would you place your food safety information exchange with the major suppliers of critical materials for your RPU?

☐ 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

D19. In which situation would you place the conditions of the logistic facilities used till the products of your RPU reach the next chain actor?

☐ Environmental conditions of all logistic facilities (till products reach next actor) are modified and/or adapted for specific type of produce and strictly controlled

☐ Environmental conditions of some of the logistic facilities (till products reach next actor) are not modified/adapted and/or not strictly controlled

☐ Environmental conditions of logistic facilities non-controlled, typically ambient conditions (e.g. harvested produce is stored in room with ambient temperature & transported in (open) truck at uncontrolled conditions) *(e.g. processed produce is stored in room with ambient temperature & transported in (open) truck at uncontrolled conditions)*

D20. In which situation would you place inspections of food safety authorities in your country in respect to your RPU?

☐ Systematic procedure-driven inspections using risk-based sampling; Providing systematic feedback and follow up; Performed by an 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

D21. In which situation would you place the variability of suppliers for initial materials for processing in your company?

☐ Company purchases from same or different suppliers but all comply with the internationally acknowledged QA requirements (e.g. Global Gap)

☐ Company purchases from same or different suppliers but some comply with internationally acknowledged (e.g. Global Gap) and others comply with nationally benchmarked QA requirements (e.g. KenyaGap, etc)

☐ Company purchases from same or different suppliers and they have no internationally acknowledged or benchmarked QA requirements (e.g. only comply to local brand requirements)

D22. In which situation would you place the specificity of external support in respect to your RPU?

☐ External support on food safety is production system specific, science based and well established; Official documents are easy access and to 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, documents not in native language and need expert to use)

☐ External support available on food safety is general for the whole food sector e.g. general information from various internet sources

D23. In which situation would you place the specificity food safety legal framework in your country in respect to your RPU?
☐ National food policy is well established with detailed specific defined food safety legislative acts (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 info 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)

II. ASSESSMENT OF CORE CONTROL ACTIVITIES

E. ASSESSMENT OF PREVENTIVE MEASURES DESIGN

E24. At which situation would you place the **hygienic design of equipment and facilities** relevant for your RPU?

☐ Hygienic design of equipment and facilities not important Or Equipment and facilities not hygienically designed (i.e. made by local small scale industries using indigenous knowledge e.g. the use of mud for floors and grass for roof to construct storage facilities hence not cleanable with water & other cleaning agents

☐ Equipment and facilities meet basic hygiene requirements (e.g. EC Regulation No.852/2004, Codex Alimentarius Code of Hygienic Practice)

☐ Standard hygienically designed equipment (EHEDG/comparable hygienic design criteria) as available by equipment suppliers, not integrated in hygienic designed facilities

☐ Integrated hygienic design of equipment and facilities (EHEDG /comparable hygienic design criteria), and modified for companies’ specific food production characteristics in collaboration with equipment and cleaning suppliers

E25. At which situation would you place your **maintenance and calibration program for** relevant for your RPU?
☐ No maintenance applied (e.g. no critical for safety equipment) or not necessary because no equipment used

☐ Maintenance is basically initiated by problems, ad hoc; No (clear) instructions about frequency and maintenance tasks; Not well documented.

☐ Maintenance program developed and implemented with support of, or by suppliers of equipment/tools; Specific instructions about frequency and maintenance tasks; Well documented (at location or at equipment suppliers).

☐ Maintenance program specifically designed for production process and implemented using data from regular inspections and breakdown analyses; Specific instructions on frequency maintenance tasks; Well documented at the company.

E26. At which situation would you place the **storage facilities** relevant for your RPU?

☐ No specific storage facilities used (e.g. simply pile produce under the shade of a tree or tent)

☐ Uncontrolled conditions of storage facilities; typically ambient conditions, bulk, non-separated areas (e.g. a common storage room with windows as a ventilation system).

☐ Industrial storage facilities (controlled temperature, and/or humidity, and/or gas composition). Information about principal storage capability is known but actual capability is not tested.

☐ Industrial storage facilities specifically modified for companies’ specific circumstances and actual storage capability is tested (e.g. for temperature, humidity, gas composition) for typical company circumstances.

E27. At which situation would you place the **sanitation program(s)** relevant for your RPU?

☐ No specific sanitation programs in place (e.g. use of plain water to clean knives and tables used for cutting fruits and vegetables)

☐ Incomplete program not differentiated for specific equipment/facilities; Common cleaning agents not specific for production system (e.g. the use of basic washing bar soap as the main cleaning agent); No instruction; operators rely on their experience.
☐ Complete program and differentiated for equipment and facilities; Cleaning agents (i.e. detergents & disinfectants) selected based on advices of suppliers; Idem for instructions about use and frequency.

☐ Complete program, tailored for different equipment & facilities, established in strict daily procedures; Cleaning agents specifically modified and tested in the companies’ specific food production system; Instructions on use and frequency based on test results.

E28. At which situation would you place the **personal hygiene requirements** relevant for your RPU?

☐ Personal hygiene requirements are not implemented (*e.g. absence of hygiene procedures to follow & operators have no requirements for their clothing and personal health care*)

☐ Standard requirements for all employees on clothing (gloves, jacks); Idem for personal care and health; Common washing facilities; 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; 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 training and hygiene instructions; All implemented in daily practice.

E29. At which situation would you place the **incoming material control** relevant for your RPU?

☐ No control on food safety level of incoming material (*i.e. control is only about quantity and visual quality aspects*).

☐ Incoming material control on food safety level is ad hoc and is mainly based on historical experience with suppliers.

☐ Incoming material control on food safety level is based on guidelines, or legislative requirements, or guidance document for sector.
Incoming material control on food safety level is based on use of statistical underpinned acceptance sampling (i.e. sampling frequency, location, analysis, rejection criteria, etc.) using actual historical data of suppliers, and is implemented in daily practice.

E30. At which situation would you place your packaging equipment relevant for your RPU?

☐ No packaging equipment used.

☐ General packaging equipment not product specific; Packaging equipment capability not known; Packaging conditions selected based on company knowledge.

☐ Best standard’ packaging equipment available in practice, product specific; Equipment is principally capable to comply with standards and tolerances (described in specifications provided by suppliers), but not tested for own production system; Packaging conditions selected based on expertise of suppliers of dedicated packaging concepts (EMAP, active packaging).

☐ Equipment specifically modified for companies’ specific food production circumstances; Equipment capability is tested in company specific circumstances and information is well documented; Packaging conditions are adapted and tested for the company specific circumstances.

E31. At which situation would you place the supplier control at your RPU?

☐ Supplier control not an issue or no supplier control.

☐ No specific supplier selection (i.e. supply based on current availability); Supplier control is ad-hoc, upon problems.

☐ Supplier selection based on certification(s); Regular evaluation of suppliers’ 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.

E32. At which situation would you place the water control relevant for your RPU?

☐ Water control is not important, not an issue (e.g. no water is used as products are only sorted, graded and packaged).
☐ Water testing is ad hoc (upon problems) and based on historical experience of water source; Water treatment is never adapted or only ad-hoc.

☐ Water program is based on expert knowledge or (sector) guideline, but is not part of structured inspections; Water treatment is 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.

F. ASSESSMENT OF INTERVENTION PROCESSES DESIGN

F33. At which situation would you place the full physical intervention relevant for your RPU?

☐ No full physical intervention used.

☐ General intervention equipment not product specific; Process equipment capability not known. ☐ ‘Best standard’ intervention equipment available in practice, product specific; Process equipment capability described in specifications (provided by equipment suppliers). Equipment is principally capable to comply with standards and tolerances, but not tested for own production system.

☐ Intervention equipment specifically modified for companies’ specific food production circumstances and Process equipment capability is tested in company specific circumstances and information is well-documented.

F34. At which situation would you place your partial physical intervention, relevant for your RPU?

☐ No partial physical intervention used.

☐ General partial physical intervention not product specific; Process capability not known.

☐ ‘Best standard’ physical intervention, and product specific; Process capability described in specifications. Process is principally capable to comply with standards and tolerances, but not tested for own production system.
☐ Partial physical intervention process specifically modified for companies’ specific food production circumstances and Process capability is tested in company specific circumstances and information is well-documented.

F35. At which situation would you place your chemical intervention strategies relevant for your RPU?
☐ No chemical intervention used.
☐ Intervention applied based on company knowledge, and experience; Potential reduction level not known.
☐ Application of intervention based on advices of specialized suppliers, but not tested for specific food production system characteristics; Potential reduction level known based on literature or expert knowledge.
☐ Intervention is modified for the companies’ specific food production system characteristics; Actual reduction level is known by testing in the real production system conditions and is well-documented.

G ASSESSMENT MONITORING SYSTEM DESIGN

G36. At which situation would you place the analysis of CCP/CPs with respect to your RPU?
☐ No analysis of CCPs and CPs executed (nor by company nor by external experts).
☐ Internal experience/knowledge used for hazard identification and risk evaluation, selection of hazards to be controlled based on internal discussions, no strict methodology used; CCP/CP determination based on consensus and not tested in practice.
☐ Hazard identification, risk analysis and allocation of CCP/CPs based on hygiene codes for sector or executed by external expertise (consultancy) who work according to official Codex guidelines; CCP/CP determination by microbial product tests and or historical data.
☐ Hazard identification, risk analysis and allocation of CCP/CPs executed by using own knowledge/ experience, additional scientific literature and or expert knowledge, according to Codex guidelines; CCP/CP determination by microbial product tests and predictive modeling of hazard behavior and/or challenge tests.
G37. At which situation would you place your **standards and tolerances design** with respect to your RPU?

☐ No written standards for product and process parameters.

☐ Standards for critical product and process parameters are specified but tolerances not clearly specified; Assessments of product/process standards basically on historical data and company experience.

☐ Standards and tolerances for critical product and process parameters are clearly specified. Standards and tolerances of product/process parameters derived from general hygiene codes and legal requirements.

☐ Standards and tolerances for critical product/process parameters are clearly specified; Standards and tolerances of product/process parameters derived from legal requirements, hygiene codes, and literature, adapted for own food production system.

G38. At which situation would you place **analytical methods to assess pathogens** with respect to your RPU?

☐ Pathogens are **not** analyzed (neither by company nor by external lab).

☐ Conventional culture-based methods used (i.e. plate counts, most probable number, presence-absence tests); No (inter)nationally acknowledged procedures is followed; Samples are analyses by non-certified lab.

☐ Conventional culture-based methods used (i.e. plate counts, most probable number, presence-absence tests) or modified quicker methods; internationally validated methods are used (not accredited); Samples are analysed by official (certified) laboratory (e.g. governmental lab) for microbial analyses, but laboratory is not accredited.

☐ Conventional culture-based methods used (i.e. plate counts, most probable number, presence-absence tests) or modified quicker methods; internationally validated and accredited methods are used; Samples are analysed by accredited laboratory.

G39. At which situation would you place **analytical methods to assess pesticides** with respect to your RPU?
☐ Chemical hazards are not analyzed (neither by company nor by external lab).

☐ Internally developed methods. No (inter)nationally acknowledged procedures are followed, not validated and accredited; Samples are analyses by non-certified lab.

☐ Conventional, internally developed methods used or modified quicker methods. Internationally validated or certified methods are used (not accredited); Samples are analysed by official (certified) laboratory (e.g. governmental lab) for microbial analyses, but laboratory is not accredited.

☐ Conventional methods used or modified quicker methods. Internationally validated and accredited methods are used; Samples are analysed by accredited laboratory.

G40. At which situation would you place measuring equipment to monitor process/ product status in your company/RPU?

☐ No measuring equipment used.

☐ No standardized measuring equipment (accuracy not tested); Off-line/ at-line measurement, not automated, no information/data history available.

☐ Standard available measuring equipment complying with ISO (other international recognized) norms (accepted accuracy); On-line/ in line measurement (immediate response), often automated, information/data history available.

☐ Specifically selected equipment and adapted to the companies’ specific production process, and tested on accuracy; On-line/ in-line measurement (immediate response), automated, information history immediately visual.

G41. At which situation would you place sampling plan for microbial assessment with respect to your RPU?

☐ No sampling plan in place.

☐ Sampling plans based on experience and in-house knowledge. No information about distribution of pathogens, samples are taken as spot-check procedure.
☐ Sampling design and measuring plan based on common sampling plans for the specific sector as available in literature (e.g. EU guidelines, or ICMSF for foods).

☐ Sampling design and measuring plan based on statistical analysis of pathogen distribution in own food production process and is implemented in daily practice.

G42. At which situation would you place sampling plan for pesticide assessment with respect to your RPU?

☐ No sampling in place.

☐ Sampling plans based on experience and in-house knowledge.

☐ Sampling plan based on common sampling plans for the sector.

☐ Sampling plan based on statistical analysis and tailored for specific production.

G43. At which situation level would you place corrective actions with respect to your RPU?

☐ No corrective actions have (yet) been described (e.g. only apply common sense knowledge when problems arise).

☐ Corrective actions based on experience, and consensus within company; incomplete descriptions of process adjustments and handling of non-compliance products; No structural analysis of cause of deviation. Corrective measures not differentiated for different deviations.

☐ Corrective actions based on hygiene codes including process adjustment measures and handling non-compliance products; Complete descriptions but not adjusted for own process, product characteristics; Ad hoc analysis of cause of deviations, no differentiated measures.

☐ Corrective actions based on systematic causal analysis of own product/process deviations, Complete descriptions including process adjustments and handling of non-compliance products; Structural analysis of cause of deviations, differentiated measures; All activities are implemented in daily practice.

H. ASSESSMENT OF OPERATION OF PREVENTIVE MEASURES, INTERVENTION PROCESSES AND MONITORING SYSTEMS

H44. At which situation would you place actual availability of procedures* in your RPU?
☐ No documented procedures in place (*i.e. memory based by operators or verbally communicated*).

☐ Procedures are sometimes/ partly available on location (often paper-based) and/or Difficult to understand by users (*e.g. technical terms or language barrier*); Not kept up-to-date- sit 2.

☐ Procedures are available at location (often paper-based) and Well understandable for most users but Kept up-to-date on ad-hoc basis.

☐ Procedures very easily available (digital, on-line) at location, and designed for specific users and updated at a regular basis.

H45. At which situation would you place the actual of compliance to procedures in your RPU?

☐ No *written* procedures; *employees typically have their own habits*; No idea about actual compliance to procedures of agricultural workers

☐ Majority of food handlers execute tasks according to own insights, because there are not aware of existence of procedures for certain tasks; Operators are controlled on compliance to procedures on ad-hoc basis.

☐ Majority of operators are familiar with existence of procedures (but not always exact content); tasks are executed based on habits. Operators are controlled on compliance to procedures on regular basis.

☐ All operators are aware of existence and content of procedures and are consciously following procedures, safety tasks are internalized; Self-control of compliance to procedures- sit 4

H46. At which situation would you place actual hygienic performance of equipment and facilities with respect to your RPU?

☐ Hygienic design is no issue, or No information/ idea about hygienic performance.

☐ Regularly unexpected and unexplainable contaminations due to inappropriate equipment or facilities; Hygienic performance of equipment and facilities never tested.
☐ Sometimes unexpected and unexplainable contaminations due to inappropriate equipment or facilities; Hygienic performance of equipment and facilities tested on ad-hoc basis.

☐ Stable hygienic performance of equipment and facilities; Hygienic performance tests are executed on regular basis according to EHEDG/similar guidelines

H47. At which situation would you place the actual storage/cooling capacity with respect to your RPU?

☐ Storage/cooling facilities not used, or no performance information known for storage/cooling facilities.

☐ Regularly unstable performance with significant variations in conditions, No automatic devices and deviations not systematically analyzed; No information about product parameters

☐ Sometimes unstable performance; Automatic conditions (temperature, humidity) control but no systematic analysis of deviations; Ad hoc information about product parameters.

☐ Stable performance of storage/cooling facilities; Environmental and product conditions (temperature, humidity, ethylene) are automatically monitored and deviations are systematically analyzed; Constant information about product parameters.

H48. At which situation would you place the actual process capability of full intervention processes with respect to your RPU?

☐ No intervention equipment in place, or No performance information known.

☐ Regularly unstable process with unexplainable deviations from mean values of process parameters; variation not constant over time; Variable differences in capabilities between different production lines; No use of control charts.

☐ Sometimes unstable process, with unexplainable deviations of process parameters; variation constant over time; Significant but constant differences in capabilities between various production lines; Control charts used but not systematically interpreted.

☐ Stable process, mean values and variation of process parameters according to specifications and constant over time; Minor deviations in mean values and variation between production lines; Control charts used and systematically interpreted.
H49. At which situation would you place the **actual process capability of partial physical intervention** with respect to your RPU?

☐ No partial intervention in place or No performance information known.

☐ Regularly unstable process with unexplainable deviations from mean values of process parameters; variation not constant over time; Variable differences in capabilities between different lines/batches; No use of control charts.

☐ Sometimes unstable process, with unexplainable deviations of process parameters; variation constant over time; Significant but constant differences in capabilities between various lines/batches; Control charts used but not systematically interpreted.

☐ Stable process, mean values and variation of process parameters according to specifications and constant over time; Minor deviations in mean values and variation between lines/batches; Control charts used and systematically interpreted.

H50. At which situation would you place the **actual process capability of packaging** with respect to your RPU?

☐ No packaging equipment in place, or No performance information known

☐ Regularly unstable packaging process with unexplainable deviations from mean values of process parameters; variation not constant over time; Variable differences in capabilities between different production lines; No use of control charts

☐ Sometimes unstable packaging process, with unexplainable deviations of process parameters; variation constant over time; Significant but constant differences in capabilities between various packaging lines; Control charts used but not systematically interpreted

☐ Stable packaging process, mean values and variation of process parameters according to specifications and constant over time; Minor deviations in mean values and variation between packaging lines; Control charts used and systematically interpreted

H51. At which situation would you place the **actual performance of measuring equipment** with respect to your RPU?

☐ No measuring equipment used, or No information about measuring equipment performance
☐ Measuring equipment very sensitive to changes in production process circumstances

☐ Measuring equipment sensitive for few specific well known production process changes

☐ Measuring equipment very stable under all different production circumstances

H52. At which situation would you place the **actual performance of analytical equipment** (both microbiological and chemical) relevant for your RPU?

☐ No analytical analyses executed (neither by company nor by external lab), or Sensitivity analytical equipment unknown.

☐ Analytical equipment in non-certified laboratory; Analytical equipment very sensitive towards minor changes in analytical circumstances

☐ Analytical equipment in certified (but not accredited lab); Analytical equipment sensitive for few specific well known analytical circumstances

☐ Analytical equipment in accredited laboratory; Analytical equipment very stable under different analytical circumstances. Analytical equipment at accredited laboratories are assumed to be stable under different product and analytical circumstances

**III. ASSESSMENT CORE ASSURANCE ACTIVITIES**

**I. ASSESSMENT SETTING OF SYSTEM REQUIREMENTS**

I53. At which situation would you place the **translation of stakeholder requirements into own FSMS requirements** related to your RPU?

☐ Not (yet) any stakeholder requirement(s) translated

☐ Translation of external assurance activities initiated by food safety performance problems (*reactive*) as perceived by stakeholders and or due to external directives, only necessary changes

☐ Translation of external assurance activities by *actively* acting on changes in external assurance and setting (new) requirements with support of external experts (e.g. consultants)

☐ *Pro-active* translation of external assurance requirements based on systematic analysis of possible changes in stakeholder requirements (e.g. new legislation, new branch demands) and evaluated on critical aspects of own food production system; well documented
I54. At which situation would you place the **systematic use of feedback information to modify FSMS** related to your RPU?

☐ FSMS has not (yet) ever been modified.

☐ Ad hoc modification of control activities, initiated by problems from own food production system; Not documented.

☐ Regular use of standard data from food production system (process/product data); modifications mainly focused on control activities in production system; Not systematically documented

☐ Systematic analysis of information from validation & verification reports, translations into concrete modifications in FSMS are established in clear procedures with assigned responsibilities; both procedures and system changes have been extensively documented

**J. ASSESSMENT VALIDATION ACTIVITIES**

J55. At which situation would you place **validation of preventive measures** with respect to your RPU?

☐ Effectiveness of preventive measures have (yet) never been validated

☐ Effectiveness of preventive measures is validated based on historical knowledge only judged by own people on ad-hoc basis; Findings scarcely (not) described.

☐ Effectiveness of preventive measures is validated from independent expert (e.g. QA manager from main office/mother company or external consultant), using expert knowledge, regulatory documents and historical results; Systematic and after system modifications; Findings described in reports

☐ Effectiveness of preventive measures is systematically validated, by independent external (scientific) experts, based upon specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials; Systematic and after system modifications; Activities and results well documented.

J56. At which situation would you place **validation of intervention processes** (both full and partial physical intervention) with respect to your RPU?
☐ Intervention processes have (yet) never been validated

☐ Effectiveness intervention processes validated based on historical knowledge only judged by own people on ad-hoc basis; Findings scarcely (not) described.

☐ Effectiveness of intervention processes from independent expert (e.g. QA manager from main office/mother company or external consultant), using expert knowledge, regulatory documents and historical results; systematically and after system modifications; Findings described in reports.

☐ Effectiveness of intervention processes validated by independent (scientific) experts, based on specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials; systematically and after system modifications; Activities and results well documented

J57. At which situation would you place validation of monitoring systems with respect to your RPU?

☐ Effectiveness of monitoring systems have (yet) never been validated

☐ Validation based on historical and/or commonly available knowledge executed by own people on ad hoc basis; Findings (not) scarcely described

☐ Validation based on comparison with regulatory documents (like specific hygiene codes) by external expert on regular basis Findings systematically described in expert report

☐ Validation based on scientific sources (reviews, historical data on hazards, reports on foodborne illnesses, data on survival or multiplication, studies on control mechanisms); By independent expert on regular basis and after system modifications; Activities and results systematically documented

K. ASSESSMENT OF VERIFICATION ACTIVITIES

K58. At which situation would you place verification of people related performance with respect to your RPU?

☐ Procedures and compliance to procedures have (yet) never been verified
☐ Verification of procedures and compliance based on *checking presence* of procedures and records, on ad-hoc basis By own people who execute system Not documented

☐ Verification of procedures and compliance based on *analyzing* procedures (both content and presence) and records; on regular basis by independent internal staff Internal report

☐ Verification of procedures and compliance based on *analyzing* procedures and records, and *observations* with defined frequency and when system modifications by independent external (official) expert Activities and results well documented

K59. At which situation would you place verification of equipment and methods related performance with respect to your RPU?

☐ Performance of equipment and methods have (yet) never be verified

☐ Verification of equipment/methods performance based on checking if product, process parameters are correctly set (e.g. of equipment, facilities, measuring, analysis methods) on ad hoc basis; by people work in the system and provide the information; Not documented

☐ Verification of equipment/methods performance based on analyzing records (e.g. control charts, records data loggers, etc.) and calibration activities, restricted testing of actual performance on regular basis; By internal staff using information from production; Internal report.

☐ Verification of equipment/methods performance based on *analyzing* records, calibration activities, and confirmation of performance by actual (e.g. microbial) *testing*, with defined frequency and after system modifications by independent experts; Activities and results well documented.

**L. ASSESSMENT DOCUMENTATION AND RECORD-KEEPING**

L60. At which situation would you place documentation with respect to your company?

☐ No documentation of procedures, information, knowledge at all (*i.e. everything is memory-based*).

☐ No structured documentation system ad hoc.
☐ Structured documentation system, de-centrally organized and kept up to date, (partly) automated, available via specific persons; access to external sources not formalized (individual contacts).

☐ Structured documentation system, kept-up-to-date with assigned responsibilities, centrally organized, automated and on-line available for all, and with access to external sources of information (libraries, databases, etc.).

L61. At which situation would you place your record keeping system with respect to your company?

☐ No record keeping of product nor process data at all (i.e. everything is memory-based) - sit 1

☐ Ad hoc registration of record keeping data (i.e. only when required by stakeholders or upon serious problems).

☐ Full registration of critical product and process data in separated systems (not integrated), accessible via specific (authorized) persons.

☐ Full registration of critical product and process data, in central integrated system, accessible to all persons.

PART V ASSESSMENT OF FOOD SAFETY PERFORMANCE

M. EXTERNAL Food Safety Performance indicators

M62. How would you typify your Food Safety Management System evaluation?

☐ An inspection or an audit of the Food Safety Management System was never performed.

☐ Inspection of the FSMS performed by national food safety agency.

☐ Audit of the FSMS performed by one accredited third party.

☐ Audits and/or inspections of the FSMS performed by several accredited third parties and/or national food safety agency.

M63. How would you indicate seriousness of remarks of the FSMS evaluation?

☐ Not appropriate because never an inspection or an audit of the FSMS was performed.
☐ Major remarks on various aspects of the FSMS

☐ Major remark only on one specific aspect of FSMS (eventually additional minor remarks on other aspects of the FSMS)

☐ No major remarks and/or only minor remarks on specific or various aspects of the FSMS

M64. How would you typify the **hygiene related and microbiological food safety complaints** of customers?

☐ Not known because no complaint registration.

☐ Various complaints which can be dedicated towards multiple problems in the functioning of the FSMS.

☐ Restricted complaints which can be dedicated to one specific problem in the functioning of the FSMS.

☐ No complaints regarding microbiological food safety

M65. How would you typify the **chemical safety complaints** of customers?

☐ Not known because no complaint registration on chemical hazards.

☐ Various complaints which can be dedicated towards (multiple) unknown chemical hazards

☐ Restricted complaints which can be dedicated to one specific chemical hazard.

☐ No complaints regarding chemical food safety (pesticides, mycotoxins).

M66. How would you typify the **(visual) quality complaints** by your customers?

☐ Not known because no complaint registration for visual quality.

☐ Various complaints which can be dedicated towards multiple problems in the functioning of the FSMS.

☐ Restricted complaints which can be dedicated to one specific problem in the functioning of the FSMS.

☐ No complaints regarding visual quality.
N. INTERNAL Food Safety Performance indicators

N67. How would you typify your product sampling to confirm microbiological performance?

☐ No samples are taken and no microbiological analyses are performed.

☐ Ad hoc sampling (on the demanding of customers or legislation) and only on final food product.

☐ Structured sampling conducted on final food product.

☐ Structured sampling (with fixed frequency and company own sampling plan is present) and conducted on final food product, initial material(s) and environmental samples.

N68. Which judgment criteria are used to interpret microbiological results?

☐ No criteria known because microbiological analyses are not performed.

☐ Only legal criteria used (restricted number).

☐ Combination of legal criteria and requirements and or specifications (set by external parties) is used.

☐ Combination of legal criteria, requirements and or specifications by external parties and additional company specific specifications established in internal guidelines.

N69. How would you typify your product sampling to confirm use of pesticides?

☐ 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)

N70. Which judgment criteria are used to interpret pesticide testing results?

☐ No criteria known because microbiological analyses are not performed.

☐ Only legal criteria used (restricted number).
☐ Combination of legal criteria and requirements and or specifications (set by external parties) is used.

☐ Combination of legal criteria, requirements and or specifications by external parties and additional company specific specifications established in internal guidelines.

N71. How would you typify your non conformance?

☐ Not known because internal product analyze, and no conformities registration.

☐ Several non-conformities which can be dedicated towards multiple problems of the functioning of the FSMS.

☐ Restricted number of non-conformities which can be dedicated to one specific problem in the functioning of the FSMS.

☐ No non-conformities regarding microbiological food safety/hygiene/quality indicators, pesticides or mycotoxins.